VN/14214/2025

Government proposal to Parliament for legislation on pharmaceutical reform and implementation of pharmaceutical savings

MAIN CONTENT OF THE PROPOSAL

The proposal proposes to amend the Medicines Act, the Act on the taxation of pharmacies, the Act on electronic prescriptions and the Health Insurance Act.

The proposal is linked to the minutes of Prime Minister Petteri Orpo's government programme on the overall reform of the pharmaceutical economy. It is proposed that the pharmaceutical tariff for prescription-only medicines, based on the Medicines Act, be cut evenly across all tax categories. The amendment would achieve the objective of a permanent annual fiscal saving of EUR 30 million. More detailed regulation would be included in the Government Decree on the pharmaceutical tariff. It is proposed to amend the pharmacy tax law in order to base the pharmacy tax on the taxable person's profit margin on pharmaceutical sales. In addition, the deductions from the taxable amount and the tax scale would be amended.

A new regulation is proposed in the Medicines Act and the Medicines Regulation to define a limited range of self-medication products. Self-pharmaceutical products in the range would be subject to a modified price regulation and would not be taken into account in the pharmacy tax base. A marketing authorisation holder could, if he so wishes, apply for an extension of the sales channel for his self-treatment medicinal product in its range to off-pharmacy sales, which would be granted under the conditions laid down by law. Sales outside the pharmacy would be based on retail licences for self-treatment medicinal products granted to traders. The conditions of the authorisation, the application for authorisation, the validity of the authorisation, the requirements imposed on the holder of the authorisation and the duties of the responsible person would be laid down separately. Provision would also be made for controls and penalties for non-compliance. The proposed amendments would implement the government programme's record that, on the basis of the PSA's report, the release of medicinal products and medication safety will be deliberately released, ensuring some of the most commonly used self-care medicinal products also for sale outside pharmacies.

The proposal is also linked to the Government bill, according to which the supply of prescription-only medicinal products is clarified so that the prescription can be applied taking into account the availability and quantity of different pack sizes. It is proposed that the pharmacy be given the right to derogate from the prescription and correct an obvious error in the prescription in certain circumstances.

In addition, it is proposed that, in the context of the financing of health insurance under the health insurance system, reimbursement payments linked to the conditional reimbursement of reimbursements of medicinal products should be fully allocated to the State. The proposal aims at savings of around EUR 30 million in public finances, which would replace the 30 million savings on statutory health checks agreed in the government programme by EUR 20.2 million, as well as the EUR 10 million pharmaceutical reimbursement savings decided on in the framework in spring 2024.

The proposal is linked to the draft state budget for 2026 and is intended for consideration in the context of the draft state budget for 2026.

The proposed laws are intended to enter into force on 1 January 2026.

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1 Background and preparation of the case

Background

The proposal is based on the records of Prime Minister Petteri Orpo’s government programme, according to which the government is carrying out an overall reform of the pharmaceutical economy. The first part of the proposal relates to the government programme, according to which the reform must take into account the pharmacy tax and the pharmaceutical tax together, taking into account the actual profitability of the pharmacies, ensuring a nationwide pharmacy network, pharmaceutical support (including medical advice), medication safety and access to medicines. Pharmacy regulation is being reformed responsibly and gradually, ensuring high-quality and safe pharmacy services throughout Finland. The reform aims at a more cost-effective system for the retail distribution of medicinal products. The reform aims at budgetary savings of EUR 30 million per year. The reform will not increase the payment burden on customers. The proposal proposes changes to the pharmaceutical tariff and the pharmacy tax, in line with the government programme, which would form part of the overall

reform of the pharmaceutical economy. A change in the pharmaceutical tax rate for prescription medicines, which would be included in the proposal to amend the Government Decree on the pharmaceutical tax rate annexed to the proposal, would result in a budgetary saving of EUR 30 million per year from the beginning of 2026.

The second part of the proposal relates to the Governmental Record, according to which some of the most commonly used self-care medicinal products are released on the basis of a report by the pharmacy safety authority, prudently, ensuring the safety of medicines and medication, also for sale outside pharmacies. Self-therapeutic medicinal product means a medicinal product which can be sold or otherwise released for consumption without prescription. A new regulation is proposed in the Medicines Act and the Medicines Regulation to define a limited range of self-medication products. Self-pharmaceutical products in the range would be subject to a modified price regulation and would not be taken into account in the pharmacy tax base. A marketing authorisation holder could, if he so wishes, apply for an extension of the sales channel for his self-medication product in its range to off-pharmacy sales. Sales outside the pharmacy would be based on retail licences for self-treatment medicinal products granted to traders.

Thirdly, it is proposed that the pharmacies be given the right to derogate from the prescription and to correct an obvious error in the prescription in certain circumstances. The proposal would implement a government programme recording to clarify the supply of prescription-only medicines and to allow the prescription to be applied in a pharmacy. The proposal would also contribute to the Government's record of efforts to make greater use of the skills of pharmacies' staff as part of social and health care.

Fourthly, it is proposed that the refund payments related to the conditional reimbursement of pharmaceuticals should be fully allocated to the State as of 2026. The aim of the proposal is to save some EUR 30 million on the national economy. The measure would replace the 30 million savings on statutory health checks agreed in the government programme by EUR 20.2 million and would fully implement the savings of EUR 10 million on pharmaceutical reimbursement decided in spring 2024 in the frame grid, with an impact on the state contribution of around EUR 5 million;

According to the government programme, pharmaceutical reform will continue during the current government term on the basis of the pharmaceutical road map. The overall reform of the pharmacy economy is part of this reform, based on the Ministry of Social Affairs and Health's Pharmaceutical Road Map (Aspects of Change Needs for Pharmaceutical Treatment and Distribution, Reports and Notes from the Ministry of Social Affairs and Health 2019:5; 'the *STM 2019:5*').

1.2. Preparation

1.2.1. Pharmaceutical reform

The pharmaceutical reform is divided into three development blocks, one of which is the development of the pharmaceutical industry and the distribution of medicines. This proposal has been drawn up on the basis of studies resulting from work on the development of the pharmaceutical economy carried out over government terms.

During the previous government, the reform of the pharmacy economy was prepared by a cross-administrative coordination group and a pharmacist appointed by the Ministry of Social Affairs and Health ('the *STM*') for the implementation of the pharmaceutical road map (VN/19676/2020, STM118/2020). The task of the pharmacy division was to prepare, as a basis for the wider reform of the pharmacy sector, a study providing a comprehensive picture of the formation and distribution of the retail price of the medicinal product and their regulatory

framework, as well as drafting proposals for further development and decision-making. Pharmacy Sector Report: The development of the pharmacy system, assessment of the current state and proposals for follow-up measures, reports from the Ministry of Social Affairs and Health and memoranda 2023:6 (‘ *STM 2023:6)* were published on 1 February 2023 (website of the publication: https://urn.fi/URN:ISBN:978- 952-00-5668-1)

The reform will continue during this term of government. By decision of 13 May 2024 (VN/7472/2024-STM-20, project website: https://stm.fi/hanke?tun nus=STM079:00/2024) to implement government programme entries on thepharmacy system for the term of office of the pharmacy reform observatory and study group from 13 May 2024 to 31 December 2025. The task of the working groups is to propose an overall reform of the pharmacy economy and a reform of the pharmacy regulation. As work progresses, it has been decided that the study group will prepare its proposal for the form of the government proposal. Reforms can be implemented in stages. The first proposals had to be made by 31 December 2024 and the work had to be completed in full by 31 December 2025. Austerity measures for the pharmacy economy should be feasible from the beginning of 2026.

The members of the study group are representatives of the STM, the Ministry of Finance (‘VM’), the Ministry of Employment and the Economy (‘the TEM’), the Centre for Safety and Development of the Medicines Sector (‘Fimea’), the Institute for Health and Welfare (‘THL’), the Social Insurance Institution (‘Kela’) and the Finnish Competition and Consumer Authority (‘KKV’), together with the State Economic Research Centre (‘ *VATT*’), the Association of Finnish Pharmacy (hereinafter ‘*SAL*’), the pharmacy of the University of Helsinki (‘ *YA*’), the pharmacy of the University of Eastern Finland, the Finnish Farmasia Association, the Finnish Association of Pharmas and Health, the Finnish Association of Doctors, the Finnish Association of Medicinal Products, Linnakkalaitos ry, Rinnakkaislaitos ry, representatives of Finnish Medicines Collection Seeders, Trade Association, PäivitaistavaraCommerce ry, Kuluuttajaliitto ry, Lääke- and Healthcare ry, the Service Sectors Trade Union and HUS Hospital pharmacy. In the preparation of this proposal, the study group has met 17 times and the follow-up group 7 times. The work on the preparation of the working groups has been carried out in the study group and its sub-group and has been brought to the discussion in the Monitoring Group. In addition, pharmacy operators have been consulted separately during the preparation of the draft.

1.2.2. Extension of the sales channel for certain self-medication medicinal products

In order to implement the government programme to expand the sales channel of some of the most commonly used self-medication medicines, the STM mandated Fimea in July 2023 to draw up a report on sales of self-medication medicines outside pharmacies. The Fimea study was finalised on 31 August 2023. It can be opened at the following web address: https://stm.fi/docu ments/1271139/148062577/Fimean+survey+self-care %C3 %A4 %C3 %A4 %A4+saleof NIST%C3 %A4+outside pharmacies+.pdf

The preparatory work was continued by the STM’s working group on the extension of the sales channel for self-treatment medicinal products (‘the self-medication group’),whose term of office was from 24 January to 202430 June 2024. Representatives of the STM, the VM, Fimea, KKV, SAL, UHP, pharmacy at the University of Eastern Finland, Social Affairs and Health ry, the Consumers’ Union, Lääke Industries ry, Rinnakkaislaitos ry and Päivittaistat Trade ry were representatives of the STM, the VM. In addition, the working group had to consult as experts Kela, THL, Valvira, the Finnish Farmasialiitto ry, the Finnish Association of Pharmacists, the Finnish Association of Doctors, the Association of Finnish Local and Regional Authorities (no statement) and Orion Oyj. The working group met 11 times during its term of office. An expert consultation took place on 3 April 2024.

The task of the group on self-care medicinal products was to propose self-medication products which could also be sold outside pharmacies and the conditions under which the sales channel could be extended. In addition, the task was to explore ways of promoting price competition for self-medicines. The proposal had to assess the need for legislative changes and the impact. The preparatory work drew on the study completed by Fimea in autumn 2023. The Working Group's note on the assessment of the extension of the sales channel for self-medication medicines, reports from the Ministry of Social Affairs and Health and memos 2024:25 were published on 3 October 2024. The Federation of Commerce, the KKV and the SAL and the pharmacy of the University of Eastern Finland submitted supplementary statements in the note (Annex 3a-3c to the Memorandum). (Link to the Working Party's note and annexes: http://urn.fi/URN:ISBN:978-952-00-8446-2 ('STM *2024:25'*).

1.2.3 Preparation and consultation

The proposal has been prepared as official work at the STM in cooperation with the VM, Fimea, Kela and THL. In addition, Ministries, other public authorities and some pharmacies, as well as associations representing pharmacies, trade and health care, have participated in the preparation as members of the working groups led by the STM. In addition, key cross-industry organisations have been consulted during the work on the proposal on conditional substitutability. The government proposal and the related draft regulations have been discussed in the Ministerial Working Party on Employment and Entrepreneurship on 27 May 2025.

The government proposal ran for a seven-week consultation period from 30 June 2025 to 18 August 2025. The referral period was extended in a week from the recommended six weeks during the summer holiday period. This longer consultation period was not considered justified as the main stakeholders have been involved from the outset in the preparation of the proposals. The seven-week consultation period will also ensure that opinions can be taken into account in the further preparation of the draft of the budget laws.

The preparatory documents for the Government bill are available on the legislative project STM044:00/2025 at: (https://stm.fi/hanke?tunnus=STM044:00/2025).

2 Current status and its assessment

2.1.The economy of pharmacies

The regulation of pharmacies is based on three main pillars: the pharmacy licensing system, the price regulation of medicinal products and the pharmacy ordinance. The Pharmaceutical Road Map highlights the interdependence of the pillars. They cannot be viewed or developed in isolation, as all other parts are affected by the modification of one part. The reform of the pharmacy economy is one of the means identified in the Pharmaceutical Road Map to balance the funding of pharmaceutical treatment and to reduce the burden of pharmaceutical fees for users and to ensure the financial sustainability of pharmaceutical matters (STM 2019:5 pp. 13 and 47, as well as STM 2023:6 p. 19). The interdependence between the pharmaceutical tax and the pharmacy tax has also been identified in government studies (Rhinish, Hycolinnen, Kok, Jauhonen and Happonen: Development of pharmaceutical tax, pharmacy fee and pharmacy tax in Finland – Explanation of proposed amendments, obstacles to modifications and possible drivers for change, Fimean develops, assesses and informs *1/2021*, *Fimea* 1/2021, pp. 8 and 60.

The link between the different pillars of pharmacy has also been identified in the government programme of Prime Minister Orpo. In accordance with the Government Programme, the reform of the pharmacy economy must take into account the pharmacy tax and the pharmaceutical tariff together. This proposal proposes reforms to the pharmaceutical tariff and pharmacy tax for the retail sale of prescription-only medicinal products. In addition, it would

be possible to sell certain medicinal products within the limited range of self-medication products also outside pharmacies and to change their pricing and pharmacy taxation. The proposal is the first step in a phased reform. The other pharmacy pillars, such as pharmacy and information management, have been examined in parallel with the preparation of this proposal and will be the subject of separate government proposals for legislative amendments.

Price of medicinal product for retail sale of prescription medicinal products

Current status

The pricing of medicinal products sold to the consumer from a pharmacy is governed by Section 58 of the Medicines Act (395/1987) and the Government Decree on the Medicinal Products Tariff (713/2013; 'the Medicinal Products *Tax*Decree'). The retail prices of prescription-only medicines, i.e. prescription-only medicines, are the same in all Finnish pharmacies due to price regulation (the so-called "equal price" principle). The price formation of prescription-only, self-treatment and pharmacy-prescription medicines is regulated separately in the Medicinal Tax Regulation. Price regulation applies to medicinal products sold only in pharmacies and pharmacies. Registered homeopathic products, registered traditional herbal medicinal products and nicotine products are thus excluded.

According to Section 58 of the Medicinal Products Act, the retail sale of a medicinal product shall be carried out at a price in accordance with the pharmaceutical tariff laid down by Government decree. The price of the medicinal product shall consist of the retail selling price of the medicinal product and, in the cases referred to in subparagraphs 2 and 3, an item-by-item delivery fee to be added to the retail price, and VAT. The retail price of a medicinal product shall be based on the wholesale price notified by the holder of the marketing authorisation for the medicinal product in accordance with Paragraph 37a and on the margin calculated on the basis of the wholesale price. The margin calculated on the basis of the pharmaceutical tax may be proportionally lower than the pharmacy tax levied on that medicinal product under Section 6 of the Act on the taxation of pharmacies (770/2016). The difference shall not exceed EUR 6 for an individual medicinal product.

The price charged for the retail sale of a medicinal product subject to prescription consists of the retail selling price of the medicinal product, calculated in accordance with the formula laid down in Article 3 of the Medicinal Product Tax Regulations, the delivery fee per item added to the retail price of EUR 2.17 and, in the case of dosage medicinal products, EUR 0.18 per week of treatment, and VAT pursuant to the Law on Value Added Tax (1501/1993).

The retail price of a medicinal product, calculated in accordance with Article 3 of the Medicinal Products Tax Decree, means the retail price of a medicinal product consisting of the wholesale price at national level ('the purchase price') declared by the holder of the marketing authorisation for a medicinal product in accordance with Paragraph 37a of the Law on medicinal products ('the purchase price') and the retail selling price of a pharmacy calculated on the basis of the wholesale price. The formula for the calculation shall be the following:

Purchase price, EUR	Retail price
0-7,49	1.42 x purchase price
7,50 – 39,99	1,35 x purchase price + EUR 0.52
40,00 – 99,99	1,24 x purchase price + EUR 4.92
100,00 TO 399,99	1,15 x purchase price + EUR 13.92

400,00-1 499,99	1,10 x purchase price + EUR 33.92
1 500	1 x purchase price + EUR 183,92

Assessment of the current situation

The aim of this proposal is to achieve a permanent fiscal saving of EUR 30 million per year in line with the Government Programme and a more cost-effective organisation of the retail distribution of medicines. The payment burden for customers should not be increased.

Preparations for the reform of the pharmacy economy have progressed gradually. In the first stage, the target status of the pharmaceutical tax rate and pharmacy taxation was modelled. In the target state, the retail price of a medicinal product would not depend on the wholesale price of the product and it would be possible to abandon the pharmacy branch, which would reduce the prices of medicines by 10 %. Separate support could target pharmacies in need that are critical for securing access to medicines in their region. A change in the pharmaceutical tariff in line with the objective and a switch to a fixed pharmacy's supply margin would have a significant impact on the prices of medicines and the position of different patient groups.

However, during the preparation, it was found that there was insufficient time to complete a major structural pharmaceutical reform in the timeframe for the preparation of the legislation with an impact on the 2026 budget. As a result, as of the beginning of 2026, the preparation of savings for the state economy shifted towards the development of a pharmaceutical tariff for prescription medicines, with a view to lowering the prices of medicines in line with the objective of savings. In parallel with the change in the pharmaceutical tax, a reform of the pharmacy tax was prepared.

A cut in the pharmaceutical tax rate for prescription-only medicines could achieve the planned permanent savings of EUR 30 million per year, as well as a cost-effective distribution system for medicinal products, since the retail price of prescription medicines plays a key role in the accumulation of state expenditure on reimbursement of medicines. The pharmaceutical road map already identified that the price of a medicine, together with the use of medicines, determines the level of reimbursement costs in society. Pharmaceutical price regulation should be used to balance appropriate funding and manage the increase in the cost of medicine (STM 2019:5 p. 13, 39-40, 43, 46 and 82).

A more cost-effective retail distribution system for medicinal products can also be achieved by cutting the price of prescription medicines by lowering the cost of medicines for consumers and the state. Several studies carried out in recent years have identified that, in its current form, a pharmaceutical tax yields excessive returns for some pharmacies and does not lead to an optimal outcome for society and users. The following studies have been carried out before the pharmaceutical tax and pharmacy tax reforms entered into force since the beginning of 2023, which needs to be considered.

A preliminary study carried out in 2020 found high retail prices for medicines and a high margin for pharmacies in Finland compared to other Nordic countries. The main means of reducing the pharmacy system's share of the cost of medical treatment was identified as changing the pharmaceutical tariff (Mäklin, Laukkonen, Aaltonen, Heino, Koskinen, Saastamoinen, Hycolinnen and Rhineikainen: Total cost of medical treatment and pharmacy – Exploratory study, ' *STM 2020* and Fimea 1/2021', pp. 59-60.

The KKV's 2020 study on the development of the pharmacy market has proposed a reduction in the pharmaceutical tariff and a change in the determination of the pharmacy tax. According to the KKV, the remuneration received by pharmacies for the sale of medicinal products is unnecessarily high, as can be seen by comparing the income of pharmacists with other professional groups and by looking at the price formation structures for medicines in other Nordic countries. The regulation should be changed to the benefit of the consumer and the taxpayer. The KKV considers that the pricing of a medicinal product is such that even a poorly profitable pharmacy will continue to be able to operate a pharmacy, which results in an unnecessarily high remuneration for the retail sale of medicinal products to the more profitable pharmacies. Although the pharmacy tax is deducted from the overcompensation, it would still be possible to regulate the pharmaceutical tax and the pharmacy tax in such a way that the result would be more optimal for society as a whole. Lowering the pharmaceutical tariff would have an impact on the margins of all pharmacies and would be directly reflected in retail prices paid by consumers and society if wholesale prices were assumed to remain constant. Anttinen, Hakola, Saastamoinen, Terävä, Valliluoto: Development of the pharmacy market, Reports 5/2020 by the Competition and Consumer Authority *('KKV* 5/2020'), pp. 7 and 29-30.

In a study carried out in 2023, the KKV has estimated that the current pharmacy authorisation process, with several qualified applicants for pharmacy licences, as well as higher revenues than control groups, indicate that the remuneration for operating pharmacies could be lower and thus cheaper for customers and taxpayers (Hakola-Uusitalo, Leppälä, Anttinen and Mäkelä: Pharmacies and Taxation, Competition and Consumer Authority Research Reports 7/2023 (' *KKV 7/2023*'), p. 36. However, Fimea has established several new pharmacies in the 2020s and it can be observed that there were only two applicants for more pharmacies. The situation has thus changed as a result of the latest changes affecting the pharmacy economy.

The reform of the prescription tax rate aims at permanent annual budgetary savings of EUR 30 million. Actual wholesale data shall be used for the calculation. The in-built assumption of the results is that there will be no material change in the structure of pharmaceutical sales in pharmacies in the short term. However, the reform and the impact assessment need to take into account the likely changes in the market situation in the coming years and whether they suggest that the pharmaceutical market would grow or decrease in the coming years, as this may have an impact on the magnitude of the tax cut to be carried out. On the basis of data on pharmaceutical sales in 2023 and 2024, small growth can be observed in the pharmaceutical market.

According to Finland's medicines statistics, total sales of medicines in 2023 amounted to EUR 3 864 million. Total sales increased by 2.5 % in 2023 compared to the previous year. According to statistics from Kela, the total sales of medicines in 2024 amounted to EUR 4 100 million, an increase of 5 % compared to 2023. In 2023, sales at retail prices of prescription medicines accounted for EUR 2 570 million and sales of self-prescription medicines at retail prices amounted to EUR 404 million. Compared to 2022, retail sales of prescription and self-prescription medicines increased by 2.3 % and 1.5 % respectively. In 2024, sales of prescription-only medicines at retail prices amounted to EUR 2 800 million, which represents an increase of 7 % (5 % if reimbursement fees paid by pharmaceutical companies are taken into account, EUR 90 million) compared to the previous year, and the share of self-medicines was around EUR 400 million. The proportion of these medicines decreased by 1.4 % compared to the previous year. The rest of the sales, EUR 900 million, were plant sales (Finnish Medicines Statistics 2023 and data from Kela of 26.2.2025).

Reimbursements for medicines totalled EUR 1 792 million in 2023. Basic-reimbursable medicines accounted for EUR 350 million, while special-reimbursed medicines amounted to EUR 1 168 million. An additional EUR 274 million was paid due to the overrun of the annual co-payments. In 2024, reimbursements for medicines amounted to EUR 1 903 million, of

which EUR 304 million for basic reimbursable medicinal products, EUR 752 million for higher-ranking medicines and EUR 570 million for the lower special reimbursement category. Additional compensation of EUR 290 million was paid (Finnish Medicines Statistics 2023 and data from Kela of 26.2.2025).

The main reasons for the increase in the cost of medicines are the emergence of new, typically more expensive, medicines in the reimbursement system, the expansion of the use of medicines for new uses, the increased use of medicines and the ageing of the population. New medicines have made it possible to obtain medical treatment for diseases that could not be treated in the past or have become more intensive in outpatient care. With the introduction of new medicines, fewer research evidence is available, challenging the cost-effectiveness assessment.

When assessing the growth rate of pharmaceutical sales, a number of factors have been identified as having a downward impact on the growth rate as it stands. Thus, as things stand, the growth rate of pharmaceutical sales should not be based solely on historical developments.

Efforts have been made to curb the increase in pharmaceutical costs through various legislative changes. The legislative amendments to reduce wholesale prices have entered into force in 2006, 2013 and 2025. In 2006 the fixed wholesale prices for all products covered by the reimbursement scheme were reduced by 5 % and in 2013 the fixed wholesale prices for all products covered by the reimbursement scheme but not included in the reference price system were reduced by 5 %. In addition, reasonable wholesale prices for medicinal products were reduced by 1.5 % in early March 2025.

The change in the drug tariff at the beginning of 2023 lowered the prices of prescription medicines and thus their reimbursement. One third (34 %) of the reimbursements paid in 2023 for cancer medicines and immune response transformers (EUR 611 million) decreased by 1.5 % compared to the previous year, i.e. around EUR 9 million. This group of medicines is used, for example, to treat rheumatic and intestinal diseases and cancers.

The price regulation system has an impact on pharmaceutical reimbursement expenditure at the end of patents and the introduction of cheaper products into the reimbursement system, triggering active price competition that lowers pharmaceutical prices. Pricing provisions for generics and biosimilars, the system of reference prices and the exchange of medicines have been effective means of curbing the cost of medicines. In the coming years, this is expected to be reflected in medicine sales and reimbursements when patents for large patient groups have just expired or are about to expire. For example, anticoagulants used as blood-strengthening medicines are one of Finland’s most sold prescription medicines every year, which were used in Finland by more than 230000 people in 2023, for which almost EUR 123 million were reimbursed (including apixaban, rivaroxaban, edoxaban and dabigatran). Patent protection for this category of products expired in 2024, triggering price competition, the effects of which will be more visible in 2025 at the earliest. In 2024, the number of people reimbursed for anticoagulants slightly increased compared to the previous year (5 %) and the reimbursements paid for medicines decreased by one fifth from 123 million to 100 million euro. For the time being, the change that started in 2024 is not fully reflected in the available data and the magnitude of the impact cannot yet be accurately estimated. (Kelasto Report on Medical Insurance Reimbursement of Medicinal Products 2023 and 2024).

In addition, the gradual exchange of pharmacies for biological medicines starting between 2024 and 2026 is estimated to curb the increase in pharmaceutical costs. In April 2024, enoxaparin products were covered by an exchange and in January 2025, with the exception of insulins, the exchange expanded to all other interchangeable biological medicines. In 2023, about 15 % of the medicines on the market in Finland were biological medicines, six of the top 10 medicines were biological, with reimbursements of EUR 230 million (Medicinal Products

Statistics 2023). In 2024, more than 300000 people used reimbursable biological medicines in Finland and the number of reimbursable medicines and indications are constantly increasing. The savings effects of changing pharmacies for Enoxaparin products were limited. However, in 2025, a number of highly used biological medicinal products, such as rheumatic diseases, psoriasis or inflammatory bowel diseases, were covered by a pharmacy exchange. The savings effect of changing pharmacies for these products is estimated to be significant, but price competition has only started and the exact impact on the pharmaceutical market cannot be assessed.

Due to the legislative changes described above, as well as active price competition, this presentation and its impact assessments assume that the pharmaceutical market will not grow in the coming years at the rate of growth in previous years. As the medicinal products covered by the health insurance are mostly prescription-only medicines, it would be justified to apply the change to the prescription-only drug tax rate.

Alternative tax models

During the preparation, three alternative drug tax models were used to assess the change in the prescription tax rate. These were the flat-rate model for all medicines, the low-priced medicines taxa model and the high-priced medicines taxa model. In the course of the preparation, a comparison of taxa models led to the proposal of a flat-rate model for all medicines. The choice is based on the fact that the model would make it possible to achieve the desired savings. Kela estimates that a steadily cutting tax rate would reduce pharmaceutical costs by EUR 36.1 million and health insurance reimbursements by EUR 29.6 million. In addition, a flat-cutting taxa model would benefit all users of medicines, so that the benefit would be clearly distributed to more than the other models assessed. The euro-denominated benefits for users of medicines would be close to EUR 6 million in a flat-cutting tax model. In addition, the tax model chosen would not affect pharmacies' incentives to keep medicines at different prices in stock.

In accordance with the government programme, the implementation of the country-wide pharmacy network, the provision of pharmaceutical support (including medical advice), safety and access to medicines in Finland must be regarded as the framework conditions for the reform of the pharmaceutical tariff. In addition, the payment burden for customers should not increase. The proposed cut-off rate for all prescription medicines would have been calibrated in such a way as to maintain, with minimal negative effects, a comprehensive network of pharmacies in the country and to achieve the intended savings. In addition, the pharmacy tax rulings contained in this proposal would aim at smoothing the pharmaceutical tax-based economy of pharmacies, which is highly polarised.

As a result of the preparation of the presentation, it is proposed that the flat-cutting tax model should have six steps, as hitherto, but the range of tax categories would change for medicines with a wholesale price of between EUR 40 and EUR 1499,99. Cutting the pharmaceutical tax would mean lowering the mark-up coefficients for pharmacies in all tax bands and changing the constants in the four major groups. The proposed uniformly cut-off tax rate model would be as follows (right-hand table):

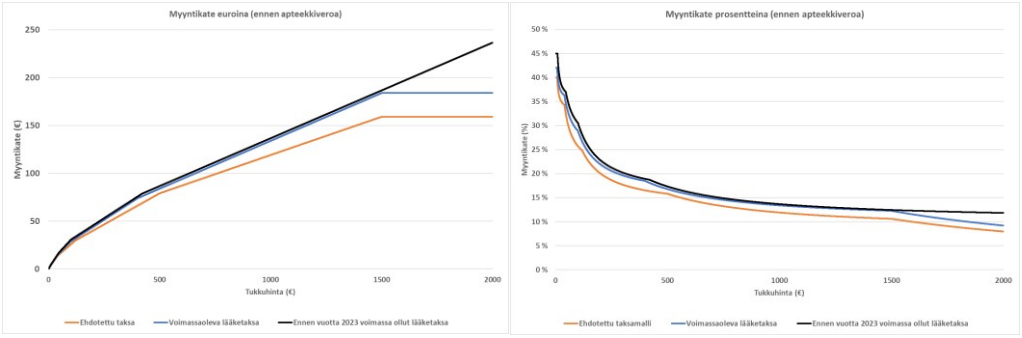
Table 1. Existing prescribing duty rate and uniformly cut-off rate for all medicines:

	Existing prescribing duty rate		**Uniformly cut all medicines taxa model**	
	Purchase price (wholesale price)	Retail price of the pharmacy (no VAT/executive payment)	Purchase price, EUR (wholesale price)	Retail price of the pharmacy, EUR (no VAT/executive payment)
1	EUR 0,00 – EUR	1.42 x purchase price	EUR 0,00 – EUR	1,40 x purchase price

	7.49		7.49	
2	BETWEEN EUR 7.50 AND EUR 39.99	1,35 x purchase price + EUR 0.52	BETWEEN EUR 7.50 AND EUR 39.99	1,33 x purchase price + EUR 0.52
3	BETWEEN EUR 40,00 AND EUR 99.99	1,24 x purchase price + EUR 4.92	EUR 40,00 – EUR 119,99	1,20 x purchase price + EUR 5,72
4	EUR 100,00 TO EUR 399,99	1,15 x purchase price + EUR 13.92	EUR 120,00 TO EUR 499,99	1.13 x Purchasing price + EUR 14.12
5	EUR 400,00 TO EUR 1499,99	1,10 x purchase price + EUR 33.92	EUR 500,00 TO EUR 1499,99	1,08 x purchase price + EUR 39.12
6	EUR 1500,00	1 x purchase price + EUR 183,92	EUR 1500,00 —	1 x purchase price + EUR 159,12

The converging effect of a taxi model that is uniformly cut from all medicines for all priced medicines is shown in the following picture, which shows the trade mark-up on a black segment before the 2023 drug tax changes, a margin based on the current pharmaceutical tax rate on a blue division and an orange cut evenly in a tax model that cuts all medicines:

Figure 1. The gross margin in euros (left) and as a percentage (right) before the pharmacy tax at the wholesale price interval between EUR 0 and EUR 2000 in a flat-rate model for all medicines.



For the modelling and impact assessment of the proposed pharmaceutical tax rate for prescription medicines alone, 2023 sales data have been used. This is due to the fact that the previous change in the pharmaceutical tariff entered into force at the beginning of 2023 and data from previous years would not be comparable. More recent pharmacies' financial data for 2024 could not be used for the analysis in the preparation of the presentation. However, the 2024 data may be processed before the presentation to Parliament and may be annexed to the explanatory memorandum to the Presentation and the Medicinal Tariff Regulation on prescription-only medicines during further preparation.

Need for further development

It is proposed to amend the pharmaceutical tax rate for prescription medicines in a situation where legislative changes to pharmacy activities are still under preparation. It is known that the supply of services in pharmacies and the provision of medical advice in connection with the supply of medicinal products vary from one pharmacy to another. On the other hand, it has been recognised that the content of pharmacy services and the network of services are currently not regularly assessed against the needs of the population in the region or other

social and healthcare services in the region. The knowledge base used has identified needs for improvement in this regard. In view of the above considerations, setting the level of the pharmaceutical tariff for prescription-only medicines at an optimal level and ensuring the cost-effectiveness of the pharmacy system will require, in addition to the proposed change in the tax rate, further development measures in the future.

Pharmacy tax

Current status

Under the Act on the taxation of pharmacies (770/2016), private pharmacists are authorised as well as the University of Helsinki and the University of Eastern Finland operating pharmacies under the Medicines Act. They are required to pay pharmacy tax to the State on the pharmacy business they operate. The Act on the taxation of pharmacies entered into force on 1 January 2017. In the meantime, pharmacies were charged a pharmacy fee instead of the pharmacy tax on the basis of the Act on the pharmacy fee (148/1946, repealed). The basic principles of the current pharmacy tax are similar to the previous pharmacy fee.

Under Paragraph 5 of the Law on the taxation of pharmacies, the taxable person's turnover is used as the basis for the pharmacy tax. The taxable amount is the same as in the past for the pharmacy fee. The general definition of turnover applies to the pharmacy tax. Under Section 1 of Chapter 4 of the Accounting Act (1336/1997), turnover includes revenue from the sale of goods and services, net of discounts granted and VAT, and other taxes directly based on the volume of sales.

In calculating the amount of the pharmacy tax for the tax year, VAT is deducted on the turnover of a pharmacy, a branch pharmacy, a pharmacy's service point, a pharmacy's online service and a medical cabinet. In addition, the following VAT-exempt proportions shall be deducted from turnover exempt from VAT: the value of sales of the contract manufacturing referred to in Article 12(2) of the Law on medicinal products and the sale of medicinal products to social and healthcare establishments, the value of sales of medicinal products for nicotine replacement treatment which may also be sold outside a pharmacy, the sale of products other than medicinal products, but not more than 20 % of the turnover deducted in accordance with paragraphs 1 and 2, and the proportion of sales of medicinal products with a wholesale price in excess of EUR 1500, in so far as the retail price, exclusive of VAT, of each of those medicinal products exceeds EUR 1683,92.

For the fiscal year 2023, pharmacies paid approximately EUR 209 million of pharmacy tax to the State (Tax Administration's statistical database). Evolution of tax revenue, tax revenue and refunds, net revenue from pharmacy tax, total fiscal year 2023. Available 1. Tax revenue and refunds changedto Tax Type, Fiscal Year, Month, Variable and Data. PxWeb). For the 2022 fiscal year, a slightly higher amount of pharmacy tax of approximately EUR 214 million was paid to the State (Finnish Medicines Statistics 2023 and analysis of the accounts of pharmacies for the years 2019-2022, Fimea develops, assesses and informs 7/2024 (' *Fimea 7/2024'*) and the Tax Administration referred to therein: Evolution of tax revenues in 2023). The tax year is the basis of assessment, i.e. the time at which the tax is determined. On the basis of the previous tax year, the tax will be paid by the end of February of the following year. In addition, the pharmacy tax is paid in small amounts in other months, mainly due to changes in pharmacists.

The pharmacy tax payable by the taxable person is calculated on the basis of a scale based on turnover groups, so that the pharmacies with the highest turnover pay the pharmacy tax the highest. The smallest pharmacies with a lower turnover than the lowest step in the lowest turnover group are not subject to pharmacy tax. Under Article 6 of the Law on the taxation of pharmacies, the pharmacy tax is calculated by turnover group as follows:

Turnover, EUR	Pharmacy tax at the lower turnover threshold, EUR	% Tax on turnover above the lower threshold
871393-1 016 139	0	6,10
1016139-1 306 607	8 830	7,15
1306607-1 596 749	29 598	8,15
1596749-2 033 572	53 245	9,20
2033572-2 613 212	93 432	9,70
2613212-3 194 464	149 657	10,20
3194464-3 775 394	208 945	10,45
3775394-4 792 503	269 652	10,70
4792503-6 243 857	378 483	10,95
6 243 857—	537 406	11,20

In 2023, private pharmacies accounted for an average pharmacy tax of EUR 281000 per pharmacy, the median being around EUR 223000 per pharmacy. Slightly less than half of the pharmacies (n= 292) accounted for pharmacy tax of up to EUR 200000 per pharmacy and about one quarter of the pharmacies (n=178) less than EUR 100000 per pharmacy. Eight pharmacies did not pay any pharmacy tax (Analysis of pharmacies' accounts for 2020-2023, Fimea develops, assesses and informs 1/2025, ' *Fimea 1/2025'*, p. 26). In 2023, the pharmacy of the University of Helsinki accounted for EUR 29 million for the pharmacy tax and EUR 1.2 million for the University of Eastern Finland. (University pharmacy. 2023 annual report; Annual accounts 2023 of the University of Eastern Finland).

Article 7 of the Law on the taxation of pharmacies provides for the calculation of the amount of the tax. The pharmacy tax is calculated for each taxable person separately. If the pharmacy does not have a branch pharmacy, the pharmacy tax shall be calculated on the basis of the combined taxable amount of the pharmacy, the pharmacy's service centre, the pharmacy's online service and the medical cabinet, on the basis of the tax scale provided for in Paragraph 6.

Separately, Section 7 of the Act on the Tax on Pharmacy provides for the calculation of the pharmacy tax if the pharmacy has one or more branch pharmacies. Where a pharmacy has one or more branch pharmacies and the combined taxable amount of the pharmacy and its branch pharmacies, service outlets, online services and medical cabinets pursuant to Paragraph 5 exceeds EUR 3500000, the pharmacy tax shall be calculated from that common taxable amount on the basis of the scale laid down in Paragraph 6. In that case, one third of the taxable amount calculated in accordance with Paragraph 5 of the branch pharmacy shall be deducted, but not less than EUR 50500, and, if the taxable amount of the branch pharmacy is less than EUR 50500, the total taxable amount before the branch pharmacy's taxable amount is added to the common taxable amount. However, no deduction shall be made if at least five years have elapsed since the establishment of the branch pharmacy at the end of the tax year and the turnover of the branch pharmacy during the tax year corresponds to at least half of the average turnover of the private pharmacies for the year preceding the tax year, excluding the turnover of the branch pharmacies. The average turnover of private pharmacies is established annually by the tax authorities.

Under Paragraph 7(4) of the Law on the taxation of pharmacies, if the combined taxable amount of a pharmacy and its branches, service outlets, online services and medical cabinets under Paragraph 5 is not less than EUR 2600000 but not more than EUR 3500000, the pharmacy tax is calculated as a weighted average as provided for in paragraphs 6 and 7. In accordance with paragraph 5 of that article, the notional pharmacy tax shall be determined in

the manner provided for in paragraph 3 on the basis of the scale laid down in Article 6 for the purpose of calculating the weighted average. In addition, the notional pharmacy tax shall be determined separately, as provided for in paragraph 4, on the basis of the scale of Article 6.

Under Article 7(6) of the Law on the tax on pharmacies, after the determination of the notional pharmacists, the amount of the pharmacy tax is to be calculated as a weighted average of those pharmacies on the basis of weighting factors determined on the basis of the total taxable amount for pharmacy activities, as follows:

Turnover, EUR	Coefficient for the tax calculated in accordance with subsection 3	Coefficient for the tax calculated in accordance with subsection 4
—2 699 999	0,90	0,10
2700000-2 799 999	0,80	0,20
2800000-2 899 999	0,70	0,30
2900000-2 999 999	0,60	0,40
3000000-3 099 999	0,50	0,50
3100000-3 199 999	0,40	0,60
3200000-3 299.999	0,30	0,70
3300000-3 399 999	0,20	0,80
3400000-3 500 000	0,10	0,90

The procedure for the taxation and appeal of the pharmacy tax is governed by the Act on the procedure for the taxation of own-initiative taxes (768/2016) and the collection of the pharmacy tax by the Tax Collection Act (11/2018). Under Paragraph 4 of the Law on the taxation of pharmacies, the tax year for the pharmacy tax is the calendar year. A similar provision is also contained in Article 11(4) of the Code of Tax Procedure. According to the explanatory memorandum to the pharmacy tax law, the taxable person’s financial year would have no effect on the tax year. The definition of the tax year has been considered necessary because, when calculating the progressive amount of pharmacy tax, it is necessary to determine which period of turnover is used to determine the taxable amount (HE 29/2016 vp).

Under Article 17(3) of the Law on the procedure for the taxation of own-initiative taxes, if the taxable person’s tax period for non-excise purposes is a calendar year, the tax return for the tax period must be submitted no later than the last day of February following the tax period. Under Article 32(3) of the Law, if the taxable person’s tax period other than excise duty is a calendar year, the tax period must be paid no later than the last day of February following the tax period. Consequently, the taxable person must submit a pharmacy tax return and pay pharmacy tax by the end of February of the year following the tax year. Under Article 8 of the Law on the taxation of pharmacies, the Tax Administration may, at the written request of a taxable person, issue a preliminary ruling on the pharmacy universal.

Assessment of the current situation

In addition to the reform of the pharmaceutical tariff for prescription-only medicines, the proposal proposes a reform of the pharmacy tax. In accordance with the Government Programme, the reform of the pharmacy economy takes into account the pharmacy tax and the pharmaceutical tariff together. taking into account, among other things, the actual profitability of pharmacies and securing a nationwide network of pharmacies. pharmacy support (including medical advice), medication safety and access to medicines for rational medicine. The need for reform of pharmacy taxation has already been identified in the 2019 Pharmaceutical Map and subsequent government studies (STM 2019:5 p. 47). In addition, the pharmacy tax has to be

seen in the light of the interdependence between the pillars of pharmacy regulation, since the proposal proposes to change the tariff of prescription medicines and the price regulation of self-medicine products within the limited self-care range.

Pharmacy tax base

Under the pharmacy tax law in force, the taxable amount for the pharmacy tax is the total annual turnover of the taxable person, i.e. a pharmacist or university pharmacy, on sales of medicinal products and certain other items. Chapter 4, Section 1 of the Accounting Act (1336/1997) provides that turnover includes revenue from the sale of goods and services, net of discounts granted and VAT, and other taxes directly based on the volume of sales. The concept of turnover within the meaning of the Law on the taxation of pharmacies is comparable to that of turnover in the Accounting Act. The turnover subject to the pharmacy tax includes, for example, sales of medicinal products and dosage distribution fees, but not, for example, Kela's single purchase fees or other operating income not directly related to the goods or services sold (STM 2023:6, p. 93 and the Rhine and others cited there). 2021).

The pharmacy's turnover as the basis for calculating the pharmacy tax is clear from the tax administration's point of view and allows for proper monitoring of pharmacy taxation (Fimea 1/2021 pp. 38-39). Pharmacy taxation based on turnover operates if the differences in costs between pharmacies are similar or can be influenced by the pharmacist. There are many common but also many differences in the costs of pharmacies, which are independent of the choice of pharmacists (KKV 7/2023, p. 36).

The problem of the taxation of pharmacies on the basis of turnover is that the structure of the pharmacy's sales of medicinal products has a stronger effect on the taxable amount. If a pharmacy sells a lot of expensive medicines, the rate of pharmacy tax based on turnover increases regardless of the size of the pharmacy, the actual financial situation of the pharmacy, its profitability or the remaining share of its pharmaceutical sales.

In addition, pharmacy taxation based on turnover leads to the problem of 'negative margins' (Fimea 1/2021 pp. 38-39). At the same time, the sale of expensive medicines increases the turnover of pharmacies rapidly and progressively, which is subject to an increase in the pharmacy tax. In this case, in some individual medicinal products, the margin on sales of a expensive medicine to a pharmacy may in fact be lower than the pharmacy tax payable on the sale of the medicinal product. In this case, it is referred to as a negative margin. However, the negative margin does not mean that the sale of pharmacies is entirely loss-making. It should be noted that while the pharmaceutical tariff and the pharmacy's sales margin are product-specific, the pharmacy tax is based on the pharmacy's turnover for the whole year (STM 2023:6 p. 95 and the Social Insurance Institution referred to therein 2022 and Fimea 1/2021 p. 25). The negative margin has been identified in the Medicines Act and the Act on the taxation of pharmacies and has been addressed by legislative amendments that entered into force since the beginning of 2023.

For the above reasons, it is proposed to base the pharmacy tax not on the taxable person's turnover but on a taxable amount that better reflects the differences in profitability between pharmacies. In its 2023 report, the KKV suggested that the pharmacy tax would be turned into a profit-based pharmacy tax, although this could lead to high tax rates if the current tax revenue were to be maintained (KKV 7/2023 p. 36). As an alternative, a pharmacy tax based on a margin is proposed, which would more fairly equalise the economic conditions for pharmacies of different sizes and where the structure of the pharmacy's sales of medicinal products would not affect the determination of the tax. However, the weak side of the Myyntita-based pharmacy tax is that it could be more difficult to control than currently taxed if it were possible for pharmacies to optimise the margin or reduce the taxable amount through the use of stock change or external services (Fimea 1/2021, p. 39).

During the preparation of the proposal, the pharmacy tax based on the margin on sales of medicinal products by the taxable person was chosen as the model to be presented. This would entail a change in the current taxable amount. The pharmacy tax base would no longer take into account sales of other products in addition to pharmaceutical sales. Under the current pharmacy tax law, the taxable person may deduct from the turnover for the purposes of the pharmacy tax the sale of products other than medicinal products, up to a maximum of 20 % of the turnover in respect of which deductions have been made in accordance with paragraphs 1 and 2.

The current pharmacy tax solution for non-medicinal products has been perceived as problematic by pharmacy operators, as only free-trade products sold by pharmacies are subject to the pharmacy tax. The solution proposed in this proposal would improve the competitive neutrality of the sale of free-trade products. At the same time, the incentive for pharmacies to operate a separate limited liability company would be reduced. The inclusion of sales of products other than medicinal products in the taxable amount for pharmacy tax is one of the reasons why separate limited liability companies have been set up within pharmacies. The amendment would not completely remove the incentive in so far as it is based on income tax criteria or the operation of a limited liability company is linked to the pharmacy's other business activities. That solution would also be justified by the fact that it would enable the purpose of the pharmacy tax to be more focused on the sale of medicinal products by pharmacies as their main function.

A pharmacy tax based on the margin on sales of medicinal products would mean that the problem of negative margins would no longer arise. The prices of medicinal products are regulated by the Medicinal Products Tax Regulation. The pharmacy's margin, which is determined by the Regulation, shows how much profit is available to the pharmacy from sales of medicinal products after deduction of purchases of goods corresponding to sales of medicinal products. In the case of taxation, the profit margin retained by the pharmacy could not give rise to a situation in which the margin would be negative. In the event of the problem of negative margins being eliminated, the provision on negative margins in Section 58 of the Medicinal Products Act on price regulation and the provision in Article 5(2)(4) of the Law on the taxation of pharmacies, which were intended to reduce the problem of negative margins, could be removed. There would no longer be any need for such corrections in the proposed pharmacy tax system.

Article 5(2) of the Law on the taxation of pharmacies provides for items to be deducted from the taxable person's non-taxable turnover. According to point 1 of that paragraph, those are the value of the sale of the contract manufacturing referred to in Article 12(2) of the Law on medicinal products and the sale of medicinal products to social and health care establishments. It is also proposed that these deductions be made from the taxable amount based on the margin on sales of medicinal products. Already at the time of the Law on the pharmacy fee, the basis for the reduction in the value of sales of contract manufacturing was that, in the absence of a deduction, 'the pharmaceutical products manufactured by*a pharmacy for another pharmacy would have a double effect on the pharmacy fee for both the pharmacy which manufactures the medicinal product and the pharmacy which markets the medicinal product to the general public. It would be appropriate for the medicinal product contracted to be taken into account only in the turnover of the pharmacy which sells it to the general public'* (HE 46/2002 vp). The starting point would not change in the proposed tax model. It is true that, in addition to the value of the sale, the items to be deducted should be the variable costs associated with the sale, i.e. the entire production under contract should be excluded from the pharmacy tax base for the manufacturing pharmacy.

Sales of medicinal products to social and healthcare establishments should also be deducted from the taxable amount, as has been the case so far. The deduction was made at the time from

the basis for the pharmacy fee, since the pharmacy fee was based on the sale of medicinal products to the general public (HE 46/2002 vp). Sales of installations, including variable costs, should be disregarded when determining the taxable amount.

Under Paragraph 5(2)(2) of the Law on the taxation of pharmacies, the value of sales of nicotine-reimbursable medicinal products which, under the Medicines Act, may also be sold outside a pharmacy could be excluded from the taxable amount for pharmacy tax. It is proposed to maintain the deduction in the Act on the taxation of pharmacies. In the case of pharmacy taxation based on the margin, the sale of these nicotine-reimbursable medicinal products should be excluded from pharmacy taxation, both in terms of sales proceeds and related direct costs (purchases of goods).

This proposal proposes that self-medicines within the limited range of self-medication products defined in the Medicines Act and the Medicinal Products Regulation could also be sold outside pharmacies. It should be possible to exclude these products from the scope of the pharmacy tax for the entire range, irrespective of whether the product in the range would be sold outside the pharmacy. The demarcation is necessary in order to allow the most equal conditions of competition for operators selling these self-care medicines. In the absence of such a delimitation, pharmacies would have to pay a pharmacy tax on the sale of a range, which would not be paid by other holders of retail licences for self-treatment medicinal products.

The pharmacy tax based on the margin on sales of medicinal products would aim at simplifying taxation. However, this tax model could present challenges in terms of tax clarity and control. The legislation should define precisely which items are included in the taxable profit margin and which items would be deductible. It would also be useful to take a position on the sequencing of the lots, on the medicinal products in the pharmacy's stock and on whether their purchase price would be determined by the tariff at the time of purchase or sale. The latter would be an important aspect as wholesale prices of medicinal products may vary every two weeks.

It is proposed that the margin on pharmaceutical sales, for which the pharmacy tax law would use the term 'margin on sales of medicinal products', be determined by deducting from the taxable person's turnover in pharmaceutical sales, i.e. VAT-exempt sales, only the variable costs associated with the sale of medicinal products, i.e. purchases of goods. The margin received by pharmacies from the sale of prescription and self-prescription medicines would be based on the pharmacies' margin under the Medicinal Tariff Regulation. A single wholesale price at the time of delivery of the medicinal product to the customer of the medicinal product at which the pharmacy buys the medicinal products from the wholesale distribution of medicinal products should be considered as the purchase price of the goods. It would be justified to determine the profit margin on the taxable sale of medicinal products at the time when the medicinal product is sold to a customer from a pharmacy, that is to say, at the same time as the price of the medicinal product.

Deductions from the taxable amount could not be made for the whole of the pharmacy's business, such as deductions of salaries, rents for premises or equipment and operating costs or investments. The pharmacy tax based on the margin would take more account of the operating conditions of the pharmacy than the previous model, but the pharmacy business as a whole could continue to be loss-making as a result of the tax. In such situations, for example, staff salaries, rental costs, investments or other costs would be unreasonably high in relation to the return on business.

Progressive or flat-rate tax system?

The pharmacy tax has a fiscal purpose in today's society. Between 2024 and 2025, the State's total annual pharmacy tax revenue has ranged from EUR 209 million to EUR 220 million. It is possible to calibrate the progressive pharmacy tax system in such a way as to achieve the target pharmacy tax revenue of approximately EUR 200 million in a way that takes into account the ability to pay of pharmacies of different sizes.

The pharmacy tax (formerly the pharmacy fee) has traditionally been found to be aimed at securing comprehensive pharmacy services in the country and at offsetting income disparities between pharmacies (HE 29/2016 vp, as well as HE 64/2014 vp, HE 171/2013 vp and HE 46/2002 vp), which also pointed out that 'the*primary purpose of the pharmacy fee is to ensure the profitability of sales of medicinal products, including in small pharmacies in small localities, together with the retail prices of medicinal products set* by a pharmaceutical tax').

The pharmacy tax is necessary to offset income disparities between pharmacies because of the specificities of the pharmaceutical market, such as uniform pricing and regulation of the number and location of pharmacies, income inequality is not levelled through normal market mechanisms. A uniform retail price level for medicinal products is defined in the pharmaceutical tariff. However, it leads to excessive profits in pharmacies on the best trading venues. The pharmacy tax is needed to cut these excessive profits.

The KKV study has found that the role of the pharmacy tax as an income equalisation mechanism between pharmacies has diminished, as it is not possible to take into account increased sales of free-trade products or reduced dividend taxation by non-listed limited liability companies for profit from the sale of non-pharmaceutical products (KKV 7/2023, pp. 5, 13-14). However, the 2023 STM report has found it necessary to continue to smooth out income disparities between pharmacies. This could be done either by means of a pharmacy tax or by supporting economically badly performing pharmacies (STM 2023:6 pp. 102-103).

Under Paragraph 6 of the Law on the taxation of pharmacies, the difference in income between pharmacies is to be offset by means of a 10-stage progressive tax scale. The progressive nature of the tax is achieved by the fact that pharmacies whose turnover in a tax year is less than EUR 871393 do not pay the pharmacy tax and pharmacies whose turnover exceeds the lower threshold are subject to a rate of pharmacy tax between 6.10 % and 11.20 % by turnover. The rate for each step applies only to the part of the taxable amount exceeding the lower limit. In this case, a small pharmacy, at the same price, retains a higher margin after pharmacy tax than a large pharmacy (see STM 2023:6 pp. 94-97 and the Rhine and Others cited there). 2021 and Fimea 1/2021, pp. 16-17, 24-42).

The preparation of the proposal identified that a progressive tax model would also be justified in the case of pharmacy taxation based on the profit margin on pharmaceutical sales of pharmacies, since it takes into account the ability to pay of pharmacies of different sizes and makes it possible to offset the differences in income between pharmacies compared, for example, with a flat-rate tax model which would treat all pharmacies in the same way regardless of their size and profitability. A flat-rate model could operate better on a less regulated market where competitive conditions, such as price and location, would not be specifically determined.

In the preparation of the presentation, in addition to the progressive pharmacy tax model based on the margin of sales of medicinal products, the flat-rate tax model was assessed. It is proposed to opt for a progressive tax model because progressive taxation would take account of taxpayers' ability to pay and target larger pharmacies and pharmacies located in areas where other pharmacies also exist. In addition, the progressive tax model sees more positive tax effects for pharmacies and less negative tax effects than a flat-rate model. In the flat-rate model, loss-making pharmacies were estimated to be higher than in the progressive model and

loss-making pharmacies would be smaller in size than in the progressive tax model and have more branch pharmacies.

Progressive taxation would also be justified from the perspective of the scalable benefits of larger pharmacies due to the cost structure, since progressive taxation and the tax exemption for small pharmacies would offset the resulting differences (KKV 7/2023, p. 28). Pharmacy regulation was reformed in Sweden in 2009. As a result of these changes, small pharmacies have faced challenges arising from the scaling benefits of larger operators in the context of economic conditions and changed regulation. Market conditions are challenging for smaller entrepreneur-led pharmacies that are not part of any pharmacy chain, as the market is dominated by economies of scale and strong bargaining power (Konkurrensverket 2025:2: Den omreglerade apoteksmarknaden). A progressive pharmacy tax model would cut similar scale advantages in Finland and even out income differences between pharmacies of different sizes, as in larger entities it is likely to be cheaper to provide services. A flat-rate model would favour larger operators.

It is proposed to base the pharmacy tax on the taxable person's sales of medicinal products in the future. In addition, it is proposed to cut the prescription-only drug tariff evenly across all tax bands. Changes in the scale of taxation under Section 6 of the Act on the taxation of pharmacies make it necessary to amend the scale. In the preparation of the tax scale, the aim was that the pharmacy tax would in the future generate an annual tax revenue of approximately EUR 200 million, comparable to the level of the 2023 tax period, after the prescription medicines had been taxed and a limited range of self-medication products, which could also be sold outside the pharmacy, would have been removed from the pharmacy tax base.

Compared to the pharmacy tax based on turnover, the pharmacy tax base based on the margin on sales of medicinal products would be about one third of the present, and the new tax rates in the tax scale would therefore have to be about three times the current rate if the tax model were to be built with an annual pharmacy tax revenue of around EUR 200 million. During the preparation, the taxable amount was adjusted to be calculated by taxable person, as has been the case so far. The calculation of the taxable amount per pharmacy office was not possible due to the necessary changes in the information system and the lack of a data base in the timeline of the presentation. The wholesale sales data per pharmacy of Fimea were used to calculate the tax model for pharmaceutical sales. The information on interchange fees was based on pharmacy-specific data from Kela. Potential discounts for self-medicines could not be taken into account in the calculation.

It is proposed to set the so-called zero limit on the tax scale at EUR 250000. The limit would be based on the amount of the margin on sales of medicinal products which the pharmacy is estimated to need to cover the minimum costs of the pharmacy. This amount would include the salary costs of one pharmacist and any technician, the cost of a stock of medicines and the cost of renting. Only a few pharmacies are estimated to fall below the zero limit. However, the margin on sales of medicinal products by a small pharmacy is likely to exceed only a small share of the margin on pharmaceutical sales, so that small pharmacies would be taxed only partially on the basis of the tax scale.

Separate support elements

According to the Government Programme, a nationwide pharmacy network is secured, if necessary, with separate support elements, such as a negative pharmacy tax. The proposal would not propose the creation of a separate support element or negative pharmacy taxation,

as there was no immediate need for the aid element, it was not possible to prepare it in the timeline of the proposal and the necessary evidence base was not available to prepare it.

The presentation proposes a cut in the pharmaceutical tariff for prescription-only medicines and changes to the pharmacy tax. According to the impact assessment, a number of new individual pharmacies, which would not be the only pharmacies in their territory, would be counter-productive as a result of the proposed changes, so that the territorial availability of medicines would not be jeopardised. On the other hand, notional loss-making would not mean that the pharmacy was incapable of operating. The notional loss-making nature of individual pharmacies would thus not require the creation of a separate support element on a country-wide basis.

In Sweden and Norway, for example, direct payments to pharmacies in remote areas are available and can be applied for by pharmacies. In Sweden, 31 pharmacies were granted support in 2020. The conditions for receiving the aid were, inter alia, a distance of more than 20 km to the nearest pharmacy, a certain value of sales of prescription-only medicines and adequate opening hours. Norway has a separate annual operating subsidy granted by the Parliament to pharmacies in areas where there is a need for pharmaceutical services but where the activity is not economically viable with a reasonable effort (Fimea 1/2021 52-53).

A new model of support for pharmacies that become unprofitable but needed in sparsely populated areas is already outlined in the 2019 Pharmaceutical Road Map (STM 2019:5 p. 47) and in the government studies completed in recent years (STM 2023:6 p. 99-100, KKV 5/2020 p. 30 and KKV 7/2023 pp. 35-36). On the basis of the impact assessments carried out, the preparation of the pharmaceutical tax rate and the size of the pharmacy tax would not threaten the maintenance of the country's comprehensive pharmacy network and therefore no separate support scheme was deemed necessary.

Special tax treatment for branch pharmacies

Branch pharmacies have been taken into account in Section 7 of the Act on the taxation of pharmacies. The turnover of a branch pharmacy is taken into account in different ways, depending on the combined taxable amount of the pharmacy and its branches.

However, the weakness of the current special treatment of branch pharmacies is that it is not possible to assess, on the basis of the existing evidence base, whether the special tax treatment of branch pharmacies is correctly allocated. In its 2023 report, the KKV has examined the pharmacy tax treatment of branch pharmacies (KKV 7/2023 Annex 4). The study finds that the tax aid for branch pharmacies does not appear to be excessive, but at the same time concludes that it does not make it possible to conclude whether the tax aid granted is necessary, i.e. whether the branch pharmacy would be kept without the tax aid in question and, if not, to what extent it would affect the pharmacy's customers.

The overall situation is complicated by the fact that there are two types of branch pharmacies in Finland. In 2023, there were 638 private main pharmacies and two university pharmacies in Finland. There were 173 branch pharmacies of private pharmacies, in addition to 16 branch pharmacies at the University of Helsinki (Fimea 1/2025 p. 12). Of the branch pharmacies, approximately 100 were so-called branch pharmacies, the obligation to keep which is linked to an open pharmacy licence, so that, when applying for a pharmacy licence, the pharmacist is obliged to operate the branch pharmacy, since it is of particular importance in order to ensure the availability of medicinal products in its territory. The rest of the branch pharmacies are so-called 'legal' branch pharmacies for which a pharmacist has voluntarily applied for authorisation to operate branch pharmacies in a given area. The Act on the taxation of pharmacies does not distinguish between branch pharmacies which are a condition and a right. However, it should be possible to apply the special tax treatment of branch pharmacies

exclusively to those sub-pharmacies which would be critical to the availability of medicinal products to the population in the area in which they are located.

The special tax treatment of branch pharmacies in the current pharmacy tax law is not as such transferable to the pharmacy tax system based on the proposed margin on pharmaceutical sales. According to Fimea's 2021 study, this is due to the lack of site-by-site information on the amount of margins of the pharmacy's branches and the fact that purchases of goods are generally dealt with as a whole at the level of the pharmacy's business as a whole. However, the study has identified the possibility of sub-pharmacies being subsidised by means other than separate taxation. As an alternative to the deduction for a branch pharmacy, the report mentions a flat-rate deduction from the taxable amount or a scheme similar to Sweden and Norway, under which direct financial aid would be granted to the pharmacy on the basis of the application. (Fimea 1/2021, pp. 39 and 48-52).

If the specific provisions in force for branch pharmacies were to be maintained, their purpose should be to ensure the provision of pharmacy services in areas where pharmacy services would not otherwise be required. During the preparation of the draft proposal, it has not been possible to find a tax solution in support of branch pharmacies that would target the aid in an appropriate way. Current monitoring data on pharmacy and activities and models for monitoring, evaluation and guidance do not allow the identification of critical branch offices. For the above reasons, it is proposed to abolish the special pharmacy tax treatment of branch pharmacies in its current form. The solution would simplify taxation and streamline tax collection.

Retail sale of self-treatment medicinal products

Current status

Self-care medicines are used to treat many common, mild and short-term illnesses and symptoms that do not require treatment or prescription by a healthcare professional. The value of total sales of medicines in Finland in 2023 was EUR 3 864 million, while sales of self-treatment medicines at retail prices accounted for 404 million of total sales. Overall sales of medicines increased by 2.5 % compared to the previous year, with an increase of around 1.5 % compared to 2022 (Finnish Medicines Statistics 2023).

The sale of a medicinal product to the general public or any other release for consumption is subject to the condition that the medicinal product has been granted a marketing authorisation valid in Finland upon application by a pharmaceutical company. Chapter 4 of the Medicines Act governs the marketing authorisation of a medicinal product and its modification.

Under Paragraph 21(2) of the Law on medicinal products, the Finnish Medicines Agency may attach conditions to the marketing authorisation of a medicinal product if they are necessary to ensure the correct and safe use of the medicinal product. The classification of a medicinal product as a prescription or self-treatment product is one of the conditions of the marketing authorisation. In a marketing authorisation procedure, an applicant for marketing authorisation may apply for a medicinal product to be classified as a self-treatment medicinal product. An application may also be made after the authorisation has been granted as an application for variation of the marketing authorisation. Similarly, if, for example, safety concerns are detected in a self-medication medicine, at the initiative of the marketing authorisation holder or Fimea, it may be converted into a prescription-only medicine. The classification of supplies is regulated at national level by Section 23b of the Medicinal Products Act, Article 9 of the Medicinal Products Ordinance and the Fimea Order on the application for and maintenance of the marketing authorisation and registration of a medicinal product (4/2019). The rules are based on Articles 70 to 72 of Directive 2001/83/EC of the European Parliament and of the Council on the Community code relating to medicinal products for human use ('the

*Medicinal*Products Directive'). The classification of veterinary medicinal products is governed by Article 34 of Regulation (EU) 2019/6 of the European Parliament and of the Council on veterinary medicinal products and repealing Directive 2001/82/EC ('the *Veterinary Medicinal*Products Regulation').

The retail and other release for consumption of self-treatment medicinal products is largely a matter for the national legislative competence of the Member States. EU legislation is silent on who can sell self-care medicines in the Member States. An operator other than a pharmacy may act as a retail distributor of medicinal products in a Member State (Articles 2, 17k and 81 of the Medicinal Products Directive, Article 103 of the Veterinary Medicinal Products Regulation).

As a general rule, self-care medicines, like all medicines, are sold in Finland only from pharmacies (Section 38a of the Medicines Act). The establishment of a pharmacy is subject to authorisation (Section 40 of the Medicines Act) and the operation of the pharmacy is supervised by Fimea. The Law on medicinal products imposes obligations on pharmacies to act, in particular as regards advice on medicinal products and prices (Section 57), staff and pharmacy premises (Article 56), as well as pharmacy stockpiling, opening hours, quality of medicinal products and marketing authorisations (Article 55). The regulation of the marketing of medicinal products, which is based on EU law, must also be taken into account.

The exception to medicinal products sold in a pharmacy is the traditional herbal medicinal products and homeopathic preparations referred to in Paragraphs 22 and 22a of the Law on medicinal products, which may also be sold elsewhere, unless otherwise decided by the Finnish Medicines Agency at the time of registration. Fimea determines the sales channel for those products when they are registered. In addition, nicotine products classified as medicinal products may be sold outside the pharmacy, with the exception of nicotine products classified as prescription-only medicinal products. The sale of nicotine products classified as a medicinal product sold outside pharmacies is governed by Sections 54a to 54e of the Medicines Act.

In addition, both in pharmacies and outside pharmacies, products which are not classified as medicinal products but which are similar in form, mode of use or strength to self-care medicinal products sold in pharmacies are sold as food supplements, medical devices or cosmetics.

As a general rule, there is no age limit for the purchase of self-medicines. Only the purchase of nicotine products is subject to a purchase age limit. A pharmacy may, in principle, supply a customer with a self-treatment medicinal product without prescription only one, the largest package of medicinal products authorised for self-treatment in a single purchase. The strength, quantity and pack size of a self-treatment medicinal product to be purchased at one time is based on the decision to classify the medicinal product as a self-treatment medicinal product. The restrictions are not of general application as they are decided on a product-by-product basis.

Pharmacies and other retailers of self-medication medicinal products purchase self-care medicines either from a pharmaceutical plant or from a pharmaceutical wholesaler (Sections 31(1) and 34(1) of the Medicinal Products Act). The safety features to be attached to medicinal products and their removal are laid down in Paragraphs 30q to 30u of the Law on medicinal products. Under Paragraph 17 of the Law on medicinal products, pharmacies and hospital pharmacies have the right to import medicinal products in order to operate a pharmacy.

Pricing of medicinal products is a national competence of the Member States (Article 4(3) of the Medicinal Products Directive and Article 2(8) of the Veterinary Medicinal Products Regulation). In Finland, a pharmaceutical company is free to set the wholesale price of a medicine and prices can vary every two weeks. However, in the event of an application for

reimbursement, the Medicinal Products Pricing Board of the STM fixes the maximum wholesale price for reimbursable medicinal products. The majority of self-medicines are not covered by health insurance. Where a self-treatment medicinal product is supplied with a refund to the customer, the customer should have a prescription for the self-treatment medicinal product.

In the case of a medicinal product sold from an out-patient pharmacy, Paragraph 37a of the Law on medicinal products provides that pharmacies must purchase self-care medicines at a uniform national wholesale price, which must be the same for all pharmacies and branch pharmacies. This uniform wholesale price must take into account all discounts, rebates and other benefits granted to pharmacies and branch pharmacies. However, the standard wholesale price does not apply to medicinal products which may also be sold outside pharmacies. For example, nicotine products sold outside the pharmacy are exempt from the uniform wholesale price.

The retail pricing of self-treatment medicinal products sold to a consumer from a pharmacy is governed by Paragraph 58 of the Law on Medicinal Products and by the Medicinal Tax Decree. The price of a medicinal product for self-treatment is made up of the retail price of the medicinal product and VAT. If a self-medicine medicinal product is supplied on prescription, the retail price is increased by the delivery fee and VAT per batch. The retail price of a self-treatment medicinal product shall not exceed the retail price of the medicinal product at the retail level and shall not be less than the wholesale price of the medicinal product available at national level in accordance with Article 37a of the Law on medicinal products. The price must be the same for all pharmacies and online services. However, the retail price of self-prescription medicinal products requiring additional advice is the retail price of the medicinal product and the retail price of a medicinal product supplied from a pharmacy without prescription is the retail price of the medicinal product, provided that the nationally uniform price is justified in the light of the medical advice required for the use of the medicinal product, the possible adverse effects of the medicinal product or public health. The price must be the same for all pharmacies and online services. Collective discounts for medicinal products are expressly prohibited.

Under Paragraph 4 of the Medicinal Products Tax Decree, when sold from a pharmacy, self-care medicinal products must be sold at the retail price at least at the purchase price of the self-medication product, which is the wholesale price indicated by the holder of the marketing authorisation for the medicinal product in accordance with Paragraph 37a of the Law on medicinal products, which is in use nationally on the day of sale of the medicinal product, and not more than the retail price determined in accordance with the following formula:

Purchase price, EUR	Retail price
0 TO 9,25	1.5 x Purchasing price + EUR 0.50
9.26-46,25	1.4 x Purchasing price + EUR 1.43
46,26-100,91	1,3 x Purchase price + EUR 6.05
100,92 TO 420,47	1.2 x Purchasing price + EUR 16.15
over 420,47	1.125 x purchase price + EUR 47.68

Article 7 of the Decree on Medicinal Products also provides for further reductions in the price of a medicinal product. War veterans have a special right of reduction. In addition, a pharmacy may grant a discount which it has decided on sales to social and healthcare establishments. No rebates or benefits may be given on the basis of purchases of medicinal products outside pharmacies. The price regulation applies to medicinal products which may only be sold in pharmacies and pharmacies. Registered homeopathic products, registered traditional herbal medicinal products and nicotine products are thus excluded.

The self-care medicines sold by the pharmacy are included in the turnover of the pharmacist, the pharmacy of the University of Helsinki and the pharmacy of the University of Eastern Finland, on the basis of which they are required to pay pharmacy tax to the State under the Act on the taxation of pharmacies. The pharmacy tax base is currently reduced by the value of sales of medicinal products for nicotine replacement treatment which may also be sold outside the pharmacy. In addition, a private pharmacist is taxed as a private entrepreneur on the sale of self-medication medicines and a university pharmacy is taxed through corporation tax. The VAT rate for self-treatment medicines is 14 % (Act amending the Value Added Tax Act 691/2024).

The Centre for Safety and Development of Medicinal Products supervises pharmacies pursuant to Sections 76 and 77 of the Medicines Act. The establishment of a pharmacy is subject to the grant of a pharmacy licence by Fimea and Fimea supervises the activities of pharmacies, including checks and requests for information. Under Section 54c of the Medicinal Products Act, the sale of nicotine replacement products is subject to supervision by the authority of the municipality where the point of sale is located. The Medicines Act provides for inspections and penalties to be carried out by the municipality.

Assessment of the current state of play of the new regulation on off-label sales of self-medical medicinal products

The Medicines Act regulates the supply of self-treatment medicines to consumers as part of pharmacy activities and the retail sale of nicotine products. The rules are not applicable to the sale of self-treatment medicinal products outside pharmacies, because they are linked to the activity of pharmacies or relate to the specific characteristics of nicotine products. The implementation of the government programme entry for self-care medicines requires new regulation in the Medicines Act. It would be necessary to amend Article 2 of the Medicinal Products Act, which concerns the scope of application of the Medicinal Products Act, so that it also applies to sales of self-treatment medicinal products outside the pharmacy.

The need for new regulation is widely assessed. The pharmaceutical road map estimated that the sale of off-label pharmacies would require new regulation in areas such as choice, portfolio management, marketing rights, ex ante and ex post control and their relationship with pharmacy regulation, service criteria, price regulation and cooperation between authorities (STM 2019:5 pp. 111-118). Similarly, the Fimea study and the note from the self-medication working group considered that regulation would be necessary, inter alia, as regards the obligations of the marketing authorisation holder, pharmacovigilance, samples of medicinal products, pharmacy activities, nicotine products, supervision, marketing, fees, pharmacy, pharmaceutical tax, compulsory stockpiling and Fimea’s obligations.

Range of self-medication products sold outside the pharmacy

According to the Government Programme, on the basis of a study carried out by the Medicines Safety Authority, the release of some of the most commonly used self-care medicinal products also for sale outside pharmacies is prudent, ensuring the safety of medicinal products and medication.

In a self-care medicine study, Fimea identified the 30 most commonly used self-care medicines in Finland between 2019 and 2022. The standardised daily doses (DDD Defined Daily Dose) for medicinal substances were used for the survey and the most accurate possible anatomical-therapeutic chemical classification of medicinal products (*ATC classification*) was used. The World Health Organisation (*WHO*) maintains the ATC classification of medicines and Fimea is responsible for its national maintenance. In the ATC classification, medicinal products are divided into groups of five levels depending on the organ or organ system they affect and on the basis of their chemical, pharmacological and therapeutic properties. The classification consists of 14 main groups (level 1), therapeutic and pharmacological sub-categories (levels 2 and 3), pharmacological, chemical or therapeutic groups (level 4) and individual chemical substances or combinations of substances in the combination formulation (level 5). The Fimea study takes into account the safety of medicines and medication, the 2023 national classification of risk medicines and the recommendation on self-medication.

In the Fimea study, the most commonly used self-care medicines were divided into four groups. Group 1 is composed of nicotine alone, which is the only self-treatment medicine sold outside pharmacies. Group 2 consists of 14 self-care medicines for which similar products are freely sold in other product categories, for example in the form of food supplements. Category 3 consists of 11 other more commonly used self-medicines and Group 4 among the most commonly used self-medicines included in the national classification of risk medicines. Fimea's report concludes that the initial release of medicinal products and medication safety risks can be reduced, mainly in the case of medicinal products for which experience has already been gained in selling active substances outside pharmacies. In addition, products with a known safety profile that are not subject to specific contraindications or precautions and which are in line with current treatment recommendations could be considered. If this wider range of medicinal products is sought, the provision of pharmaceutical advice to the user of the medicinal product should be ensured.

Preparations continued in the framework of the self-medication working group set up by the STM. Based on the Fimea report, the Working Group's note looked at the 30 ATC groups of the most commonly used self-treatment medicines in Finland. Nicotin products were excluded from the assessment as they can currently be sold outside the pharmacy (STM 2024:25).

The Working Party on Self-therapy Medicinal Products divided the self-care medicines into three portfolios based on their level of risk. Selection 1 consists of 12 self-medicines with a low level of risk whose sale without medical advice was not assessed as posing a risk from a public health perspective. Selection 1 corresponds to group 2 of the Fimea study, with the exception of the removal of melatonine and saccharomyces boulardii. In addition, according to the Working Party, on the basis of a follow-up assessment, Option 1 could be complemented by off-label formulations for the same indication, or by some products in principle in List 2, such as local pharmaceutical creams and gels (e.g. diclofenac or lower-risk medicinal products in the same therapeutic area, and mild hydrocortisone preparations (STM 2024:25 pp. 37-39).

A total of 11 self-medicines requiring access to advice, which are assessed to be at medium risk, constitute a range of 2, defined by the Working Party on Self-care Medicinal Products. Selection 2 corresponds to group 3 of the Fimea study. According to the Working Party, on the basis of a further assessment, Option 2 could be complemented by non-prepared formulations of the most used medicinal products for the same indication or by some other products deemed necessary with an equivalent level of risk. In addition, Fimea has proposed some complementary or substitute medicines for the portfolio (STM 2024:25 pp. 39-41).

The sub-option 3 defined by the Working Party on Self-therapy Medicinal Products includes medicinal substances included in the national classification of risk medicinal products. These include systemic pain and heat treatments ibuprofen and paracetamol, and possibly equivalent

less consumed medicines. The selection also includes low-dose acetylsalicylic acid and potassium chloride. Selection 3 corresponds to group 4 of the Fimea study.

According to the assessment of the Working Party on Self-medicines, if the reform were to be implemented as a stand-alone project, it should be limited to the range allowed by minor changes in existing legislation. In practice, this would mean a selection 1. Once the practical arrangements for the provision of medical advice, such as teleconsultation services, have been laid down, sales could also be extended to Pot 2. Off-pharmacy sales of medicinal products in List 3 would only be possible once an adequate knowledge base could be ensured and the current level of medication safety would not be reduced (STM 2024:25 pp. 8-9).

In accordance with its mandate, the Working Party on Self-medicines assesses the most commonly used self-care medicines in Finland. However, the note of the Working Group emphasises the importance of an indication-based assessment based on rational drug therapy and accessibility. According to the note, it would be appropriate for each point of purchase of a self-medication product to have priority self-care options in line with the recommended treatment. The Working Party considered that in some cases less used alternatives should also be assessed instead of or in addition to the most commonly used product. However, the main grouping should be done on a risk-based basis through the selections 1 to 3 (STM 2024:25 p. 37).

On the basis of the Fimea study and the note from the Working Party on Self-therapy Medicinal Products, it is proposed that the range of self-medicines, which could also be sold off-pharmaceuticals, should be based on a range 1 defined by the self-medication group. It would correspond to category 2 of the Fimea study, with the exception of the removal of melatonine and saccharomyces boulardii (STM 2024:25 pp. 32 and 36).

However, in line with the position of the Working Party on Self-therapy Medicinal Products, it would be considered on a therapeutic basis and complemented by priority self-treatment options for the same indication that were not included in the list of the 30 most commonly used medicines, but whose level of risk is assessed as being similar to the level of risk for the pharmaceuticals in List 1 and for which there are currently authorised self-treatment medicinal products in the ATC groups. The evaluation has sought to maintain a limited range of self-pharmaceuticals in line with the government plan, which would focus on the indications of products in range 1.

The solution would be justified from the point of view of the user of the medicinal product, so that the range sold outside pharmacies could also form an appropriate package of different treatment options. The solution would be justified from the point of view of pharmaceutical companies, since the market conditions for competing self-pharmaceuticals with the same therapeutic indication and with a similar safety profile would remain as equal as possible and companies would have the same opportunity to apply for an extension of the sales channel for their own-care medicinal product outside pharmacies. In practice, however, the formation of a range of self-medication products outside the pharmacy would depend on whether the pharmaceutical companies would apply for an extension of the sales channel for their product and whether holders of retail licences for self-treatment medicinal products would select all rational options.

Starvation

In the case of self-medicines used to treat starvation, only conventional aluminium/calcium/magnesium compounds belonging to ATC group A02AD01 are included in group 1 of the self-medication group and group 2 of the Fimea report. According to the note from the working group, in addition to those antasidies, there are no other starvation drugs among the most used medicinal products. For self-medication, the preferred option for self-

treatment would be different protonum inhibitors (PPIs) as the preferred option for self-treatment. A secondary option would be H2 blockers (STM 2024:25 p. 31).

On the basis of the further assessment carried out in the preparation of the proposal, protonum inhibitors in List 1 would not be proposed due to the safety concerns raised for these products. Protonum inhibitors should be used for self-treatment for up to two weeks, and those aged 55+ should seek studies when new symptoms emerge. However, undiagnosed reflux symptoms are common and protonum inhibitors are effective and long-acting, increasing the risk for the medicine's own, longer-term use. In addition, there are increased medication safety risks associated with the long-term use of PPI products in contravention of the instructions for use. In Sweden and Denmark, PPIs are also restricted to pharmacy sales. Instead, it would be possible to supplement the selection with H2 blockers such as famotidine, famotidine in combinations and products containing sucralphatate. As with ATC group A02AD01, the sale to the consumer of the above products is assessed as low-risk and suitable for the range.

Constipation

For self-medicines used to treat constipation, the list 1 and group 2 of the Fimea study would include ispaghula (psyllium seeds, ATC group A06AC01), lactulose (ATC group A06AD11) and macrogol (ATC group A06AD15). They would provide a rational range of medicines to treat constipation. It is true that, according to the Working Party, the likelihood of an expansion of the sales channel would be reduced by the fact that ispaghula self-medicines are sold almost without exception with a prescription, whereas in the case of lactulosis, the proportion of prescription-only packaging is around half. Macrogol should not be replaced, but a significant proportion of it is also sold on prescription.

It is proposed to complement Option 1 with combinations of ispaghula and macrogole, which are assessed as low-risk. The ATC group of Macrogol combinations (A06AD65) includes combinations of macrogole with electrolytes. Their indications correspond in part to those of macrogol, but some products are intended to purify the casing prior to clinical procedures or bowel moths, which should be taken into account when assessing the inclusion of individual products in the range of self-medicines sold outside pharmacies. Constipation can also be treated with sodium picosulfate preparations (ATC group A06AB08). However, they are not proposed to be added to the range sold outside pharmacies, as they are only a last resort treatment option for constipation, in line with the therapeutic advice, and their safe use would require access to medical advice.

Substitution treatment of pancreas enzymes

Of the products used for substitution treatment of pancreas enzymes, the list 1 defined by the self-medication working group and group 2 of the Fimea study included products containing several enzymes (lipase, protease, etc.) in ATC group A09AA02. However, in this category, medical diagnosis and prescription are generally required for starting treatment. A significant proportion of self-medication is de facto therapeutic experiments with gastrointestinal symptoms due to other causes. In the follow-up evaluation of the presentation, it has been concluded that, as a result, the inclusion of a category of medicinal products in the reprogramm would not have a marginal benefit in relation to the potential disadvantages of inappropriate use, and it is proposed that the group be removed from the range.

Vitamin and mineral substitution therapy

Of the products used for vitamin and mineral substitution treatment, the list 1 and category 2 of the Fimea study included combinations of vitamins B1 and B6 and/or B12 (ATC group A11DB), other combinations of vitamin B (ATC group A11EX), calcium combinations with

vitamin D and/or other medicinal substances (ATC group A12AX), ferroglycine sulphate (ATC group B03AA01) and magnesium hydroxide (ATC group G04BX01).

However, on the basis of a further assessment carried out in the preparation of the proposal, it is proposed to remove ATC Group A11EX, the other combinations of vitamin B, from the list, since no authorised medicinal product is currently included in the group.

For vitamin combination products in List 1, the follow-up assessment concluded that there is no medication safety barrier to the exclusion of groups of medicinal products containing one vitamin in combination products in List 1 as the only active ingredient, provided that the ATC group in question were self-medicated products on the market. Following this review, it is proposed to add vitamin B6 pyridoxine (ATC group A11HA02), vitamin B12 cyanocobalamin (ATC group B03BA01), calcium carbonate (ATC group A12AA04), cholecalciferol and ergocalciferol (ATC groups A11CC05 and A11CC01) vitamins, iron oxide polymaltose complexes (ATC-group B03AB05) and ferrous sulphate (B03AA07) and magnesium citrate (ATC group A12CC04) and magnesium (mixed salts, ATC group A12CC30) of iron products. There are currently no authorised self-treatment medicines in the ATC groups for vitamin B1 and other vitamin B12, calcium, iron and magnesium. In addition, vitamin D self-treatment preparations belonging to other ATC groups are currently not available for sale. For these reasons, it is not necessary to include other ATC groups at this stage.

Treatment of small skin lesions

In the case of self-medicines used to treat small skin lesions, only dexpantenol products should be included in the list 1 and category 2 of the Fimea study, as set out in the note on self-medication. Hydrocortisone, which is used to treat mild skin inflammation and rash, was also evaluated during the preparation of the presentation. However, it is not proposed to add it to the range, as the products cannot be considered as alternative treatments with dexpantenol products and the appropriate use of hydrocortisone was considered to require access to medical advice.

Artificial cupboards

In addition, artificial pens and other unclassified products belonging to the same ATC group (S01XA20) would be included in the group 1 defined by the Working Party on Self-therapy Medicinal Products and Fimea in Group 2. For these, no extension needs were identified in the follow-up evaluation.

Definition of the selection

The implementation of government programme recording requires that the choice of self-medication products sold outside pharmacies should also be defined by law in a predictable manner. In its note, the Working Party on Self-medicines examined three options. The choice could be defined by law, regulation or decision of a public authority. According to the Working Party, the benefit of defining the range in the Regulation would be predictability for pharmaceutical companies and flexible options for updating the portfolio (STM 2024:25 pp. 8 and 54). During the preparation of the presentation, it was decided to define a limited range of self-pharmaceuticals with regard to the general conditions in the Medicines Act and, more precisely, at the most precise ATC group level in the Medicinal Products Regulation. The general conditions would be based on the characteristics that have been identified as combining products in the SMP 1, such as the low level of risk and the possibility to sell the product without any medical advice.

That solution would satisfy the condition laid down in Article 80 of the Constitution that the law should lay down the grounds for the individual’s rights and obligations. On the other hand,

the general conditions laid down by law would ensure that, in the absence of a legislative amendment to be assessed by Parliament, it would not be possible to extend the range of self-medication products sold outside pharmacies to products with a higher level of risk or requiring access to medical advice. The solution would allow marketing authorisation holders to be treated more equally and the choice to be updated in a flexible way and would not become unnecessarily detailed by law. The pre-definition of the selection also makes it possible to implement the reform in an orderly manner, ensuring the conditions for the operation of pharmacies.

However, as the same ATC group may include different medicinal products, it would also be necessary to assess the suitability of an individual medicinal product for off-pharmacy sales on a product-by-product basis. The starting point should be that the categories of medicinal products included in the list of medicinal substances provided for in the Regulation meet these conditions. However, Fimea should assess the fulfilment of the conditions on a product-by-product basis.

Nicotine and veterinary medicinal products

Nicotin replacement products are the most sold self-care medicines in Finland. During the preparation of the proposal, consideration was given to the possibility of combining the nicotine regulation with the proposed new regulation on off-pharmaceutical sales of self-medication medicinal products, since, in principle, special rules for one category of medicinal products should be avoided. Regulatory alignment with the regulation of off-pharmaceuticals has already been proposed in 2019 (STM 2019:5 pp. 118-119). However, no harmonisation was introduced, since nicotine products differ, as regards their intended use, the category of users, the age limits, the monitoring and the definition of the range outside the pharmacy, from the other self-medication medicinal products proposed for sale outside pharmacies in this proposal.

It has also been agreed during the preparation of the proposal that veterinary medicinal products will be excluded from the scope of the reform at this stage. At this stage, the reform would only cover certain self-care medicinal products for human use.

Self-care medicines covered by health insurance

Some of the self-medication products are reimbursed to the user by health insurance. Reimbursement is subject to the condition that the self-treatment medicinal product has been prescribed for the user by prescription. Reimbursements for reimbursable self-prepared medicines amounted to around EUR 27 million in 2023. The underlying pharmaceutical costs were around EUR 50 million (STM 2024:25 p. 12 and the Kela Communication of 22 August 2024).

The supply of reimbursable self-treatment medicinal products to the user of medicinal products requires that the retailer of the medicinal product has access to the information on the e-prescription at the prescription centre and has the right to make a supply label there. In practice, the reimbursement is granted almost without exception to the user of a medicinal product in the form of a direct remuneration, whereby the customer is remunerated when purchasing the medicinal product in a pharmacy and pays only a co-payment. In practice, the supply of the reimbursable self-medication to the customer corresponds to the supply of a prescription-only medicinal product. It is therefore proposed that, if a self-medication product which has been granted an extension of the sales channel for sale outside the pharmacy is supplied to the customer with a prescription-required reimbursement, only a pharmacy with the capacity to supply prescription-only medicines and to enforce direct reimbursement should be supplied.

Extension of the sales channel of the self-treatment product

The Working Party on Self-therapy Medicinal Products considered it justified that, even if the self-property were defined in advance in the regulation, that definition would not mean that all self-medicines in the range would automatically be switched to sale outside pharmacies. Instead, the marketing authorisation holder should decide whether or not to apply for an extension of the sales channel for his product. The application could be made at the time of application for a marketing authorisation or at a later stage with a variation to the marketing authorisation. In such a case, the marketing authorisation holder would retain the primary responsibility for the benefit-risk balance of the self-medication product and its monitoring. In addition, the marketing authorisation holder and the authority should be able to withdraw the extension of the sales channel if the sale of the product outside the pharmacy would jeopardise the safety of the medicinal products. However, it should be noted that marketing authorisation holders may not apply for an extension of the sales channel for their products. In that case, despite the proposed changes, self-care medicines would continue to be sold only from the pharmacy, even if they are included in the defined range (STM 2024:25 pp. 9 and 54).

As an alternative, the regulatory framework applicable to nicotine products can be assessed. In 2006, an amendment to the Medicines Act exempted nicotine products from outside pharmacies. The extension of the sales channel concerned all nicotine products, which are self-treatment medicines. The decision-making power was not retained by the marketing authorisation holder. The advantage of the option in the present reform of self-care medicinal products would be to ensure that a comprehensive range of self-medication alternatives would also be available for sales outside pharmacies and that all retailers could be obliged to maintain a range of medicinal products in line with the guidelines. The disadvantage would be that the marketing authorisation holder would not be able to choose the sales channel on the basis of the risk assessment of the medicinal product or the medicinal product advice required. Finland has a relatively wide range of self-medication medicines in Europe, partly because of the availability of pharmaceutical advice from pharmacies selling self-care medicines. A categorical extension of the sales channel of some self-medication medicines without the control of the MAH could lead to a reduction in the range of self-medication products and to a request for prescription-only classification for self-treatment products.

In line with the position of the PMPG, the proposal proposes a regulation which would allow the extension of the sales channel for a limited range of self-medication products, but would not oblige operators to do so. The final composition of the range would depend on whether pharmaceutical companies would apply for an extension of the sales channel for their product and on what self-care medicines would be offered for sale by holders of retail licences outside pharmacies. This solution would be justified as the responsibility and risk management of the marketing authorisation holder would remain unchanged and a product-specific safety assessment would be possible. In addition, there is no previous experience in Finland of wider sales of self-treatment medicinal products outside pharmacies and it is not foreseeable in advance how the market will react to a changed situation. However, it would also mean that the legislation would not be able to ensure in advance that sales outside the pharmacy would have a range of self-medication products with rational and appropriate alternatives for each indication.

Supervision of the retail sale of self-treatment medicinal products

The sale of self-treatment medicinal products outside the pharmacy would require that sales be controlled. In addition, the relationship between the proposed regulation and that of pharmacies and nicotine products should be addressed.

The Working Party on Self-therapy Medicinal Products considered it justified that Fimea should supervise sales of self-medication medicines outside pharmacies for reasons of

coordination, access to information and equality in the pharmaceutical sector. Controls should be financed by fees charged to operators (STM 2024:25 p. 9). The Working Party did not consider the organisation of controls by other authorities. In the 2019 pharmaceutical road map note, control powers were anticipated to be assigned to the provinces due to the high control workload (STM 2019:5 pp. 79 and 119).

A similar solution to that set out in the Medicinal Products Map note today would be to assign the task to wellbeing services counties or municipalities. However, this would lead to the supervision of self-care medicinal products by different authorities at different stages of distribution and the supervision of retail sales by several authorities at the same time. Welfare counties or municipalities do not have the same control capacity as the national authority supervising pharmacies. In any case, controls should be coordinated and new tasks for the welfare counties and Fimea should be laid down to ensure equal scrutiny. On the other hand, it should be noted that the current supervisory role of municipalities with regard to the sale of nicotine replacement care products is related to environmental health.

For the above reasons, in line with the position of the PMPG, the monitoring task is proposed to be entrusted to Fimea. The regulatory powers of Fimea should be laid down in the Medicines Act. There would be no need to amend the Act on the Centre for Safety and Development of Medicinal Products (593/2009), as the proposed monitoring of the limited range of self-medication products should be considered to be part of the Centre’s tasks under Section 2(1)(1) of the Act.

Secondly, it would be necessary to determine what kind of control would be required to sell self-medical medicinal products outside pharmacies. Retail sales of medicinal products are subject to prior control and during operation. Medicinal products may only be sold to the general public under a pharmacy licence. Fimea supervises and inspects pharmacies. Nicotine products classified as medicinal products may be sold on the basis of a retail licence issued by the municipality where the establishment is located. The municipalities supervise and inspect retail outlets. The equality of supervision and the safety of medicinal products and medication would militate in favour of subjecting the sale outside pharmacies of self-treatment medicinal products to authorisation and supervision by the public authorities.

The number and location of pharmacies are limited by law. It is not proposed to limit the authorisations of holders of retail licences for self-treatment medicinal products accordingly. In that regard, authorisations would be assimilated to retailers of nicotine products classified as medicinal products. In the case of a very limited range of sales outside pharmacies compared with medicinal products sold by pharmacies, it was not considered justified to establish a licencing regime for a limited range of pharmacies. In the event of a significant expansion of the range of self-medication products sold outside pharmacies, consideration should be given to the coordination of the system of retail licences for self-pharmaceuticals and of the system of pharmacy licences in order to ensure a level playing field between operators. In view of the limited range and the need for the marketing authorisation holder to apply for an extension of the sales channel for his self-medication product, this presentation would not suggest imposing obligations on holders of retail licences for self-treatment medicinal products to ensure the supply of medicinal products in his territory.

A trader applying for a retail licence for self-pharmaceutical medicinal products may have one or more branches or, for example, a daily food chain. The group on self-care medicinal products considered site-specific authorisation justified at this stage of the development of pharmacies (STM 2024:25 p. 56). It is proposed that authorisations be granted by site. This would be supported by the fact that, in order to obtain an authorisation, each establishment would have to fulfil the conditions for authorisation. If there were shortcomings, it would be justifiable for the intervention of the authorities to be limited to the site concerned, unless

there is a justification for a wider inspection of the operator's other branches. An authorisation per branch would also be a more equal procedure compared to private pharmacies. The so-called chain option examined by the Working Party should provide for obligations and sanctions for two-tier operators, which would complicate the system in an inappropriate way. In the context of a retail licence, it is necessary to provide for the conditions of the authorisation, the application for the authorisation, the procedure for applying for the authorisation, the notification of a change in the circumstances of the authorisation, the possible re-application of the authorisation and the waiver of the authorisation.

In addition to prior control, provision should be made for in-service monitoring. The note of the Working Party on Self-medicines has stressed that there must be adequate means for monitoring and that all actors should be subject to supervision on an equal footing. The note mentions withdrawal of authorisation, inspection rights, temporary ban on the sale of medicinal products and periodic penalty payments as means of supervision (STM 2024:25 p. 55).

Controls should be as equal as possible between retail distributors of medicinal products. It would be necessary to provide, in Article 77 of the Medicinal Products Act, for the right of Fimea to carry out inspections also at the premises of holders of retail licences for self-treatment medicinal products, and in Article 89 of the Law on medicinal products concerning Fimea's access to information on the sale of self-treatment medicinal products. Retailers of self-medical medicines should be treated in the same way as pharmacy service desks for inspection purposes, where only self-medication products are sold. Inspections could then be carried out as appropriate. This is also supported by the fact that there could be a significant number of non-pharmaceutical outlets selling self-care medicines in the future and that there would be a significant increase in the number of operators controlled by Fimea.

Under Sections 49-51 and 80b of the Medicines Act, Fimea may address deficiencies in the operation of a pharmacist and a pharmacy. The provisions are to a large extent linked to the activities of pharmacies and to private pharmacists as persons. The power of Fimea to address identified shortcomings in the conduct of the holder of a retail licence for self-treatment medicinal products should be expressly provided for in the Act. However, in the interests of equality, the means could be equivalent to those of pharmacy control. The means of control proposed in this presentation would thus differ from those proposed in the SMP note (cf. STM 2024:25 p. 55). It is estimated that the provisions of the Medicinal Products Act on the offence of medicinal products and the offence of medicinal products also apply to holders of retail licences for self-treatment medicinal products in their current form. There is no need to amend Sections 96 and 98 of the Medicinal Products Act.

Who could apply for a retail licence for self-pharmaceuticals?

According to the memo of the Working Party on Self-therapy Medicinal Products, the law should determine who could be granted a retail licence for self-treatment medicinal products (STM 2024:25 p. 56). The starting point should be the equal possibility for traders to apply for an authorisation, unless there are specific reasons for excluding a specific group of operators. It should be possible for both domestic and foreign traders to apply for authorisation in a uniform manner. However, the natural or legal person applying for the authorisation should be required to be a legal and identifiable trader. This should be registered in the Trade Register in order to obtain a business and company identification number.

Holders of retail licences for self-treatment medicinal products, as retailers of medicinal products, would in part be in a comparable position to pharmacies. The need to take into account the vertical and horizontal integration of the pharmaceutical supply chain has been identified in the pharmaceutical road map note when considering the expansion of pharmacy ownership. Under that provision, prescribers should not own a pharmacy in order to avoid

incentives to promote unnecessary medical treatments. However, according to the note, the possibility for health service providers to sell medicinal products, at least limited, should be examined in a situation where sales of self-medication medicinal products are allowed outside pharmacies (STM 2019:5 p. 49, 111-117). The report of the pharmacist of the STM also concluded that the holder of the pharmacy licence should not have any conflict of interest links that could influence the range of sales other than on a therapeutic basis (STM 2023:6 pp. 48-49). Under the current Medicines Act, a pharmacist may not act as a responsible manager in the wholesale distribution of medicinal products, nor may wholesale medicine stores or healthcare providers own a pharmacy for community care.

The KKV considered that pharmacy should not be allowed for doctors, as they could have a business incentive to prescribe more medicinal products. Pharmaceutical companies should also not be allowed to pharmacies in order to avoid creating an obstacle to the entry of another pharmaceutical company or a patient and to allow a pharmacy to provide product-independent medical advice. In addition, in view of the exclusive agreements in force, pharmaceutical wholesalers should not be allowed to own pharmacies (KKV 5/2020, pp. 43, 46-48 and 50).

In the case of ownership of pharmaceutical companies or pharmaceutical wholesalers, the position of holders of retail licences for self-treatment medicinal products is comparable to that of pharmacies. Those operators should not be entitled to act as a retail licence holder for self-treatment medicinal products. In addition, it would be necessary to add to Paragraphs 9 and 33 of the Law on medicinal products, which provide for the responsible manager of a pharmaceutical plant and the wholesale trade in medicinal products, a prohibition on the possibility that that person may not at the same time be the holder of a retail licence for self-treatment medicinal products. The amendment would be made within the framework of EU legislation as it is included in the national regulatory margin left to the Member States (Articles 41, 46(1a), 48-49 and 79(b) of the Medicinal Products Directive and Articles 93(1) (b) and (e) and 100(2)(a) of the Medicinal Products Regulation).

The interests of the intermediaries of medicinal products referred to in Article 34a of the Law on medicinal products could be considered to be similar to those of pharmaceutical companies. Section 34a of the Medicinal Products Act is based on Article 85b of the Medicinal Products Directive, which has no national regulatory margin. However, the holder of a retail licence for self-treatment medicinal products should not have a tie that could lead to vertical integration. Provision should be made to exclude the possibility of obtaining a retail licence, including by brokering medicinal products.

The possibility for the prescriber and the healthcare institution to own a pharmacy has been rejected. However, as regards the retail sale of self-care medicinal products, the situation is different since, as a general rule, self-treatment is not prescribed by a doctor. As an exception, self-care medicinal products would be covered by health insurance, but it would be proposed that these medicinal products be distributed in pharmacies. Prescribing would not prevent the granting of retail licences for self-treatment medicinal products and the prescription and supply of a medicinal product could still be separated even if a limited range of self-medication products were sold in a private healthcare institution or, for example, opticians' shops. However, the monitoring should ensure that the use of the medicinal products sold would not be further incentivised than would be necessary to treat the patient.

Sales of a limited range of self-medication products could also be made to consumers, for example through large food supply chains with a common owner. In this respect, no immediate negative effects on consumers have been identified during the preparation. However, the regulation is not intended to enable vertical integration, i.e. the granting of wholesale and retail licences to the same operator.

Pharmacists could also have an interest in applying for a retail licence for self-medical medicinal products and in transferring sales of self-medication medicinal products that have been granted an extension of the sales channel to a pharmacy special purpose vehicle. The pharmacist may benefit from the special purpose vehicle, since some sales of the pharmacy are then subject to corporation tax and dividend taxation from the pharmacist's personal income tax (STM 2023:6, pp. 55-56 and 87). The transfer of sales of off-pharmaceuticals to a special purpose vehicle has been considered justified from the point of view of competitive neutrality between retailers. Otherwise, it could be challenging for a pharmacy operating under a business name to compete with grocery shops due to different company forms, income tax rates and the agility of company regulation (STM 2019:5 p. 117). An immediate obstacle to the possibility for pharmacies to apply for a retail licence for self-treatment medicinal products has not been identified in the preparation of the presentation. Admittedly, the solution could have an impact on the transparency of the pharmaceutical industry.

Authorisation conditions and marketing requirements

According to the Working Party on Self-Pure Medicinal Products, the conditions for authorisation for the retail sale of self-treatment medicinal products should correspond to the pharmacy's obligations. Conditions could include, for example, space and storage requirements, the obligation to deal appropriately with defects, falsified medicinal products and suspicions, maintenance of a quality assurance system, internal audit and self-monitoring (STM 2024: 25 pp. 39-40 and 56). Similarly, the Fimea report states that the requirements imposed on pharmacies as regards the conditions for authorisation of pharmacies, medical advice, premises, staff and stock of medicinal products should be reviewed and, in order to ensure fair competition, should apply to all sellers of self-medical medicines.

During the preparation of the presentation, the abovementioned conditions imposed on pharmacies were compared with the sales authorised under the retail licence for self-treatment medicinal products for which the MA holder would have applied for an extension of the sales channel. Secondly, the retail licence holders are not specialists in the pharmaceutical sector, nor could they be required, like pharmacies, to have qualified pharmacists or pharmacists. On the other hand, holders of retail licences for self-pharmaceuticals would not be in a position of social trust comparable to pharmacies either. They would not have the right to supply prescription-only medicines and would not be able to take responsibility for the regional availability of medicines. For the reasons described above, it was considered justified in the further preparation of the presentation to impose on holders of retail licences for self-treatment medicinal products the minimum requirements and authorisation conditions necessary to identify the holder of the retail licence in a reliable manner and to ensure the safety of medicinal products and medication when selling self-medicines from a limited range that would have been granted an extension of the sales channel.

The conditions for authorisation of a pharmacy are laid down in Section 43b of the Medicinal Products Act. It would not be reasonable to impose the conditions for authorisation of a pharmacy on holders of retail licences for proprietary medicinal products selling a limited range. It would be justified to make the process of applying for authorisation as smooth as possible, and it would not be justified to require authorisation holders to provide company management statements and extracts from registers of the same scope as those required of an applicant for a pharmacy licence. However, a natural or legal person applying for a retail licence should be required to be a legitimate trader who would be reliably identifiable by means of a business and company identification number, i.e. registered in the Trade Register.

The holder of a retail licence for self-treatment medicinal products could not be subject to staff requirements comparable to those laid down in Article 56 of the Law on medicinal products. However, it would be justified, from the point of view of the safety of medicinal products and

medication, to ensure that the personnel of the authorisation holder are adequately trained in the handling, storage and sale of self-treatment medicinal products. Furthermore, it would be justified to require the authorisation holder to indicate a responsible person who could act as a point of contact with the authorities and be subject to various practical obligations. Induction training should be repeated in the event of staff changes and, where appropriate, changes in legislation or other requirements. In addition, the retail licence holder should be required to ensure that up-to-date operational instructions are available to staff. Similarly, Fimea's Order on the supply of medicinal products 2/2016 requires that the functions of dispensing in a pharmacy be described in a written policy.

Section 90 of the Medicinal Products Act lays down a duty of professional secrecy for pharmacists. Similarly, the law should require that if the staff of a self-medical medicine retailer were to become aware of the secrecy of the private or family in their duties, this would be subject to the obligation of professional secrecy. Section 97 of the Medicinal Products Act provides for a penalty for breach of professional secrecy. This section could also apply to the retail sale outside the pharmacy of self-treatment medicinal products. There is a need to add a reference to the provision on the confidentiality of self-medicines.

The space allowances provided for in Article 56(2) of the Law on medicinal products and Article 15 of the Decree on Medicinal Products relate specifically to pharmacy business and would not, as such, be suitable for holders of retail licences for self-treatment medicinal products, whose main activity would not, in most cases, be the sale of medicinal products. However, space requirements should ensure that the retail authorisation for self-treatment medicinal products is site-specific and that appropriate conditions for the storage of medicinal products are safeguarded. The authorisation holder's staff would not be able to provide medical advice to customers, so similar confidentiality facilities would not be required. However, the premises should be suitable for business purposes, as public authorities should be able to check the premises. This would not allow the holding to be part of the operator's home. In addition, Order 1/2011 on service points at Fimea's pharmacy states that medicinal products must be stored at the service point in appropriate lockable cabinets/space reserved for external purposes, separately from other products. A similar requirement for lockable cabinets in the sales premises should not be required for the retail sale of self-treatment medicinal products, as the limited range available on sale would not require such measures in terms of risk. However, the authorisation holder should ensure that unauthorised persons have no access to the premises. For example, the locking of storage facilities for medicinal products should be ensured.

According to the Working Party on Self-therapy Medicinal Products, authorisation holders should be obliged to deal appropriately with product defects, falsified medicinal products and suspicions, and the authorisation holder should have a quality assurance system. In the course of the preparation of the Government proposal, it was considered that it would be justified to impose on licence holders an obligation equivalent to that imposed on pharmacies to ensure the correct quality of the self-care medicinal products which they sell and to require the retailer of self-care medicinal products to sell the self-care medicinal products in complete sales packages. The requirements would be comparable to the obligations laid down in Article 55(3) of the Law on medicinal products for pharmacies and to the Ordinance on service points at the pharmacy of Fimea (Fimea Order 1/2011). The responsible person could also have operational obligations in this regard. On the other hand, it is not proposed to impose obligations on licence holders on product defects and falsified medicinal products on these aspects, including with regard to pharmacies. It would be justified to consider the quality requirements uniform for all retail distributors at once.

The reporting of adverse reactions to medicinal products is regulated in 30a, 30e to 30 g of the Medicines Act. The Pharmacovigilance Regulation of the Medicines Act is based on the

Medicinal Products Directive. According to the Directive, only doctors, pharmacists and other healthcare professionals may be subject to adverse reaction obligations in the Member States (Articles 102 and 107a of the Medicinal Products Directive). Neither the holder of the authorisation for the retail sale of self-treatment medicinal products nor his staff would be required to be healthcare professionals or have access to medical records. Thus, an obligation to report adverse reactions to a medicinal product could not, in principle, be imposed on the holder of the authorisation. However, they should be allowed to report voluntarily, as is the case for patients. It would also be advisable to instruct the retail licence holder that when the patient informs staff about the adverse reactions of the medicine, the patient should be instructed to report to Fimea.

The Working Party on Self-therapy Medicinal Products required that holders of retail licences for self-treatment medicinal products should be subject to an obligation of internal audit and self-monitoring. A pharmacist is subject to an obligation to monitor and inspect a branch pharmacy, an online pharmacy service and a service point (Sections 52a to 52c of the Medicines Act and Article 20 of the Medicinal Products Ordinance). The responsible person of the authorisation holder could carry out an annual inspection of the sales of the medicinal product. Because of the limited choice, self-monitoring would be more limited in practice than in a pharmacy. However, in order to allow for regulatory control, it would be necessary to require that a protocol be kept.

In its note, the Working Party on Self-medicines considered that equal treatment of operators should be taken as a basis for restrictions on sales, such as restrictions on pack size, sales volume or age. Special conditions should only be imposed if the safety of medicinal products or medication so requires. As regards age limits, it should be determined whether self-care medicinal products can be sold to minors in other outlets.

When a medicinal product is classified as a self-treatment medicinal product, it may be subject to sales restrictions in terms of strength or pack size, which, in principle, allow a medicinal product to be sold to a customer in a single purchase, for example, one of the largest packages of self-treatment medicinal products on sale. These sales restrictions should also be introduced for sales outside pharmacies. In view of the level playing field, no other restrictions should be imposed on self-medication products sold outside pharmacies. In the case of sales outside pharmacies of self-treatment medicinal products based on List 1, no such need for restrictions has been identified during the preparation. Moreover, in the preparation of the presentation, there was no evidence of any limitation or age limit on the shelf-life of medicinal products due to the low-risk nature of the self-treatment medicinal products included in the selection.

According to the Self-therapeutics Working Party, the presentation of products should be considered when extending the sales channel (STM 2024:25 p. 57). The presentation requirements would depend on self-treatment products sold outside the pharmacy. For example, in the case of nicotine products, Section 54a of the Medicinal Products Act provides that the seller must be able to monitor the purchase situation and that sales may not be made from automatic sales devices. In this presentation, it is proposed that only a limited range of low-risk products be sold outside pharmacies. Therefore, it would not be necessary to keep the products behind the dish, in a locked cabinet or in a separate service point. It should be possible to sell them from open shelves. However, as mentioned above, products could be subject to product-specific sales restrictions. In order to monitor this restriction, it is necessary to provide that the sale is always carried out under the supervision of the seller’s staff. The sale could thus technically be made through self-service funds, but the seller would have to be present to confirm that the purchase was made in accordance with the sales restrictions.

In its note, the Working Party on Self-medicines identified alternative models for the organisation of drug advice. In Norway, for example, it is prohibited to give medical advice

through sales channels other than a pharmacy. In Sweden and Denmark, advice can be provided outside the pharmacy as a voluntary service. The Working Party considered that if sales outside pharmacies were to be restricted to List 1, it would be justified, from the point of view of medication safety, not to require advice to be provided. However, it should be established whether advice should be given on a voluntary basis if it met the conditions (STM 2024:25 pp. 45-46). This proposal proposes that holders of retail licences for self-treatment medicinal products should not be allowed to provide medical advice to their customers. The proposal would now lead to an initial unequal situation, as pharmacies would continue to be subject to an advisory obligation. The situation would be similar to the current situation for nicotine replacement medicines. However, the provision of medical advice should be assessed in conjunction with the obligation of pharmacies to advise medicinal products at a later stage of the pharmaceutical reform.

It should be required that the holder of a retail licence for self-treatment medicinal products is properly handled and stored. The treatment requirements for medicinal products should also cover the treatment of pharmaceutical waste. However, holders of retail licences for self-treatment medicinal products could not be subject to stockholding obligations such as Paragraph 55(1) of the Law on medicinal products, nor would they be operators under an obligation to store medicinal products within the meaning of the Act on the compulsory stockpiling of medicinal products (979/2008). The range sold outside pharmacies would depend on the marketing authorisation holder and would not necessarily include the priority medicinal product options needed by the customers in the region. In this respect, it would be necessary to monitor the development of sales following the legislative amendments. Ideally, in addition to the pharmacy network, an extra-pharmacy choice would support the implementation of rational medicine and the availability of medicines in the region.

Retail sale of self-treatment medicinal products at a distance

The number of pharmacies providing the pharmacy's online service has increased significantly in recent years. In July 2024, 256 pharmacies operated online pharmacies. However, online sales are still relatively small in most pharmacies, with the exception of the pharmacy of the University of Helsinki (STM 2024:25 a. 14-15). The area of activity of pharmacies has also expanded through distance sales of medicinal products. Nowadays, it is customary for a pharmacy to serve not only its own territory, but also customers through an online service throughout the country (STM 2023:6 pp. 20-21).

The Working Party on Self-therapy Medicinal Products considered that it should be established for holders of retail licences for self-treatment medicinal products whether they could also sell self-medicines online. As regards the level playing field between operators, it was considered justified to allow online sales, provided that a level playing field comparable to that of pharmacies was respected. The proposal would also be justified from the perspective of the customer, who could order a self-treatment medicine, for example in the case of other food orders (STM 2024:25 p. 57).

It is proposed that holders of retail licences for self-treatment medicinal products should be allowed to sell products from a limited range of self-medication products that would have been granted an extension of the sales channel, including online. Distance selling should be subject to conditions equivalent to those for online pharmacies services. The conditions for the online service of pharmacies are laid down in Section 52b of the Medicinal Products Act and Articles 21b and 21c of the Medicinal Products Decree.

The national legislation is based on Article 85c of the Medicinal Products Directive. The regulatory powers of Member States with regard to distance sales of medicinal products are limited in accordance with this Article. Article 85c of the Medicinal Products Directive requires Member States to ensure that medicinal products are offered for sale at a distance by means of information society services as defined in Directive 98/34/EC under the conditions defined in Article 85c. Directive 98/34/EC has been repealed by Directive (EU) 2015/1535 of the European Parliament and of the Council laying down a procedure for the provision of information in the field of technical regulations and of rules on Information Society services. Article 1(b) of that directive defines a service as any information society service, that is to say, any service normally provided for remuneration, at a distance, by electronic means and at the individual request of a recipient of services. Section 52b of the Medicinal Products Act regulates the online service of pharmacies at national level. According to subsection 6, the provisions on the online service of a pharmacy also apply to the sale of medicinal products by other means of distance communication.

The online service of the holder of a retail licence for self-treatment medicinal products, through which certain self-medication medicinal products would be sold, would not be an online pharmacy service, but an online service of the holder of the authorisation or another information society service through which orders for medicinal products would be received. It would be necessary to continue to use the pharmacy's online service term in the section in cases where the network operation of pharmacies alone would be subject to regulation. However, the sale of medicinal products by means of information society services by pharmacies and holders of retail licences for self-medical medicinal products would need to be collectively referred to as a 'distance sales service' of medicinal products, where pharmacies and holders of retail licences for self-medical medicinal products would be operators of the service. It would also be necessary to supplement the reference to distance communication in subsection (6) to include information society services within the meaning of Directive 1353/2015.

In the light of Article 85c of the Medicinal Products Directive, it would be necessary to amend Paragraphs 52b and 52d of the Medicinal Products Act in order to recognise holders of retail licences as distance sellers of a limited range of self-medication products. Article 85c(1a) of the Medicinal Products Directive leaves Member States national regulatory discretion as to which operators are entitled to supply medicinal products to the public. The right of holders of retail licences for self-treatment medicinal products to supply a limited range of self-medical products to the public would have been provided for in the Medicinal Products Act in accordance with this proposal. They should also be added to Section 52b as entities operating a distance sales service for medicinal products. Their right to distance sales would naturally be limited to the same range of self-care medicines as other sales of medicinal products.

Fimea's Order 2/2011 also lays down conditions for the online service of a pharmacy, in particular as regards the confidentiality of information, the transport and packaging of packets of medicinal products and storage temperatures. In addition to the proposed legal provisions, provision should be made to extend the scope of the provision to holders of retail licences for self-treatment medicinal products when selling self-care medicinal products at a distance. The law should ensure this with the necessary powers to issue orders.

Marketing of self-medicines

Holders of retail licences for self-treatment medicinal products should comply with the rules governing the marketing of medicinal products. The marketing of medicinal products is governed by Sections 91 to 93 of the Medicines Act. In addition to the provisions of the Medicinal Products Act, it is expressly stated in the articles that, in addition to the provisions of Section 91(1) and (2), the provisions of the Consumer Protection Act (38/1978) on the

regulation of marketing apply. Articles 91 and 91a of the Medicinal Products Act do not identify the person making the advertising, so that this section is also directly applicable to the holder of a retail licence for self-treatment medicinal products.

Pharmaceutical companies could also target retail authorisation holders of self-treatment medicinal products in the future. Under Paragraph 91b(1) of the Law on medicinal products, the medicinal products referred to in Paragraph 91a(1) may also be marketed to persons qualified to prescribe or supply a medicinal product, namely medicinal products subject to medical prescription and medicinal products containing narcotic drugs or psychotropic substances. This paragraph is based on an a contrario conclusion derived from Article 88(1) of the Medicinal Products Directive. It is prohibited to market the medicinal products in question to the general public. However, the definition of the person entitled to supply medicinal products is a matter for the national competence of the Member States. In Finland, it would also mean holders of retail licences for self-treatment medicinal products. However, their right to market their medicinal products would be limited to certain self-medication products. They cannot be regarded as having a right or a commercial interest at all or the need to receive advertising of medicinal products only on prescription-only medicinal products sold in a pharmacy or on medicinal products containing narcotic drugs or psychotropic substances. In that regard, it would be necessary to clarify Paragraph 91b of the Law on medicinal products. The amendment must be interpreted in the light of Article 88 of the Uniform Medicinal Products Directive.

Article 92 of the Medicinal Products Act regulates the promotion of medicinal products to healthcare staff and veterinarians, including various gifts and benefits. This section is based on Articles 94 and 95 of the Medicinal Products Directive, according to which promotion must be directed only at health professionals. Holders of retail licences for self-treatment medicinal products would not be subject to hospitality by virtue of their licence, unless they were healthcare professionals because of other activities. Retail licence holders would thus not be allowed to receive the hospitality referred to in the section. Under Article 92(2) of the Law on medicinal products, persons entitled to prescribe or supply medicinal products may not request or accept any inducements, benefits or gifts which are prohibited or otherwise contrary to the provisions of paragraph 1. This paragraph would in future also cover holders of retail licences for self-treatment medicinal products. There would be no need to amend the section.

Samples of medicinal products are governed by Article 35 of the Law on medicinal products. On 11 June 2020, the Court of Justice of the European Union (CJEU) ruled in Case C-786/18 concerning the interpretation of Article 96(1) of the Medicinal Products Directive. Under that provision, free samples may exceptionally be distributed only to persons qualified to prescribe medicinal products under the conditions set out in that paragraph. The case concerned the question of whether samples of medicinal products could also be distributed to pharmacists. The CJEU confirmed that national law may allow the distribution of free samples of self-care medicinal products to pharmacists by making it subject to restrictive conditions. The distribution of samples of prescription-only medicinal products would be possible only for those qualified to prescribe the medicinal product. Article 25f of the Medicinal Products Decree corresponds to the interpretation of the ECJ. However, the wording of Paragraph 35 of the Law on medicinal products should be clarified in that regard in order to comply with the decision of the ECJ. In addition, it is proposed that pharmaceutical companies should not be allowed to distribute samples of medicinal products to holders of retail licences for self-treatment medicinal products. The restriction would be based on the fact that the holder of the authorisation would not be required to be a health professional, such as a pharmacist or pharmacist. This would then not have the medical expertise necessary to assess a sample of medicinal products. This approach would be in line with other marketing regulations on hospitality above.

Distribution of off-pharmaceuticals for self-treatment

Holders of retail licences for self-treatment medicinal products should be able to purchase self-treatment medicines from the range of medicinal products from medicines tobacco or pharmaceutical factories, in the same way as out-patient pharmacies purchase their self-medication products. Accordingly, Sections 31 and 34 of the Medicinal Products Act also propose to take into account the supply of medicinal products sold outside pharmacies to holders of retail licences for self-treatment medicinal products. In order to streamline the practice, the authorisation holder should be required to identify, at the time of the order, in a reliable manner, as the entity entitled to receive self-care medicinal products sold outside pharmacies.

EU law allows holders of retail licences for self-pharmaceuticals to be added to articles. As regards medicinal products for human use, the Medicinal Products Directive does not specify to whom a manufacturing authorisation holder may sell or otherwise supply medicinal products. Under Article 46(b) of the Medicinal Products Directive, the holder of a manufacturing authorisation must refrain from marketing authorised medicinal products except in accordance with the legislation of the Member States concerned. By contrast, under Article 93(1)(h) of the Veterinary Medicinal Products Regulation, the holder of a manufacturing authorisation is required to supply veterinary medicinal products only to wholesalers of veterinary medicinal products. This proposal proposes that self-care medicinal products, which could also be sold outside a pharmacy, should be considered as self-care medicinal products for human use alone. Consequently, there would be no obstacle to including holders of retail licences for self-treatment medicinal products in Paragraph 31(1) of the Law on medicinal products. Article 80(c) of the Medicinal Products Directive makes it possible to supply people who are entitled to supply medicinal products to the public in the Member State concerned. Article 101(2) of the Veterinary Medicinal Products Regulation allows a wholesaler to supply veterinary medicinal products to persons authorised to retail in a Member State in accordance with Article 103(1).

In addition, the distribution of self-treatment medicines should take into account certain obligations and regulations for pharmaceutical factories and pharmaceutical wholesalers. The safeguarding of the distribution of medicinal products is governed by Sections 26 and 37 of the Medicinal Products Act. Under Article 26 of the Law on medicinal products, the marketing authorisation holder and the holder of the registration referred to in Article 22 must ensure that the authorised medicinal product and the registered traditional herbal medicinal product are available at all times to wholesalers and pharmacies of medicinal products, in accordance with the needs of patients and other users. This section is based on Article 81(2) of the Medicinal Products Directive for medicinal products for human use. According to that provision, the holder of a marketing authorisation for a medicinal product and the distributors of a medicinal product actually placed on the market in a Member State are to ensure, within the framework of their obligations, that the medicinal product in question is made available in an appropriate and continuous manner to pharmacies and persons authorised to supply medicinal products to the public, so that the needs of patients in that Member State are met. It is also in line with Article 58(2) of the Veterinary Medicinal Products Regulation. However, as proposed in this proposal, provision would be made for an extension of the sales channel for only some self-medication medicinal products for human use. It is necessary to amend Section 26 of the Medicinal Products Act to include retail licence holders.

Under Article 37 of the Law on medicinal products, the wholesale distribution of medicinal products must seek to ensure that it has the necessary quantity of medicinal products on sale. This section lays down reporting obligations in the event of a supply disruption. Section 37 is also based on Article 81(2) of the Medicinal Products Directive for medicinal products for human use. This section also fulfils the conditions of Article 101(4) of the Regulation on

veterinary medicinal products. The obligation to notify should be extended, on the same basis as to pharmacies, to holders of retail licences for self-treatment medicinal products, who are restricted by national law to the general distribution of certain self-medication medicinal products to the general public.

The definition of wholesale trade in medicinal products is laid down in Section 32 of the Medicinal Products Act. Under Paragraph 32(2) of the Law on medicinal products, wholesale distribution of medicinal products does not constitute the sale to the public of medicinal products and medicinal products within the meaning of Paragraph 38, the supply of medicinal products and medicinal products from one pharmacy to another pharmacy or social and healthcare establishment, the supply of medicinal products and medicinal products from a hospital pharmacy or a pharmaceutical centre in accordance with Paragraph 62, or marketing and invoicing by the holder of the marketing authorisation or his representative, which does not involve the holding, distribution or storage of the products. As regards medicinal products for human use, this provision is based on the definition of wholesale distribution of medicinal products in Article 1(17) of the Medicinal Products Directive. In its view, wholesale distribution would not constitute a distribution to the public of medicinal products. Similarly, Article 4(36) of the VMP Regulation excludes the retail supply of veterinary medicinal products to the public from the definition of wholesale distribution. Article 32(2) of the Law on medicinal products should be amended to refer to Article 38a of the Law on medicinal products, which also refers to the sale of medicinal products to the public by holders of retail licences for self-treatment medicinal products.

Article 30q of the Medicines Act lays down the safety features to be applied to medicinal products for human use. The regulation is based on Directive 2011/62/EU of the European Parliament and of the Council amending Directive 2001/83/EC on the Community code relating to medicinal products for human use, as regards the prevention of the entry into the legal supply chain of falsified medicinal products, and on Commission Delegated Regulation (EU) 2016/161 supplementing Directive 2001/83/EC of the European Parliament and of the Council by laying down detailed rules for the safety features appearing on the packaging of medicinal products for human use.

Self-care medicinal products do not, in principle, bear safety features unless, exceptionally, they are included in the list referred to in Article 54(2)(b) of the Medicinal Products Directive. In addition, in order to ensure patient safety, a Member State may extend the scope of the anti-tampering mechanism to any medicinal product. It is therefore appropriate to consider the situation in which the safety features should be attached to a self-medication product which could also be sold outside pharmacies.

As a general rule, the safety features are withdrawn only in the pharmacy when the medicinal product is supplied to the user of the medicinal product. In principle, holders of retail licences for self-treatment medicinal products would not have the capacity to check or decommission the safety features. Pursuant to Article 23 of Commission Delegated Regulation (EU) 2016/161, Section 30u of the Medicinal Products Act provides for specific situations in which the wholesale distribution of medicinal products removes safety features from the packaging of medicinal products.

Article 23(a) of the EU Regulation on safety features of medicinal products allows holders of retail licences for self-treatment medicinal products to be added to the list provided for in Section 30u of the Medicines Act. Article 23(a) allows Member States to require, where necessary to take into account the specificities of the supply chain in their territory, that the wholesaler inspects the safety features and decommissions the unique identifier of the medicinal product prior to the supply of the medicinal product to persons authorised or entitled to supply medicinal products to the public who do not operate in a healthcare establishment or

pharmacy. It would be appropriate to make a change to the physiotherapist in the event that the product to which the safety features are attached were included in the range of self-medication products sold outside the pharmacy.

The import of medicinal products is governed by Section 17 of the Medicinal Products Act. Under that section, pharmacies and hospital pharmacies have the right to import for the purposes of operating the pharmacy. No need has been identified for retail licence holders selling a limited range of self-treatment medicinal products to enable a corresponding right to import medicinal products. It is assumed that licence holders would resort to domestic distributors of medicinal products to acquire a range to be sold. Furthermore, Article 17 of the Law on medicinal products does not contain any provisions on the right to import of retailers outside other pharmacies. For the above reasons, it is not proposed to amend Article 17 of the Medicinal Products Act in this context.

Pricing of self-medicines

As part of the regulation of a limited range of self-medicines, the question of what price regulation would apply to self-medicines within the range should be resolved. The prices of medicinal products sold from community care pharmacies are governed by Sections 37a and 58 of the Medicines Act. More detailed price regulation can be found in the Medicines Tax Regulation.

Currently, the pricing criteria for medicinal products vary depending on the type of medicine in question. Self-care and prescription-only medicinal products sold in out-patient pharmacies are, as a general rule, subject to a uniform wholesale price under Paragraph 37a of the Law on medicinal products. The retail price of those medicinal products is based on Article 58 of the Law on Medicinal Products and on the pharmaceutical tariff, which is separate for self-treatment and prescription-only medicinal products. The pricing of medicinal products sold outside pharmacies, such as nicotine replacement treatment products classified as medicinal products, is free.

The starting point for the assessment of the pricing by the group on self-care medicinal products was that the pricing of self-medication products sold outside the pharmacy should also be consistent in pharmacies and in new sales channels. However, retail prices would not be required to be identical at all points of sale. If wholesale price reductions for self-medical products were allowed, they would have to be passed on to the retail prices of medicines. Discounts should not unduly guide available products. However, the Working Party recognised that avoiding the negative effects of wholesale discounts could be difficult or impossible in practice, as public authorities do not have the means to interfere with the content of the rebate agreements. On this basis, the Working Party assessed three different pricing models (STM 2024:25 pp. 49-51).

According to the option assessed by the first working group, the pricing of self-pharmaceuticals sold outside the pharmacy would have been based on the current self-treatment tariff and on the uniform wholesale price under Section 37a of the Medicines Act. This option would avoid any inappropriate impact of wholesale price discounts on the independence of medical advice. The option was assessed as requiring the introduction of a database of medicinal products also at self-care outlets.

Secondly, the working group assessed the option of allowing individual discounts on the wholesale price, while setting a cap on the retail price of medicinal products. Wholesale price reductions could encourage operators to compete on prices, which could lead to lower prices for products in the self-medicine range. The disadvantage would be that customers would not necessarily benefit from wholesale price reductions, as the retail price discount for the retail licensee or pharmacy would be reflected in the retail price charged to the customer on a

voluntary basis. The reductions would also reduce the transparency of the price system and increase uncertainty in the pharmaceutical consumption statistics. Setting a maximum price at the pharmaceutical tariff would be justified from the point of view of the costs of the users of the medicinal products. However, the maximum price set by the regulation could limit the ability of outlets to market self-care medicines.

As a third option, the Working Party assessed a model of free retail pricing for self-medical products in a limited range and allowing wholesale discounts. This option would be supported by its simplicity, as price limits would not have to be introduced or monitored. However, this option could lead to higher retail prices for self-medicines, especially in less competitive areas compared to the regulated maximum price.

During the preparation of the proposal, the second pricing option described above, which would allow operator-specific wholesale price discounts, was chosen as an option to be promoted. This would be regulated by the Medicines Act. It is also proposed that self-medication products in the range be subject to a maximum tariff, a ban on quantity discounts and other price provisions.

The solution would be justified because it could benefit the consumer on the one hand and safeguard the position of consumers on the other. Allowing wholesale price reductions and competition from holders of retail licences for new self-medication medicines with pharmacies could lead to price competition that could lower the prices of the off-the-shelf medicines. Consumers pay for the choice of self-care medicines to a large extent themselves and could thus benefit from lower prices. In so far as self-care medicinal products were substituted, they could only be supplied to the user of the medicinal product from a pharmacy. In this respect, increased price competition could also reduce the reimbursement of medicines on a small scale. The same maximum price in the pharmaceutical tariff would ensure that the retail price would not become unreasonably high for the consumer. However, if the maximum price is based on a single wholesale price indicated by the pharmaceutical company, inappropriate increases in wholesale prices could also lead to an increase in the prices paid by consumers for these self-treatment products in some regions.

The weak side of the proposed option is estimated to be price differentiation between different actors and difficulties in statistics and monitoring. There would also be a risk of missing the benefits of wholesale price reductions for pharmaceutical retailers, as the regulation would not oblige them to export the discounts received on the retail prices of medicinal products. The regulation would allow the retailer, in the worst case scenario, to negotiate a wholesale price reduction for a pharmaceutical company, while keeping the retail price of medicines for consumers close to the upper limit if the competitive situation in the region so permits. The Working Party on Self-medicines concluded that authorities would not have the means to interfere with the content of operator-specific discount agreements. It would therefore not be possible to interfere with the fact that different percentages of discounts were agreed with pharmacies of different sizes or holders of retail licences for self-medical medicinal products. The proposed amendment would partly reflect the pre-2006 legal situation, the effects of which have been opened in Government bill HE 107/2005 vp.

In addition, wholesale price discounts could affect the range to be sold. It is true that the range of holders of retail licences for self-medical medicinal products might otherwise not be as comprehensive as pharmacies. However, in the case of pharmacies, it is possible to influence the range. Discounts could also affect the presentation of medicinal products. However, marketing and pharmaceutical advice at a pharmacy should meet the requirements of the pharmaceutical legislation. On the other hand, allowing wholesale price reductions is estimated to have little risk in terms of medication safety due to the limited variety and the absence of products with an estimated significant potential for abuse.

However, despite the disadvantages mentioned above, the proposed option would have advantages in relation to the other two pricing solutions assessed by the Self-medicine Task Force. The first option, i.e. pricing under the current system of price regulation, could lead to the loss of the benefits of potential price competition despite the increased sales of a limited range of self-medicines outside the pharmacies. On the other hand, the establishment of an out-of-pharmacy agency would not necessarily be equally attractive for traders. As a third option, the free pricing of a limited range of self-pharmaceuticals would present risks of higher retail prices for products in the limited self-pharmaceutical range, either by region or in general, which could lead to higher costs for users of self-medicines in the range.

As part of the choice of price-setting option for a limited range of self-pharmaceuticals, it should be determined whether price regulation would be directly applicable by law to the entire limited range of self-medication products, or whether the application of pricing to a self-medication product in a given range would depend on whether the extension of the sales channel for that product was applied for and granted for sales outside pharmacies.

If the new pricing model were to be applied only to medicinal products for which an extension of the sales channel has been granted, pharmacies could have to sell self-treatment products in competition with this product belonging to the same group of ATCs or self-medicine products used for the same indication (e.g. treatment of starvation) at a higher retail price and lower cover. Such a solution could lead to unequal conditions of competition between pharmacies and holders of retail licences for self-medical medicinal products, and the model could also have effects on competition between self-medical products in a way that would unjustifiably favour low-priced self-care medicinal products. In order to address the competition neutrality concerns described above, it is proposed to provide for lower pricing for all self-medication products within the limited range of self-medication products, whether they would be sold in a pharmacy or also outside pharmacies. However, to the extent that competing products would not be included in the choice now defined, they would be subject to different pricing.

The solution described above could result in pharmaceutical companies not applying for an extension of the sales channel for their product as it would be sufficient to benefit from a lower pricing regime for the medicinal product to be included in the ATC-groups in the range. In addition, the challenges arising from discount agreements, as described above, could also become relevant only in the case of self-medication medicines in the pharmacy. In practice, the proposed pricing model would require that the new pricing model for self-treatment medicinal products within the limited self-care range be built into the current Sections 37a and 58 of the Medicines Act and the pharmaceutical tariff. *Taxation of self-treatment medicines sold outside pharmacies*

In addition to pricing, it should be decided how self-medication products, which could also be sold outside the pharmacy, should be treated for the purposes of pharmacy taxation. Sales of self-treatment medicines are included in the pharmacy's turnover, on the basis of which pharmacists, the University of Helsinki and the University of Eastern Finland pay pharmacy tax under the Act on the taxation of pharmacies. By way of derogation from the turnover for the purposes of the pharmacy tax, the value of sales of nicotine-reimbursable medicinal products which, under the Medicines Act, may also be sold outside a pharmacy, as well as certain other items, may be deducted. The proposed extension of the sales channel for certain self-medication medicinal products would lead to the distribution of medicinal products by a new category of operators, i.e. holders of retail licences for self-medication medicinal products, who would not be liable to tax under the pharmacy tax law.

In its note, the Working Party on Self-medicines assessed three different options for pharmacy engraving. The Working Party recognised that the proposed changes would have a downward impact on tax revenue if self-care medicines in the range were excluded from the pharmacy

tax. For example, if the total revenue was to be maintained, the VAT rate for non-pharmaceuticals would have to be assessed (STM 2024:25 pp. 52-53).

As a first option, the working group assessed the model of maintaining the pharmacy taxation of pharmacies and of imposing a separate tax on self-medical products on holders of retail licences for self-medical products. A separate tax could take the form of a progressive or flat-rate tax. However, the challenge of this option would be to subject the same products to a different tax, depending on whether the seller is a pharmacy or a retail licence holder for self-medical medicinal products. Secondly, it would be difficult to set the level of taxation of retail licence holders at a level comparable to the pharmacy tax paid by pharmacies. Moreover, from the point of view of the simplicity of the tax system, it would not be desirable to have two different tax instruments for the same asset.

Secondly, the working group assessed the option of exempting off-pharmaceuticals from the pharmacy and imposing a separate flat-rate tax on pharmacies and holders of retail licences for self-medical medicinal products. Such a separate tax would be assimilated to excise duties. In terms of tax rates, equal taxation would be fair for taxpayers. However, if, for example, the tax were set at 7-8 %, the amount of tax payable would increase from the point of view of pharmacies which have previously paid less or no pharmacy tax.

Thirdly, the self-pharmaceutical group assessed the option of completely abolishing the pharmacy taxation of self-medication medicines sold outside pharmacies. The advantage of this option would be tax simplicity. Sales of self-medication medicines sold outside pharmacies would also not be included in the pharmacy tax base, so that the solution would be fair. However, the option would reduce the state's tax revenue. However, the impact could be relatively small if the limited range of self-medicines were narrow. The impact would also vary from pharmacy to pharmacy, depending on the progressivity of the pharmacy tax and the pharmacy's sales of products in the range.

During the preparation of the draft, the starting point was the neutrality of taxation of self-medication medicinal products sold outside pharmacies to pharmacies and to holders of retail licences for self-treatment medicinal products. Secondly, it was considered important that any tax deduction by the State should not be accounted for by pharmacies' collections from pharmacies, as pharmacies would then have to bear the social costs of extending the sales channel for self-health medicines.

During the preparation of the proposal, consideration was given to the possibility of increasing the rate of VAT in accordance with the VAT Act on self-medicines (1501/1993). Council Directive 2006/112/EC on the common system of value added tax requires Member States to apply a standard rate and a maximum of two reduced rates. Finland has a standard VAT rate of 25.5 % and reduced VAT rates of 14 % and 10 %. Pharmaceuticals are subject to a reduced rate of 14 %. Under the regulation, the VAT rate for all self-treatment medicines should have been increased to 25.5 %, while the entire proportion of sales of self-medical medicines in the taxable amount for pharmacy tax would have been removed. The VAT rate for prescription-only medicines would have remained 14 % and the margin on prescription medicines would have formed the basis of the pharmacy tax. The proposed amendment would also have changed the taxation of sales of nicotine replacement therapy products.

However, the estimated change was not considered justified because the VAT rate for pharmaceutical products would have been divided into two different levels. Secondly, the change could have been problematic from the point of view of fiscal neutrality or the principle of equal treatment, since it would have involved treating similar and competing goods differently for VAT purposes or treating traders in a similar situation differently (judgment of the Court of Justice in Case C-481/98, paragraphs 22 to 27, C-309/06, 47 and 49 and C-74/11 k. 49). In Case C-481/98, the CJEU considered that reimbursable and non-reimbursable

medicinal products are not competing like products and that their different taxation did not infringe the principle of neutrality (pp. 25-27). This presentation suggests that only self-medication products from a limited range could be sold outside the pharmacy if the marketing authorisation holder had applied for an extension of the sales channel for his product. In that case, it cannot be ruled out that there is competition between those medicinal products and those sold exclusively in a pharmacy. An increase in the tax rate could be contrary to the principles of neutrality or equal treatment of taxation.

Secondly, an assessment was made of a separate tax which would be imposed either solely on holders of retail licences for self-medical medicinal products or, in a uniform manner, on pharmacies and retail licence holders for sales of a limited range. In Case C-53/00, the CJEU assessed the situation in which there were two competing distribution channels for medicinal products in France, wholesale distributors and pharmaceutical factories engaged in direct sales, which were placed in a different legal position. The legislation imposed a social obligation on wholesalers to make available a range of medicinal products appropriate to the needs of their territory. A tax on direct sales of medicinal products was imposed on pharmaceutical plants. The exemption of wholesalers from direct sales tax constituted State aid granted to them, except in so far as the exemption corresponded to the additional costs incurred in keeping the wholesalers' social obligations available (pp. 19-28). The separate tax imposed on holders of retail licences for self-treatment medicinal products would lead to a difference in taxation between competing distribution channels – pharmacies and retail licence holders – since it would be challenging to achieve the level of the pharmacy tax, which varies from one pharmacy to another. The first option assessed by the Working Party on Self-medicines should therefore be abandoned. A uniform excise duty imposed on pharmacies and retail licence holders would also be challenging to implement, since excise duties are generally taxes on wholesale distributors based on the quantity of products. They are not collected at the retail level and the determination of the tax would be challenging.

For the reasons set out above, it was decided to promote the third option assessed by the Working Group, i.e. a limited range of self-medication products, which could also be sold outside pharmacies, would be fully exempted from the pharmacy iver.

Fees for government services related to self-care medicinal products

The handling of an application for an extension or variation of the sales channel of a self-treatment medicinal product, the processing of the retail authorisation and the related notifications, and the checks related to the authorisation would lead to a loss of resources for the authorities. In the same way as other marketing authorisation matters and authorisations for pharmacy activities, public services should be subject to a fee. Fees for marketing authorisations and pharmacy activities are laid down in the Decree of the Ministry of Social Affairs and Health on the fees payable by the Centre for Safety and Development of Pharmaceuticals (1053/2024). As regards pharmacy activities, the Decree is based on Section 8 of the Act on Criteria for Charges of the State (150/1992), Section 28 of the Medicines Act and Section 6a of the Act on the Centre for Safety and Development of Pharmaceuticals (593/2009).

According to Paragraph 4(1) of the Law on Criteria for Charges, decisions taken on application and other activities would be subject to fees, when the provision of the service would be the result of the intervention of the recipient. Pursuant to Article 8 of the Law on Criteria for Charges, the relevant ministry decides which services or categories of services of the Ministry and other administrative authorities are subject to payment and for which services or categories of services are determined on the basis of cost value, and which services are priced on a commercial basis. The extension of the sales channel for self-care medicinal products and the fee to be paid by the retail licence holder could be based on the Act on

Criteria for Charges of the State. There would be no need to derogate from the Act, so it would not be necessary to propose specific provisions in this respect.

Under Article 6a of the Law on the Centre for Safety and Development of Medicinal Products, the Centre for the Safety and Development of Medicinal Products is entitled to charge fees for inspections which it carries out in accordance with its tasks as laid down by law, or which are conditional upon the authorisation or other service provided by the Agency, or which it carries out on its own initiative. The provisions of the Act on Criteria for Charges Payable to the State (150/1992) apply to charges for public-law services. More detailed provisions on the fees and their amount shall be laid down by decree of the Ministry of Social Affairs and Health. The fee for inspections of the holder of a retail licence for self-treatment medicinal products could be based on this article and it would not be necessary to provide for it separately. In addition, holders of retail licences for self-treatment medicinal products would need to be included in the operators under Section 84b of the Medicines Act, which would have to pay a quality control fee to Fimea on an annual basis.

Article 28 of the Law on medicinal products provides that the authorisations referred to in Articles 21 and 21a to 21 g, the registrations referred to in Articles 22 and 22a and the variation of the marketing authorisation and registration referred to in Article 23a are subject to a fee. Payments may be ordered in advance. In addition, fees may be charged in whole or in part as an annual fee for activities related to authorisation and registration. The fees shall be laid down in more detail by decree of the Ministry of Social Affairs and Health, taking into account the provisions of the Act on Criteria for Contributions of the State or under it. The Centre for Safety and Development of Medicinal Products may issue more detailed rules on the payment of fees. Since the processing of an application for an extension of the sales channel for self-treatment medicinal products would not differ from the general provisions of the Act on Criteria for Charges, it would not be necessary to add it to the specific provision of Section 28 of the Medicinal Products Act.

Entry into force and start of application

According to Fimea's assessment, with the entry into force of the Law amending the proposed Medicines Act from the beginning of 2026, marketing authorisation holders' applications for extensions of the sales channel could start to be received from 1 October 2026 due to changes to the register of authorised preparations and to the pharmaceutical search service. The receipt of applications for retail licences for self-treatment medicinal products could start from the beginning of 2027. In practice, in order to facilitate the permit-granting process, e.g. electronic access and the establishment of an electronic register would be necessary. In addition, Fimea's provisions might need to be reformed. These enforcement measures are estimated to take about one year from the entry into force of the Act. On the other hand, the price regulation for a limited range of self-treatment medicinal products and the regulation of the pharmacy tax law could become applicable to pharmacies as early as 1 January 2026, that is to say, one year before the start of off-pharmaceutical sales.

Right of pharmacies to derogate from prescription

Current status

The patient's prescription is carried out in out-patient care in such a way that the patient is supplied by the pharmacy with the prescribed medicinal product or a medicinal product which can be exchanged with it. If the prescriber or patient refuses the exchange, the patient may only be supplied from the pharmacy with the prescribed medicinal product. If the medicinal product to be supplied has to be reimbursed, the customer usually receives the reimbursement directly from the pharmacy and pays only the co-payment for the medicinal product.

The implementation of patient prescription-only medical treatment in out-patient care is based on the Act on Healthcare Professionals (559/1994), the Electronic Prescription Act (61/2007), the Medicines Act, the Health Insurance Act (1224/2004) and the Decree of the Ministry of Social Affairs and Health on Prescribing Medicinal Products (1088/2010). More detailed provisions can be found in the Fimea Order on the Supply of Medicinal Products (2/2016).

The retail sale and supply of medicinal products at a pharmacy are regulated by the Medicines Act. Under Section 57b of the Medicinal Products Act, a pharmacy must supply a medicinal product prescribed by the prescriber or a medicinal product that can be exchanged with it to the user of the medicinal product. A pharmacy may exchange a prescribed medicinal product only with an interchangeable medicinal product in accordance with the publicly available list referred to in Article 57c which is the lowest price or where the difference between the price of the medicinal product and the lowest price does not exceed EUR 0.50. No exchange shall take place where the prescriber of the medicinal product has prohibited the exchange on a medical or therapeutic basis by stating the prohibition on the prescription or if the purchaser of the medicinal product prohibits the exchange. In addition, exchange cannot take place in the case of a biological medicinal product where the user is a minor, a short-acting insulin product, a medicinal product with special authorisation or a veterinary medicinal product.

The supply of a medicinal product for human use on the basis of an electronic prescription is governed by the ePrescription Act. The pharmacy's right of access to information on medicinal products prescribed for the patient and on the national medication list is based on Article 11 of the ePrescription Act.

Under Article 10(1) of the Law on electronic prescription, if the prescription in the centre of prescription is incorrect, the prescriber of the prescription may make the necessary corrections to the prescription. In addition, pharmacists and pharmacists supplying the medicinal product from a pharmacy may make the necessary technical corrections at the time of delivery. If the content of the prescription is unclear or incomplete, the oral consent of the prescriber shall be obtained. According to Section 12 of the Act, the information on the delivery of the prescription is attached to the prescription in the prescription centre. The pharmacy that supplied the medicinal product has the right to correct the incorrect delivery information. According to section 4.12 of the Fimea Ordinance (2/2016), clarification or correction should be requested from the prescriber when the prescription is unclear or incomplete.

In addition, under Article 5c of the ePrescription Act, a nurse, pharmacist and pharmacist appointed by the service provider are entitled, in accordance with the patient's medical treatment plan drawn up by the prescriber, to make changes to the dosage instructions of the prescription if the prescriber has authorised the changes to be made. This is specified in Article 23a of the Decree of the Ministry of Social Affairs and Health on the prescription of a medicinal product. The right to record dose changes does not apply to prescriptions for an SME, to prescriptions for narcotic drugs or to prescriptions for patient-specific authorised medicinal products. A written prescription on the right to record dosage changes may be given by the responsible doctor in the healthcare institution with which the nurse, pharmacist or pharmacist is employed. According to the explanatory memorandum of the Government bill on the section (HE 246/2022, § 5a): 'The responsibility of the*prescriber for prescribing and administering the medicinal product would remain the same. Nurses, pharmacists and pharmacists would have the right to change only the dosage instructions of the prescription, not, for example, the medicinal product or the strength of the medicinal product.'*

Pursuant to Article 13(1) of the Law on electronic prescriptions, the information in the National Medical List in the medical prescription centre on medicinal products prescribed for the patient and related labelling may be disclosed, without prejudice to confidentiality

regulations, to healthcare and social care providers and to the prescriber for the organisation and implementation of the patient's health and medical care. However, the patient may refuse the disclosure of the information relating to the medicinal product prescribed to the persons and pharmacies referred to above. Paragraph 3(4) provides that, notwithstanding the provisions of subsection 1, the prescriber may, in the event of a continuing medical relationship, be provided with information on the prescriptions and indications relating to the prescriptions which he has deposited at the prescription centre and, irrespective of the medical relationship, irrespective of the prescriptions placed by the pharmacy on the basis of Paragraph 12(3) and the prescriptions recorded by the nurse, pharmacist or pharmacist at the prescription centre on the basis of Paragraph 5a, of any changes to the prescription instructions in which he is indicated as the prescriber and the indications relating to those prescriptions.

In accordance with Chapter 5, Section 1, of the Health Insurance Act (1224/2004), an insured person is entitled to reimbursement of the costs of a medicinal product prescribed by a doctor and a dentist and by a nurse entitled to prescribe a limited or fixed-term medicinal product. The insured person shall also be entitled to reimbursement of an interchangeable medicinal product listed by the Centre for Safety and Development of Medicinal Products for which the medicinal product prescribed for the patient has been exchanged in a pharmacy in accordance with Section 57b of the Medicines Act.

Based on Fimea's prescription (2/2016), a pharmacy has the right to derogate from the prescription in certain specific situations. If the patient's prescription for permanent medication has expired no more than one month before and the prescription contains a remaining medicinal product, the pharmacy may provide the client with up to one month of treatment, or the smallest package size, to ensure continuous medical treatment. The exemption does not apply to drugs and small and medium-sized drugs (cf. 4.5).

A long-term medicinal product may be replaced by a different packaging of a reusable product, the size of which is not significantly different from the prescribed product (cf. 4.6). If the quantity of the medicinal product indicated in the prescription differs from the packaging on the market, a significantly higher quantity shall not be delivered without consultation with the prescriber. Drugs and small and medium-sized drugs may not be delivered in quantities higher than prescribed, except in the case of an exchange of medicinal products in a small number of different sizes of interchangeable product (cf. 4.8).

According to paragraph 12 of the Fimea Ordinance (2/2016), in exceptional situations, for example due to a major accident, other special emergency situations or a failure of the connection between a pharmacy and a prescription centre, deviations from prescriptions may be necessary to ensure the patient's essential medical treatment. However, medicine safety should not be compromised in these situations. Deviations should be documented and documentation should be kept for five years, unless otherwise specified.

On 18 August 2022, Fimea issued a letter of guidance to pharmacies on how to ensure the patient's essential medical treatment in an emergency situation (Doc. No FIMEA/2022/004616). The pharmacy may, on the basis of the instruction, derogate from the prescription in individual exceptional situations where it is necessary to ensure the patient's essential medical treatment so that the patient's treatment is not delayed or interrupted. Medicinal safety should not be compromised in case of anomalies and advice on medicinal products should ensure that the user or purchaser of the medicinal product understands what is involved in the derogation procedure and that he is able to use the medicinal product correctly and safely. The starting point for the derogation is that the pharmacy must have an adequate stock of medicinal products adapted to the needs of the region. If the medicinal product is prescribed for a longer period, it is particularly important for the pharmacy, if necessary, to ask

the prescriber to correct the prescription. The deviation and its reasons and justification should be documented and maintained at the pharmacy for five years. This information should be recorded on the medicine's guide ticket. The recipe logbook and the recipe centre must show the product actually delivered. The deviation shall be reported to Kela.

With paragraph 12 of the above-mentioned Fimea Regulation on the supply of medicinal products and the letter of guidance, there has been a generalised practice in pharmacies to derogate from prescriptions in certain specific situations. According to information from Kela, a total of around 35000 incidents were reported in pharmacies in 2023 and almost 43000 in 2024. In the event of an exception, the pharmacy first tries to reach the prescriber to change the prescription. If this is not achieved, the pharmacy will make a documented deviation. In fact, there are more cases where there is a need to derogate from the prescription every year, since the figure does not include the number of times the pharmacy has reached the prescriber and the prescription has been modified with his authorisation or action. It is also possible that the need for a medicinal product is not acute, in which case there is no exception in the case of a supply, but a request for the need to repair the prescription is submitted to the prescriber. There is no more detailed information on the frequency of these situations, as they are not systematically collected.

The deviation may be due to a variety of reasons. Shortages of medicines were the most common cause of pharmacies' exemptions from prescriptions in 2023 (39.3 %). The second most common reason was that the medicinal product prescribed for the customer had left the market and, at the time of supply, was no longer on the list of interchangeable medicinal products (24.7 %). The third most common reason was that the one-year validity period for biological medicinal products had not been updated and it was necessary to supply the medicine after the validity period (6.3 %). Other reasons for deviations were that the prescription form was not suitable for the client (approximately 2.9 %). In addition, 11.9 % of the deviations were not reported or could not be resolved.

According to the 2023 STM's pharmacy system development report, despite the generalised practice of pharmacies in recent years to deviate from prescriptions in certain situations, it has nevertheless become difficult to implement. The supply of medicines should be developed to ensure continuity of treatment in order to address shortages and ambiguities of prescription in situations that could be adequately resolved in a pharmacy (STM 2023:6 pp. 104-110).

Assessment of the current situation

According to the Government Programme of Prime Minister Orpo, the supply of prescription-only medicinal products will be clarified so that the prescription can be applied taking into account the availability and quantity of different pack sizes, without, however, deviating from the total volume of the prescription. In addition, the government programme has stated that efforts are being made to make greater use of the skills of pharmacies' staff as part of social and health care.

On the basis of the government programme, this proposal proposes that the right of pharmacies to derogate from prescriptions be created in legislation to ensure the safety of the customer's medicinal products and medication. Non-prescription delivery would mean that a pharmacy would supply the customer, on a single delivery basis, with a medicinal product other than a medicinal product prescribed for or exchanged with him, and would amount to a discrepancy with the information on the supply of the medicinal product. In addition, the pharmacy has the right, in accordance with Article 10 of the Law on electronic prescription, to correct technical errors found in the prescription. It is also proposed to extend the rights of pharmacies to make independent corrections to prescriptions.

Pharmacy's right to derogate from prescription

The right of pharmacies to derogate from prescription should only apply in exceptional circumstances. The presentation would not be intended to change the role or division of responsibilities between the prescriber (doctor) and the medicine supplier (pharmacy). As a general rule, prescription-only medicinal products would be supplied by pharmacies, as has been the case until now. The pharmacy's right to exchange medicinal products, which is governed by Paragraph 57b of the Law on medicinal products and is based on a list of interchangeable medicinal products drawn up by Fimea, would be part of the normal supply of medicinal products. Pharmacy switching should always be the preferred approach before any derogation from the prescription is considered.

The proposed amendment would entail an extension of the rights of pharmacies. The Medicinal Products Act should provide exhaustively for the situations in which a pharmacy could deviate from the prescription. Based on the most common reasons for anomalies reported in 2023, pharmacies would need to be able to derogate from the prescription, at least in the event of shortages, in situations where the prescribed medicinal product has left the market and in situations where the prescription has expired.

National shortages of medicinal products should be provided for as one of the exceptional situations in which the pharmacy could depart from the prescription. In recent years, shortages have become more frequent in Finland and Europe. In part, they can be countered by the exchange of medicinal products by pharmacies. However, problems arise in the case of shortages, which would require contacting the prescriber in order to resolve them. In such situations, the prescriber may not be reached (Lehtinen, Linnolahti, Luhtanen and Myllyntaus: Availability of medicines in Finland- Overview of shortages of medicines. Fimea develops, evaluates and informs series 8/2022 (' *Fimea 8/2022'*). Communication tools and communication approaches between pharmacy and healthcare are also often lacking (STM 2023:6).

The high number of prescribing incidents in 2023 and 2024 shows that there are many situations in practice, due to shortages and other causes, where the prescriber cannot be contacted when needed. However, it should be required that the shortage should be national. A deviation should not be possible as a matter of principle due to the pharmacy's own lack of storage.

The withdrawal of a medicinal product from the market could also be a reason to deviate from the prescription. The situation would be equivalent to a shortage of medicinal products in the absence of a prescribed medicinal product available in any pharmacy. A medicinal product which has been withdrawn from the market would no longer be included in the list of interchangeable medicinal products, with the result that the supply of the medicinal product to the customer could not be made through the exchange of medicinal products either.

An outdated or expired prescription could also be a reason to deviate from the prescription if the customer's need to receive the medicine was so acute that the prescription would not be renewed. Under Fimea's prescription (2/2016), despite the expiry of the period of validity, the medicine used may be regularly supplied with up to one month of treatment or the smallest pack size. The prescribing practice of Fimea should be made more flexible and taken into account as a basis for derogating from the prescription.

In addition, it is recognised in practice that a pharmacy may face specific exceptional situations where the customer has an acute need to immediately accompany the medicine, but it or a medicinal product that can be exchanged with it is not available in the pharmacy. This could be the case, for example, where a customer enters a pharmacy in the evening or at weekends and a prescribed medicinal product or a medicinal product that can be exchanged

with it would not be present in the pharmacy's warehouse and, as a result of the exhaustion of the medicinal products available to the customer, could be significantly harmed by delays or interruptions in the treatment of medicinal products. In such specific exceptional situations, it would be necessary to allow a pharmacy to derogate from the prescription, provided that the prescriber is not reached and the immediate need for the customer to accompany the medicinal product is really acute. However, it would be necessary to monitor the use of this ground for derogation with particular attention.

The purpose of derogating from the prescription would not be to reduce the stockholding obligation for pharmacies under Section 55 of the Medicinal Products Act. The pharmacy is obliged to maintain a stock of medicinal products in accordance with the needs of its customers. This means that, in practice, situations such as those in which the medicinal product would not be available in a pharmacy would be extremely rare. The regulation of non-prescription should not lead to inappropriate approaches. There should never be any derogation from the prescription on account of the financial interests of the pharmacy or the client.

The content of the prescription is governed by Article 6 of the ePrescription Act and Article 13 of the Decree of the Ministry of Social Affairs and Health on the prescription of a medicinal product. In the information content of the prescription, information on the prescriber, the patient and the medicinal product can be distinguished.

Information on the prescriber shall include the name and contact details of the prescriber, the date and handwritten signature, the identification code, the professional law and, where appropriate, the field of specialisation, the contact details of the healthcare institution and the identifier of the prescription. The need to deviate from the prescribing information in the exceptional circumstances described above has not been identified during the preparation and should therefore not be allowed for pharmacies. A derogation from the validity period related to the date of the prescription should be provided for separately.

The patient's data shall include the patient's name and personal identification number or name and date of birth if he/she does not have a personal identification number, as well as the weight of a person under 12 years of age in the electronic prescription. The pharmacy should not have the right to derogate from the prescription with regard to patient information. Under Article 12(1) of the Law on electronic prescription, the purchaser of a medicinal product must reliably demonstrate that he is entitled to receive the medicinal product. In the event of an exception, there would be a risk that the purchaser of the medicinal product would in fact be deprived of the right to purchase a prescription and that there would be an increased risk of abuse.

The information on the medicinal product requires that the prescription contains information on the medicinal product or the pharmaceutical substance (such as the trade name or name of the active substance, pharmaceutical form and strength) or the composition of the pharmacy (and, where possible, the quantity, form and strength where possible) and the information necessary for the supply and use of the medicinal product (such as the quantity of the medicinal product in package or in total or in terms of duration of treatment, the dosage guide for the medicinal product, whether the medicinal product is to be used regularly or, where appropriate, the intended purpose of the medicinal product, unless there is a legitimate reason to exclude it, labelling in the case of the start of the medicinal product). In addition, the prescription shall contain the identifiers of the medicinal product in use, the information necessary to resolve any sickness insurance cover, any prohibition of exchange where there is a medical or therapeutic reason, and any patient-specific medical or therapeutic justification for not prescribing the cheapest, comparable and alternative biological medicinal product, as well as any SIC marking, iteration or limitation of the period of validity of the prescription. In accordance with Article 10 of the ePrescription Act, the prescription may also be annulled or

the medicinal product may be terminated by means of a discontinuation mark on the prescription. In addition, re-prescription can be prevented.

A derogation from the prescription would not mean that a pharmacy would carry out separate diagnosis, diagnosis or other prescribing activities. The supply of a non-prescription medicinal product would only ensure continuity of treatment by supplying a medicinal product that meets the therapeutic objective of the prescriber. If it is not possible to supply a medicinal product meeting the therapeutic objective, the pharmacy should contact the prescriber or refer the patient to healthcare. The criterion should be that the intended effects on the user of the medicinal product should not change.

Pharmacies should be able to deviate from the prescription in terms of strength, pharmaceutical form, package size and dosage instructions if, for example, medicinal products in one pharmaceutical form or medicinal products of another strength would be available despite shortages. In case of deviation from strength, there would also be a need to deviate from the dosage instructions of the medicinal product, e.g. by having a half-dose dose of a twice-higher medicine. An indication of the abnormal dosage should be recorded for the supply of the medicinal product.

A medicinal product containing a specific active substance is usually prescribed for the customer and is specified in the prescription under the trade name. Under the legislation in force, a pharmacy has the right to exchange a medicinal product prescribed for the customer at the time of delivery of the medicinal product with a medicinal product which can be exchanged with it. It is legitimate for a pharmacy, even in cases where a prescription is waived or corrected, to seek, in principle, to resolve the situation by checking whether, for example, a different strength, pack size or pharmaceutical form of a tradable medicinal product would be available, so as to ensure the safety of the patient's medical treatment. This is because only interchangeability of interchangeable medicinal products has been established in the marketing authorisation authority process. In the absence of a different strength, pack size or pharmaceutical form of an interchangeable medicinal product, there could be a situation where a pharmacy would have to depart from the prescription by switching to another medicinal product which is not interchangeable with the prescribed medicinal product. In such a case, the pharmacy should, on the basis of pharmaceutical considerations, take special care to ensure that the safety of the medicinal product or medication would not be compromised as a result of the incident.

The pharmacy's right to derogate from the prescription could not extend to the active substance(s), since the active substance is the basis for the entire customer's medical treatment. According to the THL's current recommendation, no prescriber can correct the active substance of the prescription (THL ePrescription Pathways Recommendation THL 5/2023, ' *THL 5/2023'*). The pharmacy's right to derogate from the prescription could not extend beyond the right of the prescriber to repair. Similarly, information about the intended purpose of the medicinal product, whether it is starting and whether it is a regular or, where appropriate, used medicinal product relates generally to the diagnosis of the patient's medical treatment, and deviations from the prescription should not be extended to this information.

A derogation from the prescription could not, in principle, be possible in situations where a pharmacy would prepare a medicinal product to a customer on the basis of a prescription. An exception could be the obsolescence of the prescription. Even in that case, the preparation of the medicinal product would take time and the exception would not ensure immediate access to the medicinal product. The derogation could therefore not apply to medicinal products prepared in a pharmacy.

The prescriber shall have the right to make specific indications on the prescription, such as, for example, the information necessary to resolve any sickness insurance cover, any prohibition of

exchange where there is a medical or therapeutic reason, and any patient-specific medical or therapeutic justification for not prescribing the cheapest, comparable and alternative biological medicinal product, as well as any SIC marking, iteration or limitation of the period of validity of the prescription. Under Section 10 of the ePrescription Act, the prescription may be annulled or the medicinal product may be terminated with a discontinuation mark on the prescription. In addition, re-prescription can be prevented. There is always a specific reason for including labelling on the prescription. Since the prescriber is responsible for the patient's entire medical treatment, a pharmacy cannot be regarded as having the right to depart from those indications given by the prescriber. Moreover, unlike a prescription, a pharmacy should not be able to supply a medicinal product on the basis of an invalidated or discontinued prescription to its client without contacting the prescriber.

The Government Programme limits that the total amount of the prescription should not be exceeded. As a general rule, such a demarcation shall be made in the case of derogations from prescriptions. However, it is suggested to derogate from the limitation if the quantity of medicinal products not supplied on prescription would be less than the smallest available packaging or the most economically advantageous package, where it would be cheaper than the smallest package per dose, or where the medicinal product would be of such a dosage form that it would not be possible to split the pack (e.g. cream). In such situations, it is considered justified that the packet of medicinal products should not have to be distributed in a pharmacy, but that the customer could be supplied with the smallest available package or package which would be the most economically advantageous and could be supplied in full.

It is proposed that a second exception to the total amount of a medicinal product may be made in situations where the prescription used regularly by the customer is fully used or outdated and the prescription has not been renewed, but the customer needs the medicine immediately. In this case, it is proposed that the customer be able to supply up to three months of treatment with a medicinal product. The proposal would reduce unnecessary urgency in healthcare and a pack of medicines for up to three months would almost always be a cheap option for the customer and society. The prescription would be renewed in the healthcare sector within three months. The proposal would also be consistent with the provisions of Chapter 5, Section 9 of the Health Insurance Act on medicinal products eligible for single delivery.

Pharmacy's right to autonomously correct prescriptions

Under Paragraph 10(1) of the current Law on electronic prescriptions, pharmacies have the right to make the necessary technical corrections to the prescription independently. Technical correction is a correction that does not change the information content of the prescription, e.g. writing the dosage manual open. A change in the information of a medicinal product or patient or prescription data is not considered a technical correction (THL ePrescription Recommendation THL 5/2023).

In other cases, repair requires contact and action by the prescriber. Article 10(1) of the Law on electronic prescription provides that, where the content of the prescription is unclear or incomplete, the oral consent of the prescriber must nevertheless be obtained. According to the THL's recommendation, after obtaining the consent of the prescriber, a pharmacist or pharmacist working in a pharmacy may, on the basis of oral instructions from the patient's treating physician, correct the prescription's dosage instructions, intended use, SIC labelling, separate examination and prohibition of exchange (THL 5/2023). In addition, a pharmacy or hospital pharmacy may correct other information not related to the product, such as a dosage distribution label. The pharmacy makes a repair to the prescription information centre. The doctor must also ensure that the entry is corrected in the health information system.

Currently, it is only possible for the pharmacy to inform other members of the pharmaceutical chain about the technical repairs they have made. The recipe centre does not have the technical

capacity to reliably pass on other changes to the prescription to the prescriber and to another patient's therapeutic chain. As of 1 October 2027, the situation is changing by the third stage of the Kanta National Catalogue. It would then be possible for the pharmacy to report other corrections to the prescription. It would therefore be necessary to assess the extent to which a pharmacy's right to correct a prescription should be available after 1 October 2027.

The correction of unclear and incomplete prescriptions in the current section 10 of the ePrescription Act would be justified as a correction requiring the consent of the prescriber. The prescriber has studied and diagnosed the patient and has the best view of the patient's medical treatment. Corrections by pharmacies should not be based on assumptions or speculation in a situation of uncertainty. The right of pharmacies to correct errors in prescriptions should be limited to manifest errors. If a pharmacy is suspected of a defect, but it is not obvious, the pharmacy should, in order to ensure the safety of medication, if necessary, lock a prescription and contact the prescriber for repair.

The obvious error should be deduced from the information available in the pharmacy and should be present in the non-delivered prescription. If the error was not discovered at the time of the first transmission, that would be an indication that there was no manifest error. What matters is that the assessment of the obviousness of the error should always be carried out by a pharmacist or pharmacist working in a pharmacy. As a health professional, he would have the necessary training and skills to assess the obviousness of the error.

In the information content of the prescription, information on the prescriber, the patient and the medicinal product can be distinguished. According to the THL's recommendation, the prescriber cannot correct the patient's name, personal identification number, information from the original prescriber, the date and the type of prescription at the pharmacy, even if there should be no independent right to correct the prescriber's or patient's details. As described above, there could be no derogation from the prescription for medical records due to the risk of misuse of medicinal products. Similarly, the pharmacy should not be able to correct errors in the patient's personal data, but should always be in contact with the prescriber in these situations. A similar risk would apply to the prescribing information and the possibility of repair could lead to attempts to obtain medicines from a pharmacy with falsified prescriptions.

Pharmacies should be able to correct obvious errors in the prescription information on the medicinal product in the form, strength, pack size or dosage instruction, for example if, unlike a previous medication, the customer had been prescribed a medicinal product in a different pharmaceutical form, a medicinal product of a different strength or an obvious error in the dosing instruction. The pharmacy should also have the right to remedy a manifest error in the brand name of the medicinal product. However, particular care should be taken to confirm that the correct repair is carried out and that the correct medicinal product containing the active ingredient is supplied to the customer.

As far as the information on the medicinal product is concerned, it has been estimated above that a pharmacy should not have the right to derogate from the active substance prescribed, the indication of the intended use of the medicinal product, whether it is starting and whether it is a regular or, where appropriate, used medicinal product, nor should it be permitted to derogate from the specific indications on the prescription made by the prescriber. Similar restrictions would also apply with regard to the correction of prescriptions. In the case of a medicinal product prepared on prescription in a pharmacy, the pharmacy should, if it finds that there is an inaccuracy in the information contained in the prescription, communicate with the medicinal product to be prepared in order to ensure the accuracy of the medicinal product. In such situations, it would not be possible to correct the prescription.

The Government Programme limits that the total amount of the prescription should not be exceeded. This limitation is proposed when correcting obvious errors in prescriptions and

should be taken into account, for example, when correcting the strength of the medicine, pack size, pharmaceutical form and dosage instructions.

Medical safety

Any deviation from or correction of a prescription by a pharmacy should not jeopardise the safety of medicinal products or medication. This could be ensured by requiring that the decision to depart or correct the decision always be made by a pharmacist or pharmacist working in a pharmacy. As a health professional, it should be able to make a decision in a medication-safe manner on the basis of his training and skills.

The physician treating the patient has overall responsibility for the patient's medical treatment. A nurse with limited prescription is responsible for his own activities when prescribing medicinal products (see Laukkanen and Ruokoniemi (eds): Safe medicine, guide to the preparation of the medication plan, Ministry of Social Affairs and Health publications 2021:6 pp. 32-34. A pharmacist and pharmacist working in a pharmacy are, in principle, responsible for supplying a medicinal product to the customer. A pharmacist or pharmacist working in a pharmacy, who departs from or corrects a prescription, would also be responsible for those acts.

Ensuring the safety of medicinal products would also be essential when assessing what kind of derogation or repair could be made by a pharmacy to the prescription. The limits described above have been designed to ensure that the intended effects of the patient's treatment would not change. Moreover, if a pharmacy deviates from or repairs a prescription, a medicinal product that has been granted a marketing authorisation within the meaning of the Medicines Act or the EU Medicines Regulation and whose effectiveness and safety has been verified by the authorities would always be supplied to the customer.

Medicinal safety should also be taken into account in relation to what would be necessary to make an exception and the procedure to be followed in the pharmacy. The decision-making pharmacist or pharmacist should decide, on a case-by-case basis, whether a deviation or correction can be made in a medication-proof manner, i.e. in such a way as not to jeopardise the aim of the treatment, its implementation or the patient's status. When making a decision, the pharmacist or pharmacist should assess the harm that delays in treatment would cause to the patient. This assessment of harm should be weighed against possible harm caused by non-prescription or repair. The assessment should also take into account the health and cognitive status of the user of the medicinal product. The client should always be referred to healthcare if the pharmacy cannot solve the situation in a medication safe manner. The need to contact the pharmacy should be assessed on a case-by-case basis.

In the event of a departure or repair, the pharmacy should provide the patient with the necessary medical advice to ensure that the user or purchaser of the medicinal product understands the procedure and that the medicinal product supplied would replace the medicinal product prescribed for the user of the medicinal product. Medical advice would also ensure that the user of the medicinal product is able to use the medicinal product actually supplied to him correctly and safely and that he would understand the effects of the change on the use of the medicinal product.

In addition, successful follow-up care should be ensured. The pharmacy should invite the user of the medicinal product, if necessary, to contact the prescriber for the renewal of the prescription and, at the request of the purchaser, forward the prescription to healthcare for renewal if the prescribing entity receives requests for renewal. The need to renew a prescription could be considered not only when the prescription is time-barred, but also, for example, where the medicinal product has left the market or it is known that the shortage would persist for a long time. The request for renewal should take into account that renewal is

not done for the same product, but for a product that would replace a previously prescribed product.

Incidents

In the case of prescriptions, special circumstances are also laid down, such as when a prescription may be given in writing or by telephone, how to prescribe medicinal products with special authorisation, or to issue a pro auctore or European prescription. Provision is also made for the right of the prescriber to prohibit the transfer of a pharmacy, to derogate from the prescription of the cheapest biological medicinal product, to iteradicate the prescription, and to indicate the SIC on the prescription. Medicinal products suitable for misuse, narcotics, small and medium-sized products, medicinal products containing alcohol are subject to specific rules. The prescription of veterinary medicinal products is also regulated separately.

Prescriptions may be issued not only electronically, but also in writing or by telephone. According to Article 5 of the ePrescription Act, a written prescription may be used in the case of medicinal products subject to a pro auctore prescription, the prescription of medicinal gases or medicinal products subject to a patient's special authorisation. In addition, a written or telephone prescription may be used where, due to a technical failure, electronic prescription is not possible or there is an urgent need for medical treatment and the prescription cannot be issued electronically because of exceptional circumstances or for any other specific reason. The telephone prescription shall not be renewed and shall be valid for a maximum period of three months. Article 15 of the Regulation on the prescription of a medicinal product contains more detailed rules on the prescription of a telephone order. Pursuant to Article 12(4) of the Law on electronic prescription, if, due to a technical failure or for any other reason, the prescription was issued in writing or by telephone and was not stored in the prescription centre, the pharmacy must store the prescription and the related delivery data at the prescription centre when the prescription is submitted or when a technical failure prevents immediate recording, as soon as possible.

The issuing of a prescription in writing does not preclude a departure from it or a correction of the prescription, as the written prescriptions are taken to the prescription centre, making the changes available to all professionals involved in the treatment of the medicinal product. However, the nature of the medicinal products prescribed with a written prescription may give rise to obstacles to anomalies or repairs. Special rules apply to prescriptions issued by telephone. The order is made in such a way that the prescriber of the medicinal product is in contact with the pharmacy by telephone. During contact, it is possible for the pharmacy to check the availability of prescribed medicinal products and to verify the accuracy of the information provided by the prescriber. For these reasons, waivers from or correction of prescriptions should not apply to prescriptions issued by telephone.

A prescription may be given for a medicinal product prepared in a pharmacy. In the case of medicinal products produced in a pharmacy, deviation from the prescription due to shortages of supply, exit from the market, lack of stockpile of individual pharmacies or obsolescence of prescription would not be possible because the pharmacy manufactures or prepares the prescribed medicinal product for the customer. It might, however, be possible that such a prescription would be vitiated by a manifest error or be time-barred. However, a prescription for the preparation of a medicinal product differs from prescriptions which are normal in nature to such an extent that it would be appropriate to require that, in such situations, the pharmacy should always be in contact with the prescriber. The provisions on exemptions from prescriptions and their correction should be limited to industrially manufactured medicinal products.

The government programme did not specify whether veterinary medicinal products would also be covered by the possibility of medical prescription. However, the prescribing of veterinary

medicinal products and medicinal products for human use is based on different regulations, there are differences between their markets and veterinary medicinal products are not subject to an exchange of medicinal products or to an electronic prescription system. In view of these differences, the proposed changes would not concern prescriptions for veterinary medicinal products or their supply from pharmacies, and it is appropriate to limit that the derogation and the correction of the prescription would apply only to medicinal products for human use.

It has been pointed out above that the prescriber would have the right to make specific indications on the prescription, such as, for example, the information necessary to resolve any sickness insurance cover, any prohibition on switching, any patient-specific medical or therapeutic justification for not prescribing the cheapest, comparable and alternative biological medicinal product, any SIC marking, iteration or limitation of the period of validity of the prescription. In addition, the prescription may be invalidated or the medicinal product may be terminated with an indication of termination marked on the prescription. In addition, re-prescription can be prevented. In those circumstances, it would be legitimate for a pharmacy not to be able to depart from, correct and correct the special label provided by the prescriber and, for example, not to supply a medicinal product to the customer on the basis of an invalidated prescription without contacting the prescriber. There is always a specific reason for including labelling on the prescription. These entries should be excluded from the derogation and repair rights of pharmacies.

Under Section 56a of the Medicinal Products Act, a pharmacy may supply a medicinal product on the basis of a European prescription. In addition to the provisions of Article 13(1) and (2) of the Regulation on the prescription of a medicinal product, the European prescription shall contain the direct contact details and the professional address of the prescriber. The medicinal product shall be prescribed by the name of the active pharmaceutical substance, unless a biological medicinal product is prescribed or if the use of the trade name is deemed necessary by a healthcare professional for medical reasons. In that case, the reasons for the use of the trade name shall be briefly set out. Under Section 56a of the Medicinal Products Act, a pharmacy may refuse to supply a medicinal product prescribed by a European prescription if there are reasonable grounds to doubt the authenticity or medical appropriateness of the prescription, or if the prescription is unclear or incomplete.

The European prescription is based on Article 11 of Directive 2011/24/EU of the European Parliament and of the Council on the application of patients' rights in cross-border healthcare ('the *Patients'*Directive'), according to which, where a medicinal product may be marketed in a Member State, it must be ensured that prescriptions issued to a designated patient in another Member State for such a medicinal product can be used on its territory in accordance with its national law in force and that restrictions on the recognition of individual prescriptions are prohibited, unless (a) these restrictions are limited to what is necessary and proportionate to safeguard human health and are non-discriminatory; or (b) are based on well-founded and legitimate doubts as to the authenticity, content or comprehensibility of an individual recipe. The recognition of such prescriptions shall not affect national rules governing prescribing and dispensing, if those rules are compatible with Union law, including generic or other substitution. The Member State of affiliation shall take all necessary measures, in addition to the recognition of the prescription, in order to ensure continuity of treatment in cases where a prescription is issued in the Member State of treatment for medicinal products or medical devices available in the Member State of affiliation and where dispensing is sought in the Member State of affiliation. Commission Implementing Directive 2012/52/EU laying down measures to facilitate the recognition of prescriptions issued in another Member State provides for non-exhaustive information on European prescriptions.

Under Article 11 of the Patients' Directive, the right of pharmacies to derogate from prescriptions in the event of a national shortage, the withdrawal of the product from the market

and specific situations would contribute to the recognition of European prescriptions, even if they entail the supply to the purchaser, for example, of a medicinal product of a different strength from that referred to in the prescription. The proposed regulation on exemptions from prescriptions would thus be in line with the objectives of the Patients' Directive. The regulation should also apply to European prescriptions.

Correcting obvious errors in the prescription would mean that the prescription of the prescriber of another Member State would be amended. It is questionable whether recognition of a prescription within the meaning of the Patients' Directive could be fulfilled in that case, since there is no indication in that directive that a pharmacy may change the labelling of a European prescription. However, from the point of view of the purchaser of the medicinal product, the effect would be the same as in the case of a derogation from the prescription and, as a general rule, restrictions on the recognition of individual prescriptions are prohibited under Article 11 of the Directive. This would suggest that it should also be possible to correct obvious errors in European prescriptions. However, if the pharmacy has doubts about the obviousness of the defect, there should be contact with the prescriber, as in the case of national prescriptions.

A prescription may be used to prescribe medicinal products which are compassionate for the patient. There is always a special reason for prescribing these medicinal products. The particular nature of prescriptions does not justify a pharmacy being able to deviate from or correct such prescriptions without contacting the prescriber. Similarly, the specific nature of a pro auctore prescription implies that a pharmacy should not depart from it or correct it on its own initiative, since the prescriber issues a prescription to order medicinal products which he needs for his own work.

A prescription may be issued for medicinal products containing narcotic drugs, mainly medicinal products acting on the central nervous system, alcohol-containing medicinal products or an otherwise abusive medicinal product. A prescription may be required to be kept in a pharmacy. The common feature of these situations is that they involve the possibility of misuse of medicinal products and the risk of drug addiction. It is therefore proposed that the pharmacy's right to derogate from the prescription or the right of the pharmacy to correct the prescription should not extend to prescriptions for these medicinal products or to prescriptions to be stored. If the prescribed quantity of medicinal products is lower than the smallest available pack, that package should be distributed.

Recording of deviations and corrections in the systems

The legislation should require the pharmacy to document and store information on the deviation from the prescription in the prescription centre, which would act as a communication channel between the pharmacy and healthcare. As a first step, prior to the switch to production of the third phase of the national Kanta medication list, information about the deviation from the prescription, the timing and the reason for any contact with the prescriber should be recorded in the prescription centre. The so-called DP code and the reason for the deviation should be recorded in the data on purchases of medicinal products submitted to the Social Insurance Institution. The dosage instructions corresponding to the use of the supplied medicinal product should be indicated in the instructions on the pack of the medicinal product supplied. After the switchover to the production of the national Kanta medication list, from 1 October 2027, deviations could be recorded in the customer's supply data according to nationally defined cause codes.

The legislation should also require the pharmacy to record the correction of an obvious error in the prescription. Prior to the entry into production of the national Kanta list on 1 October 2027, it would not be possible for the pharmacy to make non-technical corrections to the prescription. Therefore, it should be possible for pharmacies to correct obvious errors only

after that point in time, when it is possible to record them in the customer's prescription data in accordance with the nationally determined cause codes.

Secondly, it should be required that the prescriber, irrespective of the status of the relationship, be able to become aware of any deviations and corrections made to a prescription issued by the prescriber in pharmacies. Section 13(3)(4) of the ePrescription Act has been amended due to dosing changes in accordance with Section 5c of the Act. It would also be necessary to include information on deviations and corrections made by pharmacies to prescriptions.

Overall economy of medical treatment

The pharmaceutical legislation imposes a number of obligations on prescribers and pharmacies to ensure the overall financial efficiency of the patient's medical treatment (Article 10(2) of the Regulation on prescription, Article 5b of the Law on electronic prescription, Articles 55, 57, 57b and 57c of the Medicinal Products Act). The obligations would also apply to a pharmacy in the event that he would have to deviate from the prescription or correct manifest errors found in the prescription and provide the customer with the corrected prescription medicinal product. The pharmacy should choose the cheapest or reference medicine to be delivered to the customer.

Any deviation from or correction of a prescription should be made in agreement with the purchaser of the medicinal product, including as regards the price of the medicinal product. The purchaser of the medicinal product should accept any additional costs associated with the waiver or repair of the prescription. From the point of view of the customer, it would also be justified that, despite the deviation or correction made, he should be compensated for the medicinal product actually supplied to him if that product had to be replaced. When stipulating the right of pharmacies to derogate from prescriptions in specific exceptional situations or to correct prescriptions, it is not intended to modify the basic principles of reimbursement of medicinal products. The right of pharmacies to derogate should also be recognised as part of the reimbursement system for medicinal products. It is therefore proposed to include in Chapter 5, Section 1(1) of the Health Insurance Act references to the rules on exemptions from and corrections to prescriptions. The basis for reimbursement in the event of a discrepancy or correction in respect of the supply of medicinal products covered by health insurance would not change from the current situation.

Refund payments to the State in connection with conditional reimbursement of pharmaceuticals

Current status

The conditional reimbursement of the medication reimbursement scheme is governed by Chapter 6, Section 6a of the Health Insurance Act. This provision has been in force on a temporary basis since 2017 and was made permanent from the beginning of 2025. Under that provision, the Committee on the Pricing of Medicinal Products may approve, for a specific reason, the substitutability and the wholesale price of a proprietary medicinal product for which reimbursement and a reasonable wholesale price have been sought. The Price Board may make a reimbursement and wholesale price decision subject to the condition that a specific medical need for the new medicinal treatment has been identified and there is significant uncertainty as to the medical cost of the medicinal product concerned, its therapeutic value, cost-effectiveness or other similar factors affecting the substitutability of the medicinal product or the assessment of the reasonableness of the wholesale price.

Part of the decision on conditional substitutability is an agreement between the Pharmaceutical Price Board and the marketing authorisation holder on the division of responsibilities in relation to the health benefits, cost-effectiveness, costs or other similar factors of the product, as well as the monitoring of the performance of the contract and the effects of the termination of conditional substitutability. If the marketing authorisation holder has a contractual obligation to pay a refund and the conditions are met, the refund shall be paid to the Social Insurance Institution's health insurance fund in accordance with the criteria laid down in the contract. The Medicines Price Board and Kela are responsible for the enforcement of the refund fee.

The reimbursement of medicines by Kela is financed by health insurance under the health insurance scheme. Chapter 18, Section 10 of the Health Insurance Act provides for a State contribution. Accordingly, the State's contribution to health insurance costs is 51.40 % and 48.60 % of insured persons, i.e. employees, beneficiaries and pensioners. Reimbursement payments (around EUR 60 million) related to the conditional reimbursement of medicines are currently allocated to the State (around EUR 31 million) and to insured persons (approximately 29 million) in proportion to the contributions to health insurance. Nowadays, reimbursement fees have reduced government expenditure and, for insured persons, reduced the medical contribution.

Assessment of the current situation

The reimbursement of conditional substitutability payments by pharmaceutical companies to Kela increased in 2024 compared to previous years. In 2024, pharmaceutical companies paid EUR 109 million in return payments, compared to EUR 76 million in the previous year. In 2019, reimbursement payments amounted to EUR 13 million. The procedure seems to be well established and has become more widespread as new medicines are being used more quickly (Kela's Bulletin of 26 February 2025)
"The reimbursement of medicines increased by EUR 124 million in 2024 – growth picked up again after more moderate years").

It is proposed that the reimbursement fees related to the conditional reimbursement of pharmaceuticals be fully allocated to the State as of 2026. Despite the higher total refund rates in recent years, EUR 60 million is estimated to be the amount that would be achieved annually. With reimbursement payments estimated at around EUR 60 million per year, this would mean that the share of insured persons, i.e. around EUR 29 million, would also be allocated to the State.

With regard to the financing of health insurance under the health insurance system, the full allocation of refund payments related to conditional reimbursement to the State's contribution wouldmake it possible to strengthen the state's finances by around EUR 29 million and offset the savings of EUR 10 million in reimbursement of medicines decided in spring 2024 in the context of statutory health checks**.** The amendment would require an amendment to Chapter 18, Section 10 of the Health Insurance Act.

3 Objectives

The amendments to the pharmaceutical tax rate for prescription-only medicines and the pharmacy tax law proposed in the government proposal are part of the overall reform of the pharmaceutical economy, aiming at permanent savings of EUR 30 million per year in public finances and a more cost-effective retail distribution system for pharmaceuticals. The government programme requires that the reform should take into account the actual profitability of pharmacies, as well as the safeguarding of the nationwide pharmacy network, pharmaceutical support (including medical advice), safety of medication and access to

medicines necessary for the implementation of rational pharmaceutical care. The reform will not increase the payment burden on customers.

By making it possible to sell certain self-medication medicinal products outside pharmacies, with separate authorisation and conditions, a government programme record is carried out, according to which, on the basis of a report from the pharmacy safety authority, the release of medicinal products and medication safety is prudent, while ensuring some of the most commonly used self-medication medicinal products also for sale outside pharmacies. The aim of the amendment is to improve the accessibility of self-medication medicines and to create price competition between self-medicines in a limited range.

By granting pharmacies the right to derogate from prescriptions and to correct prescriptions in certain situations, a government programme record is carried out, according to which the supply of prescription-only medicinal products is clarified so that the prescription can be applied taking into account the availability and quantity of different pack sizes. The aim of this amendment is to ensure better access to medicines and continuity of medical care for customers. At the same time, efforts would be made to make greater use of the skills of pharmacies' staff as part of social and health care.

The full allocation of refund payments for the conditional reimbursement of pharmaceutical reimbursements to the State would aim at strengthening the state's finances by around EUR 30 million and offset the savings in the statutory health checks agreed in the government programme, as well as the savings of EUR 10 million in pharmaceutical reimbursement decided in spring 2024 in the frames.

4 Proposals and their impact

Key proposals

The package proposed in the proposal includes a proposal to amend the Government Decree on the Medicinal Duty to cut the pharmaceutical tax on prescription medicines equally across all tariff categories based on a uniform wholesale price of medicinal products. The surgery would target the share of the pharmacy margin in the price of the prescription-only medicine.

It is proposed to amend the pharmacy tax law so that the taxable amount for pharmacy tax would in future be the combined profit margin for pharmaceutical sales by the taxable pharmacies, excluding VAT. The profit margin on pharmaceutical sales would be calculated on the basis of the margin on pharmaceutical sales. The pharmacy tax scale would be progressive, as has been the case so far. However, the tax scales would be based on profit bands for pharmaceutical sales, with six steps. The tax scale would have been designed to achieve an annual pharmacy tax revenue of around EUR 200 million. It is proposed to amend the items to be deducted from the taxable amount as it would no longer be necessary to deduct sales of non-pharmaceutical products or part of the retail price of expensive medicines from the profit margin on pharmaceutical sales in order to correct the so-called negative margin. The negative margin regulation would also be repealed from the price provision of the Medicines Act. The exceptional methods of calculating the amount of tax relating to branch pharmacies would also be waived. A new item to be deducted from the pharmacy iver would be the sale of self-treatment medicinal products within the limited range of self-medication medicines in the Medicines Act.

The Medicines Act would define a limited range of self-medication products, which would consist of categories of medicinal products which are assessed to present low risks and which are expected to be safely carried out without medical advice. In more detail, the pharmaceutical categories would be defined by ATC group in the Medicinal Products Regulation. Wholesale and retail discounts below the single wholesale price would be allowed

for products in the range. However, the retail pricing of products should respect the maximum price of the medicinal product and other price regulation of the pharmaceutical tariff. A limited range of self-medication products would be removed from the taxable amount for pharmacy tax. The price and tax rules would apply to the whole range, irrespective of whether or not an extension of the sales channel to sales outside pharmacies was requested for the products covered.

It is proposed to transfer the regulation on the classification of the supply of self-treatment medicinal products from the Medicinal Products Regulation to the Medicines Act. In principle, a medicinal product classified as a self-treatment medicinal product could only be sold in a pharmacy. The marketing authorisation holder could, if he so wishes, apply for an extension of the sales channel for his product outside pharmacies. It would have to be granted if the product were included in a limited range of self-medication products and met the conditions laid down by law.

The Law on medicinal products would provide for a retail licence for self-treatment medicinal products, which would authorise, on a stand-alone basis, the sale of self-medication medicinal products for which an extension of the sales channel would have been sought. The Act would lay down the conditions for authorisation, the permit application, the notifications, the validity of the licence, the requirements for the licence holder and the duties of the responsible person, as well as penalties. Advice on medicinal products should not be given to customers outside pharmacies and the authorisation holder and their staff should not be subject to professional secrecy. Further regulation would be included in the Medicinal Products Regulation.

In addition, the regulation of the Medicines Act would be amended to enable the retail sale of self-treatment medicinal products outside the pharmacy as part of the pharmaceutical supply chain. The amendments would concern the scope of the law, the responsible manager of the pharmaceutical plant and the pharmaceutical wholesale trade, the procurement of self-treatment medicines from the wholesale and pharmaceutical manufacturing industry, the removal of the safety features of medicinal products, the obligation of the marketing authorisation holder and the wholesale distribution of medicinal products to keep medicines available, the right to sell medicinal products, distance sales of medicinal products, samples of medicinal products, the right to inspection and information by public authorities, the obligation to pay a quality control fee, appeals and criminal liability for breach of professional secrecy.

In addition, it is proposed to specify the distribution of samples of medicinal products in the Medicines Act so that only self-medication products can be used for pharmacists and pharmacists, and the provision on marketing of medicinal products is proposed to be clarified in order to prevent holders of retail licences for self-treatment medicinal products from marketing prescription medicines. It is proposed to add the system for recording the safety features of medicinal products and the operator of the recording system, which were mistakenly deleted from the provision on official inspections, which should also be subject to the right of inspection. As regards the provisions on the wholesale distribution of medicinal products and the sale of nicotine products, it is proposed to amend the reference to the article.

A provision would be introduced in the Medicines Act on the right of pharmacies to derogate from prescription in the event of a national shortage, after the product has left the market, for a specific reason in specific exceptional situations where the medicinal product would not be available in the pharmacy’s stock and in situations where the prescription of a medicinal product used on a regular basis has recently become obsolete or exhausted. The Medicinal Products Act would lay down the extent to which a pharmacist or pharmacist working in a pharmacy could derogate from the prescription and under what conditions. As a general rule, the total quantity of medicinal products should not be exceeded, except for individually

regulated exceptions. The deviation should be made in agreement with the purchaser of the medicinal product, the latter should be given the necessary medical advice and the deviation should be recorded in the prescription centre and in the information received by Kela. It is proposed to amend the Health Insurance Act so as not to affect the user's right to reimbursement of the medicinal product supplied to him.

It is proposed to amend the ePrescription Act to give pharmacies the right to correct manifest errors in the prescription addressed to the user of the non-delivered medicinal product. The law would lay down the extent to which the prescription could be corrected and under what conditions. The repair should be carried out in agreement with the purchaser of the medicinal product and should be accompanied by the necessary medical advice. Repair information should be recorded in the recipe centre. Irrespective of the relationship of treatment, the prescriber would be given access to the labelling of deviations and repairs of pharmacies in the case of prescriptions in which he is labelled as a prescriber.

It is proposed to amend the provision on state contribution in the Health Insurance Act so that, for the financing of health insurance under the health insurance system, reimbursement payments related to the conditional reimbursement of reimbursements of medicinal products would be fully allocated to the State as of the beginning of 2026.

Main effects

4.2.1. Economic impact

4.2.1.1. Economic and budgetary implications

The following table summarises the impact of the proposed legislative amendments on the state finances, based on the assumptions and conditions described below.

Table 2. Summary of the proposal's impact on the State's finances.

Measure	**Estimated impact on government finances**	**Start date**
Savings on state finances		
Change in the pharmaceutical tax rate for prescription-only medicines	Savings on state reimbursement of medicines – EUR 31.4 M/year	1.1.2026
Allocation of refund payments related to conditional substitutability to the State	Savings on state reimbursement of medicines -29 M EUR/year	1.1.2026
Fiscal implications for the State's finances		
Cutting the pharmaceutical tax rate for prescription medicines, amendments to the Act on the taxation of pharmacies and the removal of a	The revenue from the State's pharmacy tax would be reduced to around EUR 200 million per year.	1.1.2026 (pharmacy tax payable for the first time in 2027).

limited range of self-treatment medicines from pharmacy taxation.		
Prescription-only medicine taxa	The State's tax revenue would be reduced by around EUR 16 million per year (including income tax, municipal tax, corporation tax, ecclesiastical tax and health insurance fees). In addition, there is a slight reduction in VAT.	1.1.2026

The estimated impact of the proposed pharmaceutical savings on the state economy is estimated at around EUR 60.4 million per year. In the preparation of the proposal, it can be seen that the income tax revenue of the State would be reduced by approximately EUR 16 million. The effects of the pharmacy tax have been examined in more detail below.

The proposed change in the pharmaceutical tax rate for prescription medicines aims at a permanent annual budgetary saving of EUR 30 million per year, in line with the government programme. The savings would be on the reimbursement of medicines by the health insurance system.

The proposed change in the pharmaceutical tax rate for medicinal products subject to prescription would reduce the cost of medicines by EUR 34 to 38 million per year and reduce the cost of health insurance by EUR 28-31 million per year for the simulation data of the reimbursed purchases of medicinal products produced by Kela for the period 2022-2024. The proposed change in the pharmaceutical tax rate for prescription medicines is thus estimated to result in a permanent annual savings of EUR 30 million per year, assuming that the pharmaceutical market would not increase substantially from the 2024 figures in 2025 or 2026. It was not possible to make further forecasts of developments in the pharmaceutical market. The modelling of the effect of change for previous years based on the consumption of medicines is presented in Table 3.

Table 3. To propose a uniform cut-off rate for all wholesale price categories, based on the microsimulation model of Kela, based on pharmaceutical costs and reimbursements.

Flat rate model for different wholesale price categories			
	2022	2023	2024
Costs	—34.3 million e	—36.1 million e	—38.1 million e
Compensations (spending 67 %)	—28.1 million e (-18.8 million e)	—29.6 million e (-19.8 million e)	—31.4 million e (-21.0 million e)
Proportion of patients	—5.7 million e	—5.9 million e	—6.2 million e
Average excess (change)	180,68 e (ka -1,49 e, min - 14,60 e, max + 0,03e)	186,27 e (ka - 1.51 e, min - 14.42 e, max + 0,01 e)	191,71 e (ka -1.57 e, min - 14.85 e, max + 0,01 e)

A reduction of EUR 30 million in public expenditure on reimbursement of medicines would affect the State and insured persons in proportion to the current contributions under the Health Insurance Act, with a government contribution of around EUR 15 million (51.4 %) and a share of insured persons of around EUR 15 million (48.6 %). However, in line with the government's budget balance for 2023 and the Government's decision of 25 April 2024 on the

Fiscal Plan for 2025-2028, the share of insurance premiums of about EUR 30 million of the fiscal savings to be achieved by the amendment to the Health Insurance Act (693/2024) proposed in this draft has already been fully channelled to the State in advance.

Without this channelling, the EUR 30 million reduction in public expenditure on reimbursement of medicines would affect insured persons by around EUR 15 million, which would computationally reduce the medical contribution by around 0.01 percentage points. However, this reduction in the contribution of insured persons has been previously channelled into savings by the State, so that the proposal would maintain the level of contributions. In view of the channelling, the state saving on the change in the pharmaceutical tariff for prescription-only medicines would amount to approximately EUR 30 million.

It is estimated that the full redirection of refund payments to the State related to the conditional reimbursement of pharmaceutical reimbursements will reduce the state's financing needs for medical insurance by around EUR 29 million. The contribution of insured persons would increase by the same amount. The measure would replace the 30 million savings on statutory health checks agreed in the government programme by EUR 20.2 million, as well as the savings of EUR 10 million on reimbursement of medicines decided in the framework in spring 2024. The above-mentioned amending law (693/2024) would have channelled in advance from the pharmaceutical savings obligation of EUR 10 million the contribution of EUR 3 million in insurance premiums.

This estimate is based on an estimated annual return payments of EUR 60 million, of which 51.4 % (about EUR 31 million) and 48.6 % (about EUR 29 million) reduce the contribution of insured persons to the State. In the case of the State, the refund payments have reduced government expenditure and, in the case of insured persons, reduced the medical contribution. In the future, the benefit of the refund payments would be fully redirected to the State, so that they would no longer reduce the burden on insured persons. The change would not have a negative impact on public finances, as both the government contribution and insurance premiums are part of the public finances. The contributions of the insured persons are covered by the levy on employees, beneficiaries and entrepreneurs. As a result of the proposal, the notional need for an increase in the medical contribution of insured persons would be 0.02 percentage points.

It is proposed to grant pharmacies the right to derogate from the prescription and to correct manifest errors in the prescription. The proposal is not assessed as having a significant impact on the level of reimbursement of medicinal products, as the proposed amendments would aim at ensuring that the implementation of reimbursement is not affected by anomalies or repairs and that anomalies are already a practice in pharmacies. The pharmacy should make an exception or correction in accordance with Section 57 of the Medicinal Products Act.

Surgery of prescription medicines would reduce the tax revenue of the State on the income of pharmacies. The income earned from the activity of a pharmacy is calculated as the income of the pharmacist, which is taxed by means of income tax. The proposed change in the tax rate for prescription-only medicines is estimated to reduce the State's earnings tax revenue by EUR -11.6 million. Municipal tax revenue is estimated to decrease by EUR 1.5 million. In addition, the change is estimated to have a limited impact on the state corporate tax revenue, the church tax and the health insurance contribution (less than EUR 1 million). The overall net effect of the proposed change in the pharmaceutical tax rate of prescription medicines on the state tax revenue (excluding pharmacy tax) is estimated at around EUR -16 million.

A cut in the pharmaceutical tax rate for prescription-only medicines would also have an impact on the State's VAT revenue revenue. However, it should be noted that at the same time a

number of changes are underway that affect VAT revenue, such as a change in the VAT rate on pharmaceuticals and a decrease in pharmaceutical prices. VAT revenue is likely to decrease slightly as a result of the changes, but due to uncertainties, the size of the decrease was not modelled in euro.

The pharmacy tax is paid to the State in several instalments each year. The tax period for pharmacies is the calendar year. The pharmacy tax of the previous year must be paid by the end of February of the following year. In addition, if a pharmacist retires during the year or renounces a pharmacist, he must also pay the pharmacy tax for the same year in advance. The pharmacy tax due for the remainder of the year is usually around EUR 5-6 million. Therefore, the impact of the proposed changes on the pharmacy tax can be assessed on the basis of two pharmacy tax figures.

The revenue from the State pharmacy tax in 2025 is based on the tax collected for calendar year 2024 (tax period) and on pharmacies paid in advance during 2025, e.g. due to the closure of the pharmacy business. The total revenue for 2025 is estimated to exceed EUR 220 million. At the end of February 2025, the revenue from the pharmacy tax, which is expected to be entirely attributable to the 2024 tax period, amounted to EUR 213 million.

The revenue revenue from the State pharmacy tax in 2024 amounted to EUR 209 million (Tax Administration's statistical database. Evolution of tax revenues. Tax revenue and refunds, net revenue from pharmacy tax, total fiscal year 2023. Available 1. Tax revenue and refunds variables Tax Type, Fiscal Year, Month, Variable and Data. PxWeb). Based on the 2023 turnover, pharmacies accounted for approximately EUR 200 million of pharmacy tax by the end of February 2024.

The amendments to the pharmaceutical tax rate for prescription medicines and the pharmacy tax law, which enter into force on 1 January 2026, would apply for the first time to the pharmacy iver based on the 2026 tax year, which would be paid to the State by the end of February 2027. It is also proposed that the new price regulation of the limited range of self-pharmaceuticals and their removal from the pharmacy tax base apply from 1 January 2026, i.e. they would appear for the first time in the pharmacy ordinance to be paid in 2027.

The proposed change in the pharmaceutical tax rate for prescription medicines and the change in pharmacy taxation are estimated to reduce the State pharmacy tax revenue so that the pharmacy tax due in 2027, based on the calendar year 2026, would amount to approximately EUR 207 million per year, assuming that the amount of the pharmacy tax would not be affected by other market changes. The new pricing and removal of a limited range of self-medication products from the pharmacy tax base is estimated to reduce the pharmacy tax revenue by a further EUR -7 million.

The revenue from the pharmacy tax for 2027 would therefore correspond to the pharmacy tax collected for the 2023 tax period. Compared to the total accumulated pharmacy tax revenue in 2025, the decrease would be around EUR 20 million. Looking at only the pharmacy tax collected for the 2024 tax period (accounted by end-February 2025), the reduction would be around EUR 13 million. The 2026 State pharmacy tax revenue to be collected for the tax period 2025 cannot be taken into account in the calculation, as the tax period is ongoing in the preparation of the proposal. ~~However~~, given the uncertainties surrounding the development and calculation of the pharmaceutical market, it is not possible to provide an accurate estimate of the revenue from the State pharmacy tax for 2026.

It is proposed to allow retail prices below the uniform national wholesale price for products within the limited range of self-medication products. The proposed amendment may have a limited impact on state pharmaceutical reimbursement expenditure, as some of the products in the range are reimbursable medicinal products. A change in price regulation may also have an

impact on the government's tax revenue revenue. Given the uncertainties surrounding the start of price competition and regional disparities, it was not possible to assess ex-ante the effects in euro. In view of the uncertainties surrounding price competition and the likely regional differences, it is not possible to carry out an ex ante assessment in euro. In addition, as from 1 January 2027, the range of self-medication medicinal products sold outside the pharmacy may be transferred to the pharmacies under a limited liability company, provided that the pharmacy is accompanied by a special purpose vehicle. Changes in state tax revenue in this respect are presumably small and not modelled in euro.

Factors affecting the financial impact on the State

The proposed changes to the pharmaceutical tax rate and the pharmacy ordinance for prescription-only medicines are made in a context where there are a number of changes to the financial conditions of pharmacies. The pharmaceutical tax rate and the pharmacy tax have been last amended by amending provisions that entered into force since the beginning of 2023, the pharmacy exchange of biological medicines has gradually started between 2024 and 2026, the VAT rate on pharmaceuticals has increased from 10 % since the beginning of 2025 to 14 % and will decrease to 13.5 % with the implementation of the government's spring 2025 stripe decisions. In addition, wholesale prices of medicines were reduced by 1.5 % since the beginning of March 2025. All these changes have an impact on the pharmacies' finances and have made it possible to model their effects only to a limited extent as part of the impact assessment.

A separate assessment of the growth rate of pharmaceutical sales was carried out as part of the preparatory work. As things stand, several factors were identified to slow down growth rates. Several legislative changes have been introduced to curb the increase in pharmaceutical costs. As regards changes, in particular the start of pharmacy exchanges for biological medicinal products, it is expected that the cost of medicines and reimbursement costs will have a significant impact since the beginning of 2025, but the magnitude of the change is not yet visible in the documentation.

In addition, the increase in pharmaceutical sales is influenced by the expiry of patents for certain products used for the treatment of certain large patient groups and the consequent entry of cheaper products into the reimbursement system, as well as active price competition, which is expected to lower the prices of medicines. For example, in the group of anticoagulants used as blood abbreviation medicines, the effects of price competition will be felt by 2025 at the earliest. However, we estimate that as a result of a number of parallel changes, the pharmaceutical market will not grow as in previous years in the coming years. At the same time, we consider that the impact of these factors will not be such that the size of the pharmaceutical market would decrease in the coming years.

During the current government term, following the adoption of the Government Programme, the Health Insurance Act has been amended by Act (693/2024). The legal amendment changed the contributions to health insurance to 51.4 % for the State and 48.6 % for the insured. In line with the decision of the government budget for 2023 and the government decision of 25 April 2024 on the Fiscal Plan 2025-2028, the purpose of the legislative amendment was to channel in full the savings to the state and municipalities resulting from government measures for the social security funds to reduce debt (HE 123/2024 vp). The channelling of savings consisted of a number of measures, one of which was to reduce the financial liability for the benefit costs of the state health insurance and to increase the contribution of insured persons to the costs of health insurance. The channelling took into account in advance the cost of pharmaceuticals and savings in the pharmaceutical economy, as provided for in the Government Programme and the Framework Care Decision, EUR 30 million and EUR 10 million in pharmaceutical

savings, for which the savings were fully allocated to the State. In practice, this was done by increasing the contribution of insured persons to health insurance.

This presentation has been prepared using contributions from the government during the pharmaceutical tax cut on prescription-only medicines, with the government contribution of 67 % of pharmaceutical reimbursement expenditure and 33 % of insured persons' contributions. This is because the above-mentioned Amending Law 693/2024 already channelled in advance the share of insurance premiums from the budgetary savings targeted by the proposed change in pharmaceutical tariffs in this proposal. If the contribution rates changed during the government term had been used in the calculation, the cut would have to be significantly higher than the cut envisaged at the time of the adoption of the government programme.

Economic impact on households

It is estimated that the proposed medicine taxa surgery for prescription medicines will benefit the users of medicines in terms of reduced pharmaceutical costs. Users of medicines pay a co-payment for the reimbursed medicines they buy. The annual benefits for users of medicines are estimated at around EUR 6 million per year (Table 3). The average patient's co-payment of medical treatment after the proposed amendment would be about EUR 190. On average, the cost of the medicine per user would decrease by around EUR -1.57 (Table 3). In addition, the proposed change in the price of non-reimbursable prescription medicines is also estimated to lower the prices of non-reimbursable prescription medicines, which would directly benefit patients as they fully pay for non-reimbursable medicines themselves.

It is proposed to change the price regulation of medicines in the limited range of self-medication products. The change is likely to benefit at least part of the users of medicines, as higher discounts would be possible in the retail prices of products in the range. It is estimated that users of medicinal products will benefit from discounts, especially in areas where there are several pharmacies and holders of retail licences for self-treatment medicinal products. As price competition increases, the prices of a limited range of self-medicines could be expected to fall.

However, the benefits for users of medicinal products would be less if price competition and any rebate agreements did not lower the prices of medicinal products within the limited range of self-medication products. The benefits would probably vary from region to region. In its note, the Working Party on Self-medicines considered that the impact on the burden on consumers would depend on the strength of the conditions of price competition for products authorised for sale in other sales channels. The intensity of price competition would depend on the size of the range and the incentives to enter the market for retail outlets outside pharmacies. The wider the choice, the higher the incentives for other operators to enter the market.

The burden on users of a medicinal product could also increase if a pharmaceutical company were to decide to increase wholesale prices in order to increase its ability to grant discounts on its proprietary medicinal product in a limited range of self-medication medicinal products to certain pharmacies or to holders of retail licences for self-treatment medicinal products. An increase in wholesale prices would then change the maximum price of those medicinal products in the self-treatment rate at all outlets. It is proposed that the capped choice of self-medicines be subject to maximum pricing under the Medicinal Tariff Regulation, but this would not prevent consumers from increasing their retail prices above the current tariff if the pharmaceutical company were to act as described above. The legislation in force allows the prices of self-medicines to be adjusted every two weeks. It is conceivable that in the future the maximum price would be applied only in less competitive areas, with the result that the price for consumers dealing in pharmacies in such areas or at the retail outlets of the holder of a

retail licence for self-medical medicinal products would be the price for a limited range of self-medication products. In view of the uncertainties surrounding the pricing model with regard to changes in the market, it is not possible to estimate ex ante the level of benefits for consumers.

The change in the rate of prescription medicines is not estimated to have a significant impact on consumers' purchasing behaviour, as prescription-only medicines are largely substituted medicines and their use is subject to prescription. The impact of a change in the price regulation of proprietary medicinal products in the limited range of self-medication products on consumer purchasing behaviour would depend on the composition of the range of self-medication products sold outside pharmacies and on the participation of pharmaceutical companies, on the one hand, and pharmacies and holders of retail licences for self-medicine medicinal products, on the other. Due to these uncertainties, it is not possible to further assess the impact on consumers in advance.

The proposal proposes that refund payments related to the conditional reimbursement of reimbursements of medicinal products should be fully allocated to the State in the financing of health insurance under the health insurance system, so that reimbursement fees would no longer reduce the burden on insured persons. The change would have a notional impact on the contribution of insured persons to health insurance costs and a notional increase of 0.02 percentage points in the contribution of employees, beneficiaries and entrepreneurs.

It is proposed that the pharmacy should be able to derogate from the prescription and correct the prescription in certain circumstances in order to ensure continuity of treatment. The proposals would mean that the practice already existing in pharmacies would be backed up by regulatory arbitrage. The proposed amendment to the Health Insurance Act would aim to ensure that any deviation or correction made would not affect the right of the user of the medicinal product to be reimbursed for his purchase of medicinal products, as long as the medicinal product supplied to him would have to be reimbursed. It is also required that the deviation or correction should also be made in terms of costs, in agreement with the user of the medicinal product. However, it is possible that, in individual situations, the cost to the user of the medicinal product would increase.

On the other hand, challenges related to the procurement of medicines may create additional burdens. This can undermine care commitment, which faces significant challenges in the light of international studies (Kvarnström, Westerholm, Airaxony, lira). Factors Contributing to Medication Adherence in Patients with a Chronic Condition: A Scoping Review of Qualitative Research. Pharmaceutics. 2021 Jul 20;13(7):1100). The right of pharmacies to derogate from prescriptions in certain specific situations, which has already been the practice already in force in recent years, means that the burden on the user of a medicinal product when purchasing medicinal products is reduced and that the continuity of medical treatment in the pharmacy can be assured without urgent contact with healthcare and any additional costs for the user of the pharmacy or establishment.

4.2.1.3. Economic impact on pharmacies

Starting point for the pharmacy economy and activity

In 2023, the Finnish pharmacy network consisted of 638 private pharmacies with a total of 173 branch pharmacies and 115 pharmacies. In addition, there were two university pharmacies and 16 branch pharmacies at the University of Helsinki. A total of 253 pharmacies offered distance sales of medicines. On average, Finland had around 6780 people per pharmacy (pharmacies and branch pharmacies) in 2023. However, there were differences in the number of pharmacies between provinces and municipalities. (Fimea *1/2025*, pp. 12-13).

The pharmaceutical tariff on retail pricing of prescription medicines and the pharmacy taxation of expensive medicines were amended by legislative and regulatory amendments that entered into force since the beginning of 2023. Following the changes, in 2023, private pharmacies were generally commercially profitable in Finland. Between 2022 and 2023, the total turnover of private pharmacies increased by 1.6 % (EUR 43 million). The average VAT-free turnover of private pharmacies in 2023 was around EUR 4.5 million (excluding university pharmacies) and the median turnover was around EUR 3.9 million. However, the turnover of pharmacies is very different and their economic conditions depend, inter alia, on the place of business. Universities' pharmacies were excluded. The smallest pharmacies have an average turnover of EUR 1.1 million and the largest have a turnover of more than EUR 10.1 million. 216 pharmacies in the two largest categories of turnover accounted for 56 % of their total turnover. Changes that entered into force at the beginning of 2023 reduced not only the growth rate of turnover but also the growth rate of pharmaceutical turnover beyond total turnover (Fimea 1/2025, pp. 21-22 and Rhine and Hycolininen: Pharmacy Economy, p. 28-32, Finnish Medicines Statistics 2023. The annual financial statements analysis published by Fimea repeatedly includes several pharmacies where the notional operating profit is below EUR 0 (Fimea 1/2025, p. 33). This reflects a strong polarisation of the pharmacies' economy.

The turnover of pharmacies consists of the sale of medicinal products, the sale of foodstuffs and general commercial goods, the manufacture of medicinal products and the sale of pharmaceutical services. A distinction can be made between the sale of prescription-only medicines and the sale of self-medicines. Pharmaceutical sales accounted for around 94 % of total pharmacies' sales in 2023 (Fimea 1/2025, pp. 21-24).

The margin for pharmacies shows how much the pharmacy will retain when sales revenue is deducted from purchases of goods corresponding to sales. The Myyntika figures include all the business of the pharmacy name, not the exclusive sale of medicinal products. The gross margin figure 1 for pharmacies is obtained by deducting from turnover the costs directly related to the medicinal product. In addition, Myyntikate 2 takes into account the pharmacy tax paid. In 2023, the average margin 1 for private pharmacies was EUR 1.2 million and the 1 % margin was 26.7 %. Compared to 2022, the percentage of sales margin decreased by 3.6 %. The average margin 2 for private pharmacies in 2023 was EUR 917 000 and the margin was 220.4 %. The 2 % decrease compared to the previous year was 2.9 %. Average margins in euros for private pharmacies have increased between 2020 and 2022, but the figures have decreased since then. Average sales margins have decreased in recent years, but in 2023 the decrease was faster compared to 2020-2022. The decrease in sales margins is explained by the increase in the share of sales of expensive medicines with lower margins and the consequent increase in the pharmacy tax, as well as the changes in pharmaceutical tariffs for 2023 (Finnish Medicines Statistics 2023, article 30, Fimea 1/2025, pp. 27-28).

Between 2021 and 2023, the sales margin for prescription medicines for pharmacies consisted mostly of medicinal products in the two lowest tax bands, in terms of packaging volumes. However, when looking at the construction of the margin based on the value of medicines, it is observed that the largest margin accrues from medicines with a wholesale price of between EUR 7.5 and EUR 39.99 and between EUR 40 and EUR 99.99. In addition, the sale of prescription-only medicinal products includes delivery fees, which remain unchanged, and their impact is not taken into account in the calculations. The total margin received by all Finnish pharmacies from sales of self-treatment medicines in 2023 amounted to around EUR 130 million. The average margin obtained by pharmacies from sales of self-treatment medicines was EUR 202380 per pharmacy and the median margin of EUR 155640 per pharmacy.

The total margin for pharmacies is calculated on the basis of self-treatment products which are sold in pharmacies in the Fimea wholesale register and are subject to a pharmaceutical tax. As

of 1 April 2022, it is possible for pharmacies to grant discounts on self-medical medicines' margins. However, the discounts have been moderately applied, so their impact has not been taken into account above (Fimea7/2024, p. 19).

The operating profit of a pharmacy is the pharmacy's operating profit before interest, financial transfers and taxes. The operating profit of the pharmacies also includes the pharmacist's salary, business risk and return on equity. The average operating profit before transfers and taxes of the private pharmacies assessed in the financial statements analysis of Fimea (n=534 excluding transfers of ownership) in 2023 was around EUR 226500 and median EUR 207600. In 2023, the operating profit or operating loss fluctuated between around EUR -380 000 and around 1.6 million. Compared to 2022, the average operating profit per pharmacy of private pharmacies decreased by around EUR 38500 (ca. 14.4 %). Business profits have been weakened, among other things, by the 2023 medicine tax cuts and the general increase in costs. There is no generally accepted definition of the amount of the salary adjustment for pharmacists. It may vary between EUR 64000 and EUR 94 000. If the salary adjustment of the pharmacist described above is included in the calculation, the average salary adjusted operating profit after tax would fluctuate between approximately EUR 99000 and EUR 81 000 (Fimea 1/2025, pp. 29-32).

An analysis of the pharmacies' accounts has estimated that the pharmacy's business is positive if the pharmacy's output covers the operating costs and the pharmacist's salary. In 2 023.96 % of the estimated pharmacies (n= 534) were pharmacies with an operating profit before balance sheet transfers and taxes and a pharmacist's salary adjustment higher than 0. 19 of the pharmacies (approximately 3.6 % of the pharmacies) were loss-making, i.e. their result was negative and was not sufficient to cover the operating costs. 13 % (72) of the pharmacies had an operating profit of less than EUR 100000. Almost half of private pharmacies (47 %) had a EBIT before transfers and taxes of less than EUR 200000 in 2023 (n=253, Fimea 1/2025, pp. 32-34).

The business of pharmacies also includes the sale of free-trade products, i.e. cosmetics and other non-pharmaceutical products, which are partly used to support the success of pharmaceutical treatments. No information is available on sales of free-trade products from pharmacies. However, non-pharmaceutical products accounted for around 14 % of the total pharmacy market in 2021 (note also sales of limited liability companies). Non-pharmaceutical products accounted for a higher share of profits, since free-trade products can have a significantly high operating profit. According to a study by the Competition and Consumer Authority (2020), the profits of a limited liability company can account for up to one third of the total profits of the sector. More than half of the combined sales of non-pharmaceutical products by pharmacies and limited liability companies are sold through limited liability companies (STM 2023: 6 p. 97 and Fimea 2022b).

In assessing the overall profitability of pharmacies, account should also be taken of limited liability companies attached to pharmacies, known as 'special purpose vehicles', through which the pharmacy can sell free-trade products and carry on other business activities. The potential turnover of a pharmacy is reduced if the pharmacy transfers the sale of free-trade products to a limited liability company attached to it. Moreover, transactions between a pharmacy and its limited liability company, such as the renting of premises and staff, may affect the pharmacy's profitability. These factors make it difficult to assess the pharmacy's profitability and to make it more comparable between pharmacies. In 2023, around 38 % of all private pharmacies had transferred the sale of non-pharmaceuticals to a limited liability company attached to the pharmacy. In the case of those pharmacies, it is assumed that the pharmacy's result would be almost exclusively the sale of medicinal products. In 2023, a total of around 240 limited companies operated in almost 270 pharmacies (some companies are divided between pharmacies). The average turnover of these limited liability companies in

2023 was EUR 946000 and the average operating profit before transfers and taxes was EUR 255000 (Fimea 1/2025, pp. 37, 39-40).

It should be noted in the impact assessment that pharmacies have recently undergone a number of changes. The last cut in the price of prescription medicines was introduced with changes that came into force since the beginning of 2023, the VAT rate on pharmaceuticals has increased, wholesale prices of medicines were cut since March 2025, and pharmacies have started to exchange biopharmaceuticals. Several assumptions have been used to assess the overall impact of the changes. The calculation has estimated that the pharmaceutical market would not decline (the value of sales of medicines is not decreasing) despite a number of measures to reduce pharmaceutical prices, as the population is ageing and, despite the expiry of patents for some categories of medicinal products, the number of users of expensive and patented medicines is projected to increase accordingly.

Based on Fimea's 2023 annual accounts analysis, it can be observed that more pharmacies appear to be in a notionally challenging economic viability situation. However, these pharmacies in a challenging situation vary from year to year. The change of pharmacist and the investments made are also reflected in the profitability figures of pharmacies. Since the entry into force of the previous amendments since the beginning of 2023, the proposed amendments can only be assessed with 1 year (2023) wholesale and pharmacy data. When the evaluation is limited to one year, there is significant uncertainty in the assessment of impacts. The further preparation of the presentation and the draft HE to be submitted to Parliament aim to extend the evaluation to the 2024 figures, once Fimea has been analysed.

Amount of taxa surgery proposed for prescription-only medicines

The average rate cut per pharmacy with the proposed change of prescription medicines would be EUR -48 800 on average sales data for 2021-2023. The median pruning would amount to almost EUR -39 800, the minimum cut to EUR -6.900 and the maximum amount to -EUR 2.65 million. The average cut per pharmacy with the average 2023 data would be slightly higher at -EUR 50 800. The median pruning would amount to EUR -41 600 per pharmacy, a minimum of EUR 6900 and a maximum of EUR -267 million. The evaluation includes both private pharmacies and university pharmacies.

If the rate of taxi surgery of prescription medicines were estimated only in private pharmacies, average sales data for 2021-2023 would result in an average per pharmacy taxi surgery of EUR -44 600 and a median cut of around EUR -39 700. The maxima would then be around EUR -169 800 and the minimum cut would be EUR 6900. Based on the 2023 sales figures alone, the average cut would be -EUR 46 600 and the median cut would be EUR -41 500. The maximality based on 2023 figures would be EUR -172 200 and the minimum cut would be EUR 6900. In private pharmacies, taxi cuts would only be slightly higher than in 2023 compared to 2021-2023 figures. The effects of the proposed change in the taxa of prescription medicines are summarised in Table 4.

Table 4. The impact of the proposed tax change per pharmacy on average sales data for 2023 and 2021-2023. The table only takes into account taxiing of prescription-only medicines, not amendments to the pharmacy tax or to self-care medicines.

	2023	2021-2023
Number of pharmacies	641	628
Average cut EUR/all pharmacies	—50 800	—48 800
Average pruning, EUR/pharmacy,	—46 600	—44 600

University pharmacies removed		
Median pruning EUR/all pharmacies	—41 600	—39 800
Median surgery, EUR/pharmacy, university pharmacies removed	—41 500	—39 700
Minimum surgery EUR	—6900	—6900
Maximum level EUR	—2 670 000	—2 650 000
Maximisation EUR (University pharmacies removed)	—172 200	—169 800

Assessment of the proposed change in the rate of prescription medicines based on the location of the pharmacies;

The impact of the proposed change in prescription medicines on pharmacies can be assessed;

separately for urban, densely populated and rural municipalities, based on 2021-2023 and separately 2023 figures. The cuts resulting from the tax change proposed are the largest in pharmacies located in urban municipalities and the smallest in pharmacies located in rural municipalities. On the basis of 2023 figures, the impact of the tax cut is somewhat higher than when looking at the averages of the 2021-2023 figures. This is due to the amendment of the Medicinal Tariff Regulation, which entered into force in 2023.

In urban municipalities, the average cut for pharmacies (n=381), based on 2023 figures, would be EUR -61 300 and the median of the cuts would be EUR -49 700. Based on the average figures for 2021-2023, the average cut would be around EUR -58 800 and the median EUR -47 300. If the average cuts in urban municipalities only take into account private pharmacies, the average cut would amount to -EUR 54 200 based on 2023 figures and the median cut to EUR 49 300. The maxima would be EUR -172 200 and the minimum cut would be EUR 6900. Based on 2021-2023 figures, the average cut would be -EUR 51 700 and the median of the cuts would be EUR 47 000. The estimated pharmacy-specific cuts in urban municipalities are therefore smaller if only private pharmacies are taken into account. The largest difference is reflected in the size of the maximum cut based on 2023 sales figures.

Based on 2023 figures in densely populated municipalities, the average cut for pharmacies (n=110) would be EUR -47 800 and the median surgery -EUR 46 300. Based on the average figures for the period 2021-2023, the average cut would be EUR -45 900 and the median EUR -44 700.

Average cuts in pharmacies in rural municipalities (n=150), based on 2023 figures, would be around EUR -26 300 and the median of the cuts would be EUR -24 500. Based on the average figures for 2021-2023, the average cut would be around EUR -25 700 and the median cut would be EUR 23000.

Effects on pharmacies of the extension of the sales channel of a limited range of self-medication products

According to the proposal, some self-medication medicinal products within the limited range of self-medication products would also be allowed to be sold outside pharmacies. On the basis of the work of the Working Party on Self-therapy Medicinal Products, a so-called “limited range of self-medicines” was shaped as described above. Based on 2023 figures, the economic impact of the changes on pharmacy activities has been estimated as follows.

The wholesale value of the limited range of self-medicines proposed in the proposal would be around EUR 53.7 million, the value of retail sales excluding VAT would be around EUR 82.3 million and the value inclusive of VAT would be around EUR 90.6 million. The current turnover-based pharmacy tax model (7 % estimate of the pharmacy tax) would have an impact on the pharmacy tax of EUR -5.8 million. The range would account for 22 % of the value of the turnover of self-treatment medicines in pharmacies (16 % in pieces).

Assuming that 20 % of sales would be transferred outside pharmacies, the impact on the value of pharmacies' wholesale and retail sales would be around EUR -10.7 million and EUR 16.5 million respectively. In practice, this would mean a loss of retail sales of around EUR -26 000 for value exclusive of VAT/private pharmacy (n=638). The preparation of the presentation also assessed the impact of moving from pharmacies to 50 % of sales of products from the restricted self-pharmaceutical range. However, it is considered unlikely that this option will be achieved, since a significant proportion of the sales of some products in the proposed range will be supplied from the pharmacy to the user, with the result that sales are expected to remain in the pharmacy.

However, the expansion of the sales of a limited range of self-pharmaceuticals beyond pharmacies is expected to improve the financial position of pharmacies. This is because the proposed regulation would allow pharmacies to deduct the value of sales of medicinal products from the pharmacy tax base from the pharmacy tax base, irrespective of whether they would be sold inside or outside the pharmacy. This would bring benefits to almost all pharmacies, with the exception of pharmacies whose profit margin on sales of medicinal products remains at the lowest tier of the pharmacy tax and which do not pay the pharmacy tax. Moreover, it is possible that only some of the products in the range would, at the request of the marketing authorisation holder, be sold outside pharmacies. In addition, the majority of sales of these products are likely to remain in the pharmacy after the change, in particular self-treatment medicines, which are dispensed with a prescription. This estimate is based on the purchasing behaviour of users of the medicine in other Nordic countries, where the vast majority of self-medicines are sold from pharmacies, although self-care medicines can also be purchased elsewhere. However, the proposed change could also have a change in the behaviour of the user of the medicinal product, which it has not been possible to assess in advance.
For example, the pharmacy's customer flows may change, which could affect the pharmacy's finances.

Cumulative effects of the proposals on pharmacies

The proposed change in the pharmaceutical tax rate for prescription-only medicines and the extension of the sales of a limited range of self-medicines outside pharmacies are estimated to have an impact on the overall pharmacy's economy of -EUR 6000 per pharmacy on average. The median impact is estimated at -EUR 48 600 per pharmacy.

The package of changes affecting the pharmacies' finances also includes a proposal for an amendment to the pharmacy tax, the effect of which is estimated to have an average net impact of EUR -34 800 per pharmacy and a median impact of EUR -19 800 per pharmacy.

In addition, the expansion of the sales channel for self-medication medicinal products could have a dynamic effect as customer flows change, which could also have an impact on the structure and profitability of non-pharmaceutical sales of a pharmacy. However, the effects can be estimated to be relatively small, as pharmacies would continue to maintain a significantly wider range of self-care medicines, compared to holders of retail licences for self-care medicinal products, who could only sell self-medicines from a limited range of self-care products that would have been granted an extension of the sales channel. The potential impact of changes in customer flows on the pharmacy economy has not been estimated in euro. The

notional profit of pharmacies, after all the changes proposed in the government proposal, is shown in Table 5. The reference year for the calculation is 2023 and all pharmacies (n=640) have been included in the comparison. The comparison also takes into account the activities of pharmacies in limited liability companies, but not the remuneration paid to him by the pharmacist.

Table 5. The pharmacy's notional profit after all proposed operations. Reference year 2023 Includes all pharmacies (n=640). Limited liability company activities taken into account.

	Post-Actions teekki	**pharmacy & Company**	**Pharmacy victory 2023**	**Pharmacy & Company Profit 2023**
min	—959 798	—959 798	—681 981	—681 981
median	185 222	242 464	209 361	260 990
Average	205 061	307 997	240 226	343 323
Max	1 581 083	2 169 979	2 903 092	2 903 092
sum	131 238 871	197 118 164	153 504 403	219 383 696

Following the proposed changes to the notional profit of the pharmacy, it is estimated that a slightly smaller decrease will occur in Table 5, which shows the impact of all the proposed changes on the notional profit of pharmacies, compared to Table 6, which includes the proposed changes to the pharmaceutical tax rate for prescription-only medicines and the pharmacy tax without the effects of self-medicines. Table 6 therefore does not include the removal of the limited range of self-medicines from the pharmacy tax base. The consideration of limited liability companies attached to pharmacies in the assessment seems to increase, in particular, the profitability of larger pharmacies.

Table 6. The pharmacy's notional profit after the proposed actions in the pharmaceutical tax rate and the pharmacy ordinance for prescription-only medicinal products, with the exception of the proposed changes to self-medication products. Reference year 2023 Includes all pharmacies (n=640). Limited liability company activities taken into account.

	Post-Actions tea pharmacy & Company		**Pharmacy victory 2023**	**Pharmacy & Company Profit 2023**
min	—1 155 809	—1 155 809	—681 981	—681 981
median	180 447	237 332	209 361	260 990
Average	196 378	299 314	240 226	343 323
max	1 571 442	2 134 852	2 903 092	2 903 092
sum	125 681 978	191 561 271	153 504 403	219 383 696

The assessment of the computational effects of the proposed changes suggests that there is a large dispersion between pharmacies, but the business loss based on sales of medicinal products does not appear to focus in particular on small pharmacies.

Prior to the proposed changes, the number of computed loss-making pharmacies on the Finnish market totalled 25 (Fimea 1/2025 pp. 32-34). With the proposed amendments, a simulation based on 2023 data estimates that a total of eight additional pharmacies would become notionally loss-making. As a whole, it is estimated that 111 pharmacies on the

pharmacy market would have a profit of less than EUR 100000. Taking into account the results of limited liability companies operating in the context of pharmacies, it is estimated that 76 outlets would remain on the pharmacy market with a notional operating profit of less than EUR 100000. Table 7 summarises the impact of the government proposal on the distribution of the pharmacies' imputed profitability.

Table 7. Breakdown of the notional profit of pharmacies after operations, estimated on the basis of 2023

	After amendment		Reference year 2023		Post-operation rate	Comparison 2023 share
	Pharmacy & pharmacy company		**Pharmacy & 2023 Company 2023**		**Pharmacy**	**Pharmacy 2023 section**
& 0	33	24	25	21	5 %	4 %
0-100 000	78	52	64	48	12 %	10 %
100000 – 200 000	237	185	210	161	37 %	33 %
200000-300 000	153	138	172	141	24 %	27 %
300000-400 000	81	86	77	92	13 %	12 %
400000-500 000	31	49	48	52	5 %	8 %
500000-600 000	17	36	22	34	2 %	3 %
≥ 600000	10	70	21	90	2 %	3 %
Total	640	640	639	639	100 %	100 %

With the proposed amendments, the profitability distribution of pharmacies will be shifted to smaller operating profit categories. Due to the limited number of comparable data available, the comparison has been made in the assessment until 2023. If a comparison were made with the previous notional profit level of pharmacies, the proposed changes would have a greater impact. The smallest pharmacies are unlikely to have a limited liability company to compensate for the reduction in profits from pharmaceutical sales. On the other hand, for some pharmacies, the influence of a limited liability company may be significant.

In particular, the impact assessment looked at the location of pharmacies below EUR 0 and EUR 100000 respectively per wellbeing services county and group of municipalities. New notionally loss-making pharmacies appear to be located mainly in urban municipalities. Pharmacies with a notional operating profit of less than EUR 100000 could also be located in densely populated or rural municipalities.

The proposed changes would result in eight new pharmacies not exceeding EUR 0 (if there were three new pharmacies below 0). Taking into account the 25 pharmacies which were already at a loss prior to the proposed changes, 33 pharmacies would not be calculated in total. Of these, the branch pharmacy would be the nine pharmacies and the sub-pharmacy would be subject to the condition of two pharmacies. New pharmacies accounting for less than EUR 0 would be located in different welfare areas, but seven of them would be located in Uusimaa.

Pharmacies which, after the proposed changes, would have a notional operating profit of less than EUR 100000 in Finland would have a total of 110 units. However, they would be divided into different welfare areas, with 30 pharmacies in Uusimaa. 33 of these pharmacies would have branch pharmacies, with a total of 19 sub-pharmacies. It is possible that branch

pharmacies, which are subject to a pharmacy licence, would be presented by the holder of the pharmacy licence as a result of the proposed amendments to be abolished. Some of the branch pharmacies have been part of a notional loss-making pharmacy even before the proposed changes.

Following the proposed changes, it is estimated that there is a significant difference in the imputed profit of the pharmacies between the various branches. These changes are summarised in Table 8.

Table 8. A summary of the estimated impact of the proposed changes on pharmacies.

Impact/pharmacy, EUR	**Knock-on effect: taxi and self-care**	**Tax impact progressive model**	**Net effect**
Average	—60 715	25 925	—34 790
Median	—48 608	23 948	—19 790
Number of pharmacies	**Knock-on effect: taxi and self-care**	**Tax impact progressive model**	**Net effect**
Improves by more than EUR 100 t	0	36	14
Improvement of 30-100 tEUR	0	235	31
Improve between EUR 0 and EUR 30 t	0	231	66
Decrease between EUR 0 and EUR 30 t	166	70	281
Decrease between EUR 30 and 100 t	414	61	189
Decrease between 100 and EUR 200 t	59	7	51
Decrease of 200-400 t	0	0	7
Decrease > 400 t	1	0	1
	640	640	640

The proposed changes are estimated to result in eight pharmacies for which the change would result in a disadvantage/loss of more than EUR 200000. Similarly, 14 pharmacies are estimated to benefit from the proposed changes more than EUR 100000. The proposed changes are estimated to be beneficial for the business of some operators for at least two reasons: If the structure of the pharmacy's sales is focused on expensive medicines, it would benefit from a mark-up tax and could improve the profitability of its pharmaceutical sales. In addition, pharmacies would benefit from the fact that self-medication products within the limited range of self-medication products would be removed from the pharmacy tax base. It is estimated that the majority of sales of these medicines would remain in the pharmacy after the change, which would overall improve the profitability of pharmacies' sales of self-care medicines. The impact of the proposed changes on pharmacies is summarised in Table 9.

Table 9. Summary of the pharmacy effects of the proposed changes

Change	**Impact on pharmacies**
Pharmacy margin	Net average – EUR 34 790 Net median – EUR 19 790
Imputed profit of pharmacies (Impact of joint stock company taken into account)	average EUR 205061 (EUR 307997) median EUR 185222

	(EUR 242464) min – EUR 959 798 (EUR 959 798) max EUR 1581083 (EUR 2169979)
Losers, pharmacies (> 200000)	8
Winners, pharmacies (> 100000)	14
Operating profit before balance sheet transfers and taxes & EUR 0 (Employment of a share company taken into account) (25 (21) pharmacies were already in & EUR 0)	25 + 8 pharmacies = 33 pharmacies (21 + 3 pharmacies = 24 pharmacies)
Operating profit before financial statements and taxes & 100 EUR 000 (Inclusion of the share company) (Also includes & EUR 0 pharmacies)	110 pharmacies (75 pharmacies)

It is proposed to grant pharmacies the right to derogate from the prescription and to correct them in certain situations. It is estimated that the legislative amendment will streamline the work of pharmacies by reducing contact with healthcare by telephone. The communication of information on deviations from prescriptions and their correction from a pharmacy to healthcare would require the development of information systems. This can be done in the context of the development phases of the national Kanta pharmacy list and, as a single functionality, would not entail significant costs for pharmacies. The obligation to record deviations from prescription in a pharmacy is not expected to have an impact on pharmacies' information systems, as the obligation would not change the current situation based on Fimea's guidance letter.

Adaptation measures for pharmacies

It would be likely that some pharmacies would adapt their business as a result of the proposed changes. The adjustment effort would depend on the conditions of the pharmacy. Examples of adjustments could include changes in product range or opening hours, increased choice of free-trade products, changes in paid services provided by a pharmacy, changes in the place of business of the pharmacy within the region in which the pharmacy is located, delays in investments or purchases of available IT technology, changes in staff advantages, redeployment of tasks and staff reductions. It is also assumed that, for reasons of income tax, a pharmacy could be interested in applying for a retail licence for self-medical medicinal products in order to sell self-care medicinal products in a limited range through a pharmacy special purpose vehicle. At most, a pharmacy adaptation measure could consist of the cessation of the activities of a pharmacy's establishment (service point, network service or branch pharmacy) or the disqualification of the pharmacist. It is not possible to assess in advance the magnitude of the adaptation measures or the effects per pharmacy.

Adaptation measures by pharmacies could also have an impact on the level of service provided by pharmacies. The risk would then be to reduce the level of service to such an extent that it would affect the safety of medicinal products or medication. On average, however, this should be considered unlikely in view of the relatively low number of new loss-making pharmacies and other pharmacies in the same area and less-impact adaptation measures.

For some pharmacies, the proposed changes might make it impossible to continue the business without business-oriented changes. The areas where the pharmacy is located, as defined in the pharmacy licence, are extensive, allowing the pharmacist to relocate the pharmacy within the area. In spite of this, it might be possible that a pharmacist would like to leave the market and close the pharmacy business as a result of the changes. Impact assessments at the level of

well-being districts and municipalities have estimated that small pharmacies could exit the market. However, these pharmacies would not be the only pharmacies in the area in which the population of the region is operating and working, i.e. the accessibility of the country's pharmacy services is not assessed as being compromised by the proposed amendments.

If a pharmacist renounces a pharmacist, this pharmacy licence would have to be re-applied if Fimea considered that there was still a need for pharmacy services in the area. If this were to prove that there were no applicants for the pharmacy, it would be for Fimea to assess whether there are business conditions for an independent pharmacy in the area in question. If those conditions were no longer considered to exist, the availability of medicinal products in the area could be secured by the establishment of a branch pharmacy, the operation of which would be made conditional on the operation of another main pharmacy. The pharmacy services of the population in the area can also be estimated to be secured by the services of the service points or, in part, by online and remote connections.

4.2.1.4. Economic impact on public social and health care

A change in the price of prescription-only medicines and changes in the prices of products in the limited range of self-medicines would only have an impact on the prices of medicinal products sold in out-patient care. They are not identified as having a direct economic impact on public social and health care. However, if, due to the proposed surgery of prescription medicines, the coverage, quality or ability of pharmacies to develop their services would be reduced, this could result in indirect costs for primary care. It is possible that on-call visits to healthcare would increase or, for example, the provision of a dosage service at social care customers in pharmacies would become more difficult. It is not possible to estimate the amount of indirect healthcare costs in advance.

In view of the low-risk nature of these products, the extension of the sales channel for products in the limited range of self-medicine products is not estimated to increase the cost of healthcare. However, it is possible that an extension of the sales channel in individual cases would lead to an increase in the number of on-call visits. On the other hand, given the increased accessibility of medicines, the proposed extension of the sales channel for self-medicines could also potentially reduce healthcare costs. The effects would depend on whether the citizen would be able to correctly identify and manage his symptoms with the right product and in the right way, without any pharmaceutical advice.

A 2022 study by Fimea has estimated that shortages of medicines cause additional work and costs, including for healthcare. According to the study, 22 % of shortages of medicines are those where a substitute would be available for the affected medicinal product, but a new prescription would be required to be issued by the prescriber. (Fimea 8/2022.). It is proposed to grant pharmacies the right to derogate from prescriptions in certain situations and to correct manifest errors in prescriptions. Proposals are expected to reduce contact with healthcare, e.g. in situations where a national shortage or incorrect prescription would require changes to the prescription. However, the effects are not expected to significantly change the current rate of repair of prescriptions. The reason for this is that derogations from prescriptions have been established as a general practice in pharmacies even before the entry into force of the regulation.

However, the proposed change would reduce the need for pharmacies to contact their prescriber, especially in the case of prescriptions that are obviously flawed. The change could also improve the means of information management than is currently the case, allowing for a smoother derogation for unavailability or out-of-pocket products, and would better inform other actors involved in the treatment of medicinal products.

4.2.1.5 Economic impact on grocery trades and other businesses

It is proposed to make it possible to sell a limited range of self-medication products, for example in grocery stores and also in other companies that do not act as wholesalers, pharmaceutical companies or brokers of medicines. Operators who could apply for authorisation to act as an outlet for the sale of self-care medicinal products would benefit financially from the presentation by generating revenue from a limited range of self-medication products. However, the extent of the economic benefit would be affected by the willingness of pharmaceutical companies to extend the sales channel of their products beyond pharmacies and the extent of the range of self-medical products that could be sold outside pharmacies.

The proposed change to the extension of the sales channel for self-medicines could lead to an increase in the current consumption of these medicines, which would benefit pharmaceutical companies financially. Processing an application for an extension of the sales channel of a self-treatment medicinal product or an application for a change would increase the administrative burden for pharmaceutical companies and, accordingly, an application for a retail licence for self-treatment medicinal products would increase the administrative burden on the trader seeking to become a retail licence holder. The level and costs of the administrative burden have not yet been assessed, as this would require more detailed information on the form of the application and any required annexes.

In its report, the Working Party on Self-medicines has estimated that, for a limited range of self-medicines, an extension of the sales channel would potentially increase the conditions for price competition between retail outlets and would open up and improve the functioning of the market by diverting demand for products to a wider range of operators than pharmacies. From the point of view of the functioning of the market, increasing customer choice can be seen as a positive impact. The intensity of competition would depend on the choice of pharmaceutical companies' applications, the willingness of non-pharmaceutical outlets to market products and the possibility for consumers to compare prices.

Private healthcare purchases medicines used in reception activities, such as vaccines, from out-patient pharmacies. The proposed change in the rate of prescription medicines would also reduce the prices of these medicines. Private healthcare would benefit from the change if it did not pass on the benefit to the final customer by changing the pricing of its own service.

4.2.2 How has the economic impact been assessed?

The economic impact of the proposed changes has been assessed in the computation group under the pharmacy reform study group and in cooperation between the Ministry of Social Affairs and Health, Fimea and Kela.

The impact on pharmaceutical reimbursement expenditure, the cost of reimbursable medicines and patient contributions is based on the microsimulation model of Kela's pharmaceutical reimbursement system. For the simulation, a sample of 20 % of reimbursed purchases of medicines has been taken. For the comparison of taxa models, the simulation was performed with data from 2022, 2023 and 2024. From one year to the next, the data were modified so that the data are aligned for comparison purposes in terms of the tax rate, the annual contribution and the cap. However, the model does not take into account the change in the value of money.

The economic impact of the changes on pharmacies was at the heart of Fimea's calculation. The calculation and modelling of taxa models of prescription-only medicines in Fimea, as well as the margin estimates for self-medicines, are mainly based on pharmacy-specific wholesale data. In the analysis of the wholesale pharmacy data, the results of the branch pharmacies have been aggregated at the level of the pharmacy company, using the Fimea pharmacy register of

the national code-catalogue service. Fimea did not have retail data on medicinal products. The data used for the calculation and modelling covered all Finnish pharmacy sales and wholesale sales per pharmacy at packaging level on an annual basis. Data on the wholesale distribution of medicinal products do not include so-called free-trade products sold by pharmacies. The wholesale sales per pharmacy used by Fimea in the alternative taxa developed by Fimea were received in response to a request for information from Fimea's wholesale register, which limited the extraction to wholesale sales targeting pharmacies and machine-dose distribution units between 2021 and 2024.

Modelling the effects of changes in the drug tariff based on wholesale price limits requires the use of a wholesale price per packet, which means treating the different strengths and pack sizes of the product separately. In practice, the packaging has been identified in the modelling using the VNR identifying medicinal products. The wholesale price per pack was calculated as an average over the whole calendar year by dividing the annual value of wholesale sales per packet by the corresponding number of packages. On the basis of the wholesale price per package, the retail price exclusive of VAT was determined by applying the pharmaceutical tax rate for prescription-only medicines or an alternative pharmaceutical tariff model (corresponding to all wholesale price categories, low-cost cutting and high-cost cutting).

Fimea assessed the impact of different tax models on the pharmacy economy by calculating, on the basis of wholesale data per pharmacy, the pharmacy-specific pharmacy-specific sales margin for prescription-only medicines at the current state level and correspondingly estimated. The difference between the former was calculated as the reduction in the margin per pharmacy as a result of the tax scheme under examination. In all the scenarios studied, the limits, coefficients and standard terms of the tariff bands based on the wholesale price of prescription medicines have been changed compared to the current prescribing rate, reducing the spread between the retail price and the wholesale price (purchase price), which remains the pharmacy's margin.

No changes to the drug tax rate for self-treatment medicines were planned. The margin for self-medical medicinal products was thus determined directly by means of the wholesale register as the difference between retail and wholesale, excluding veterinary medicinal products supplied without prescription. There were no retail values in the wholesale register for veterinary medicinal products, where the retail value was assumed to be 1,5 times the value of the wholesale sales. The value of retail sales in the Wholesale Register is based on the maximum price set by the self-treatment tariff, thus excluding any discounts granted by pharmacies. According to the results of Fimea's economic survey, the importance of these discounts has been relatively limited so far. Based on pharmacy-specific wholesale data, the economic impact of the extension of the sales channel for self-treatment medicines was also assessed.

As the wholesale data already realised are historical data, the built-in assumption of the results is that there will be no material change in the structure of pharmaceutical sales of pharmacies in the short term. In other words, the calculations based on wholesale data reflect what the pharmacy's margin would have been in the 2021-2024 sales structure, but assuming a new pharmaceutical tariff model and the shift of a certain part of the range of self-medicines to sales outside the pharmacy. However, in the case of an individual pharmacy, the wholesale structure may vary significantly from one year to the next, in which case the result of the simulation may be unrepresentative when it is based on sales in a given year.

The notional pharmaceutical mark-up was used to determine the tax base of the new pharmacy tax based on the margin on pharmaceutical sales. In addition to the prescribing tax margin, the sales margin for pharmacies accrues from fees for the delivery of prescription-only medicines, as well as from self-medicines. The margin on sales of non-pharmaceutical products was not

included in the taxable amount for the margin on pharmaceutical sales, but this margin was taken into account in subsequent profitability analyses. Estimating the margin of sales of medicinal products through pharmacy-specific wholesales makes it possible to take into account the new prescription model. Similarly, it was possible to take into account a limited range of self-medicines in relation to the pharmacist. The margin for nicotine-reimbursement products was not included in the pharmacy's sales margin because nicotine products would be removed from the pharmacy tax, as in the current pharmacy tax law.

Fimea has asked Kela to provide pharmacy-specific information on the supply of medicinal products to complete the data base for wholesale sales. The number of deliveries made it possible to estimate the amount of the fees per pharmacy. There would be no changes to the interchange fees here, so the proposal does not have an actual impact to be assessed. However, the fees are taken into account for the purposes of determining the pharmacy tax.

The margin on sales of medicinal products was determined as the sum of prescription and self-care margin and delivery fees and amounted to a total of around EUR 790 million for all pharmacies, based on the 2023 sales structure. This constitutes the tax base of the new pharmacy tax, which is less than one third of the current turnover-based pharmacy tax base. Following the determination of the tax base, alternative tax scales aimed at a total tax revenue of EUR 200 million were created. The tax models examined were a flat rate tax and a progressive tax scale. In both models, the tax was collected for a margin exceeding EUR 250000. By applying the taxable amount to the estimates per pharmacy determined on the basis of wholesale sales and supply data, an estimate per pharmacy of the new amount of pharmacy tax was obtained. This was further used in the profitability analyses.

In practice, the pharmacy tax will be determined per taxable person, but estimates have been calculated on the basis of the data base used at pharmacy level. In the calculation per pharmacy, the data of the main and branch pharmacies are aggregated into a single total tax base to which the tax scales apply. The calculation by taxable person and by pharmacy differs in cases of change of ownership. In that case, the overall margin on sales of medicinal products, which constitutes the taxable amount, is also allocated to pharmacies in a slightly different way from that allocated to different taxable persons. The number of persons liable to pay the pharmacy tax is slightly higher than that of pharmacies due to the fact that pharmacies are outgoing in the course of the year and start new ones. A larger number of pharmacists' pharmacies means that the tax base is distributed among more taxpayers and that there are probably more taxable persons below the tax-free threshold than pharmacies below the tax-free threshold. In this case, the tax revenue should be slightly lower than the estimate calculated per pharmacy.

Moreover, the taxable amount calculated from the wholesale data does not take into account the right of pharmacies to deduct any part of the taxable amount from sales of establishments. On the assumption that medicinal products purchased from hatchies are sold to the establishments, the taxable amount does not arise in so far as the right to deduct can be exercised. However, in the calculations, the accrual of the tax base is calculated for the whole wholesale of pharmacies. This is relevant if the proportion of sales of establishments is significant. This is typically not the case.

The analysis of the profitability of pharmacies used the financial data of the pharmacies collected by Fimea for both the pharmacy name and the pharmacy name and the associated joint stock company. The profitability indicator reported for 2023 was based on the profit/loss before financial transfers and taxes adjusted with estimated mark-up and tax effects. The profitability figure for 2023 reflects the situation following the change in the tax and pharmacy tax that entered into force since the beginning of the previous year 2023. However, one year's profitability per pharmacy may vary due to occasional short-term factors. It would therefore be

useful to look at profitability over several years. However, data for 2024 were not yet available.

The 2023 profitability ratio was adjusted to reflect the post-change situation. The change in the prescription rate was taken into account by subtracting from the profitability indicator the decrease in the prescription rate calculated in the test simulations as described above. In the case of self-treatment medicinal products, the basic assumption was that 20 % of sales of a limited range would be taken away from pharmacies and that pharmacies would also lose the margin in this respect. A further limited range of self-pharmaceuticals was presumed to be exempt from the pharmacy tax. In other words, it is not included in the taxable amount for pharmacy tax, even in so far as it is assumed that the sale will continue to be made through pharmacies.

The effect of the former turnover-based pharmacy tax on the index was removed and replaced by a new estimate per pharmacy of the tax based on the margin for pharmaceutical products. The receptacle is reduced in all cases because the coefficients forming the taxa have been reduced throughout. By contrast, the net effect of the current and the new margin-based pharmacy tax may be either positive or negative per pharmacy. As the targeted tax revenue was EUR 200 million and slightly lower than the actual 2023 accrual, the net impact of the tax change on pharmacies is mostly positive.

According to information from the working group, cost inflation has continued in 2024 and several changes in the pharmaceutical market have taken place or are taking place, the effect of which is not yet reflected in the profitability figures for 2023. A separate assessment of the growth rate of pharmaceutical sales was carried out as part of the preparatory work. As things stand, several factors have been identified which have a downward impact on the growth rate. Several legislative changes have been introduced to curb the increase in pharmaceutical costs, which are described in more detail in the description of the current state of play (for a more detailed assessment see Section 2.2 above). The result of this assessment is that with a number of parallel changes, the pharmaceutical market will not grow at the pace of previous years in the coming years. At the same time, the impact of these factors is not estimated to be large enough to reduce the size of the pharmaceutical market in the coming years.

The challenge of the economic impact assessment is compounded by the need to assess at the same time the effects of the proposed change in the drug tax rate, the extension of the sales channel for self-medicine medicinal products and the change in the pharmacy tax. The evaluation is characterised by a high degree of uncertainty, some of which are already listed above. It is possible that sales of medicinal products will not develop as expected in the coming years and the structure of sales in the future would be fundamentally different from the years when the material on which the assessment was based has been generated.

It is possible that the intended changes will have dynamic or behavioural effects. In this case, wholesale prices and the pharmaceutical industry, pharmacists or other providers of self-care products offering the supply may start operating in an unpredictable and unpredictable manner as a result of the changes. If the margin of sales of medicinal products, assessed as the basis for the pharmacy tax, were materially different, the tax revenue for the State would also differ from the estimated EUR 200 million. The reasons for the differences could be, for example, inaccuracies in the census or the difference in the statutory margin used in the calculation.

Furthermore, the profitability estimates do not take into account the adaptation measures taken by pharmacies, such as cost reductions, changes in opening hours, changes in staff numbers or stocks. If the impact estimates are based on profitability and wholesale figures for one year, it is possible that the figures examined include annual variations per pharmacy. In such cases, the result per pharmacy is not a representative description of the profitability of the pharmacy in question.

4.2.3 Impacts on people and society

The proposed changes are not assessed as having a negative impact on the availability of medicines. However, it is conceivable that some pharmacists would take adaptation measures which could also affect the availability of medicines for the population in the region. It is estimated that adaptation measures could most likely arise in urban municipalities with several pharmacies. For this reason, it is estimated that the country's comprehensive pharmacy services will remain at an adequate level after the proposed changes.

The sale of prescription-only medicines is at the heart of the pharmacy's business. Cutting the margins of prescription medicines at the same time encourages pharmacies to develop other areas of the pharmacy business, such as cooperation with wellbeing services counties and pharmacy health services. The change could also lead to increased sales of free-trade products in pharmacies. Such a trend would not be appropriate for the user, healthcare and rational treatment of medicinal products. In the context of the proposed cut of prescription medicines and changes in the pharmacy tax, the proposed cut in university pharmacies would also have an indirect impact on the revenue from sales to universities from university pharmacies. The proposed amendment would therefore also have an impact on the funding received by pharmacies owned by the University of Helsinki and the University of Eastern Finland.

Changes in the margin and retail price of prescription medicines could also indirectly affect the functioning of the pharmaceutical market more broadly, for example the wholesale pricing of medicines by pharmaceutical companies (Etla, 31 December 2024). The impact of such changes has not been assessed in advance.

According to reports from the Finnish Association of Pharmacists, the supply of pharmacies is at a good level. The security of supply of private pharmacies in 2021 was between 97 % and 99 % (Association of pharmacy of Finland 2020, Association of pharmacy of Finland 2021). This is partly due to the fact that pharmacies have a comprehensive stock of medicines and interchangeable medicinal products. However, challenges have also been identified in the implementation of pharmacy services and there are country-wide variations in the accessibility of medicines, for example due to the opening hours of pharmacies. Especially at weekends, opening hours are narrower than weekends. The opening hours of branch pharmacies have been found to be shorter than for stand-alone pharmacies (STM 2023:6, pp. 27-29).

It is estimated that consumers will benefit from an extension of the sales channel for a limited range of self-medicines due to the improved accessibility of these medicines. Day-to-day food chains have extensive nationwide networks and have long opening hours. The effect would, however, depend on whether marketing authorisation holders for self-treatment medicinal products would apply for an extension of the sales channel for their product and whether traders would become licensees for the retail sale of self-treatment medicinal products. The impact would also vary between regions and between different groups of people. The increase in accessibility would be greatest where the nearest pharmacy would otherwise have travelled and for groups of people with few pharmacies in their area.

In its note, the Working Party on Self-medicines has estimated that the effects of the extension of the sales channel of a limited range of self-medicines on the accessibility of self-medicines are likely to differ in urban and peripheral areas. For example, in areas where the pharmacy network is more frequent, the impact could be lower than in areas where pharmacy conditions are less extensive, but where other sales channels operate and can therefore contribute to supporting the accessibility of products sold outside pharmacies.

An extension of the sales channel for a limited range of self-pharmaceuticals could also have a negative impact on the availability of medicinal products in the range, as the proposed change would involve not only pharmacies but also a completely new group of operators, which could

include up to a few thousand retail licence holders. This would imply a possible increase in the demand for off-pharmaceuticals for self-treatment by licence holders who would order self-medication from a wholesale or a pharmaceutical factory. An increase in demand at the retail level could mean, at least during the initial period of entry into force or application of the Act, a reduction in the security of supply of pharmacies for the medicinal products in the range before the change in retail demand would become a new practice. The effect would depend on what products would be covered by off-pharmacy sales and how many traders would apply for authorisation to retail self-care medicines.

The Working Party on Self-medicines has estimated that a change in the sales channel of a limited range of self-medicines could also have an impact on the treatment and safety of medicines. In situations where easier access to products authorised for sale in sales channels outside pharmacies would facilitate the timely and appropriate use of medical treatment, an extension of the sales channel could improve the health of the population and reduce the need for healthcare services. On the other hand, wider accessibility could lead to an increase in unnecessary sourcing, thus increasing the misuse of medicines, adverse synergistic effects or delays in the start of the necessary other treatment. In practice, it is not possible to distinguish between the quantities of sales that can be observed and the extent to which the medicinal product would end up for actual use. Thus, the impact of the reform should be monitored not only in terms of sales volumes, but also in terms of the impact on the health of the population.

4.2.3.1 Government effects

The models for calculating retail prices of prescription-only medicines under the proposed prescription tax rate should be updated to the systems operated by operators and public authorities. In addition, a limited number of requests for advice could be received by public authorities when introducing a new rate for prescription-only medicines. In addition, the authorities will have to monitor the implementation of the proposed changes, which is likely to result in some resources, but would be part of the current work of the authorities. It is not possible to monitor the price developments that may result from the expansion of sales of self-treatment medicines and this change in routinely compiled pharmaceutical statistics. The follow-up to this change would require planning and carrying out a study separately.

With the proposed amendments, it is possible that the holder of a pharmacy licence for some pharmacies would apply for authorisation from Fimea to relinquish the operating of an obligated branch pharmacy or decide to dispose of the pharmacist altogether. These changes to the network of services require the resources of the public authorities in order to take a decision on, for example, the closure of a branch pharmacy, the transformation of the main pharmacy into a branch pharmacy or the complete discontinuation of pharmacy services without undue delay and financial burden on the holder of the pharmacy licence. The holder of a pharmacy licence is obliged to continue the business until the new licensee takes over the business or Fimean has decided to terminate the licence and related services.

In its study, Fimea has estimated that, if the legislation allowing for an extension of the sales channel of a limited range of self-medicines were to introduce as transparent as possible suitability criteria for operators, the resources needed to process marketing authorisation applications and applications for variations resulting from the extension of the sales channel would increase the initial amount of around 1-2 person-years. It is estimated that the ex-ante control of holders of retail licences for self-treatment medicinal products will result in a significant amount of regulatory work, new regulatory orders and the development and induction of internal operational and work instructions at the start of the activity. In addition, advice and guidance should be resourced. According to Fimea’s estimates, the amount of control resources needed is estimated to increase up to five times from the current six experts.

The dispensation of non-prescription medicinal products or the correction of obvious errors in prescriptions in the pharmacy should not have a significant impact on the implementation of reimbursements.

4.2.3.2. Employment effects

According to a labour barometer run by the Centre for the Development and Administration of Centres for Economic Development and Economic Development (KEHA), in early 2025 there is a shortage of pharmacists working in pharmacies in Kainuu Province. On the other hand, there is an oversupply of pharmacists in Uusimaa and Åland. There was an oversupply of pharmacists in the first half of 2025 in North Savo and North Ostrobothnia. Labour mismatches are found in the provinces of South-East Finland and South Savo. According to the Labour Barometer, 154 pharmacists and 50 pharmacists were unemployed at the beginning of 2025. Pharmacies include pharmaceutical technicians and other technicians, whose employment and unemployment situation is not up-to-date since the beginning of 2025;

The proposed changes can be considered likely to have a detrimental effect on the employment of the pharmacy's staff, as pharmacies could adapt their business through lay-offs or dismissals. The impact of such measures on the level of service and advice of pharmacies would depend on the pharmacy's staff structure and on the need to reduce the pharmacy's workforce. It is also possible that the urgency affecting the working conditions of staff could increase, making it more difficult to provide medical advice. A reduction in the number of staff could also affect the attractiveness of pharmacy work.

4.2.3.3 Impacts on municipalities and welfare areas

The proposed changes could have an impact on municipalities and wellbeing services counties. With the proposed amendments, it is possible that the holder of a pharmacy licence for some pharmacies would apply for authorisation from Fimea to relinquish the operating of an obligated branch pharmacy or decide to dispose of the pharmacist altogether. Under Article 41(4) of the Law on Medicinal Products, those changes to the network of services would require the Centre for Safety and Development of Medicinal Products to consult the municipality concerned before taking decisions relating to the network.

During the preparation, the wellbeing services counties have been informed about the potential impact on pharmacy services in their territories. In addition, the expectations of welfare counties and plans for cooperation with pharmacies have been explored. The proposed changes could have an impact on the ability and capacity of pharmacies to develop cooperation with wellbeing services services, for example on services that contribute to the safety, effectiveness and appropriateness of medical treatments for older people and people with multiple illnesses. On the other hand, it has been recognised during the preparatory work that, at this stage, the welfare areas have not yet developed a holistic view of the need to develop pharmacies and the pharmaceutical services provided there. However, cooperation with pharmacies has started in all welfare areas.

4.2.3.4 Environmental impact

An extension of the sales channel for the products included in the proposed limited self-pharmaceutical range could potentially have an impact on the environment if the proposed change would lead to an increase in the use or loss of medicines. Metabolites of pharmaceuticals resulting from the use of medicines, which cannot be purified by sewage treatment techniques, are the main contributors to the environmental impact of medicines in Finland (pharmaceuticals and the environment). L Hanski, etc. Holda Open books. DOI: 10.31885/9789528401261).

In its note, the Working Party on Self-medicines considered that the amount of drug losses could change depending on whether the wider accessibility of some self-medicines would increase or reduce the number of medicines stored in the home of users. On the basis of the medicines returned by the pharmacies of the users of the medicinal product, it has been estimated that the total cost of drug losses in Finland would amount to approximately EUR 81 million per year. Around 30-40 % of the losses are generated by self-medicines (SMPG report with reference to Louhisalmi et al., 2024; Salimäki & Kujala, 2016). In addition, the extension of the sales channel for products in the limited range of self-pharmaceuticals is likely to result in annual losses of medicinal products remaining in the stock of self-medicine holders. In view of the expansion of retail outlets for self-treatment medicinal products, it is possible that the number of unused self-medication medicines remaining in the shops' stock would increase, at least immediately after the entry into force of the Act, before sales outlets have gained experience of the volume of demand for self-medication products.

5 Other options for implementation

Options and their impact

5.1.1. Modification of prescription medicines

Three alternative models of prescription medicines were assessed during the preparation of the presentation and the accompanying amendment to the Medicinal Tariff Regulation. In addition to the flat-rate model proposed in this presentation, a low-priced drug tax rate model was assessed, which would reduce the pharmacy mark-up coefficients in the first two tax bands for the cheapest medicines. Based on Kela's 2023 reimbursement data for cheap medicines, the cost of medicines would have been permanently reduced by EUR 39.6 million per year and health costs by EUR 26.6 million per year. Patient ownership would have decreased by around EUR 12.1 million per year. In the low-prescription taxa model, average and median cuts affecting the pharmacy's economy would have been higher than other alternative tax models in all types of regions. The average cut in all pharmacies would be -EUR 54 200, based on 2023 figures. The minimum cuts in all pharmacies, based on 2023 figures, would also have a peak of -EUR 8700.

Thirdly, an assessment was made of the model of high-priced medicines, which would reduce the margins of pharmacies in the bands between EUR 7.50 and EUR 39.99 and over EUR 1500. Based on Kela's 2023 reimbursement data for expensive medicines, a tax model would have reduced pharmaceutical costs by EUR 36.0 million and health insurance reimbursements by EUR 31.5 million. This tax model would have reduced patient ownership by EUR 4.2 million. In a taxa model that cuts expensive prescription medicines, average and median cuts affecting the pharmacy's economy would be at the same level as the proposed flat rate for all wholesale price categories. The territorial impact of these models is also almost the same. In a taxa model that cuts expensive prescription medicines, the average surgery in all pharmacies would be -EUR 50 900 and the median surgery would be -EUR 40 900.

If the assessment of taxa models were to focus solely on which tax models would lead to the highest reduction in pharmaceutical costs, the low-cost model would have to be chosen, as it would reduce both the cost of medicines in general and the cost of medicines paid by patients far more than other tax models. However, in cheap medicines, the pharmacy's margin is already small in euros and its surgery could undermine pharmacies' incentives or the possibility of stockpiling a number of cheap alternatives, which could affect the availability of the cheapest medicines. For the above reasons, the model of cutting from cheap medicines was not feasible.

Based on an estimate for 2023, all tax models were calibrated to achieve the targeted fiscal and health insurance savings of around EUR 30 million. Based on 2023 figures for a flat-cut

pharmaceutical tax model, the savings would be EUR 29.6 million and the cost-cutting model would be around EUR 31.5 million. Only patients using expensive medicines would have benefitted a taxi model that cut expensive medicines. A flat-rate cut-off model for all tax categories would benefit all users of medicines, thus clearly spreading the benefit to more. The benefits for users of medicines in euro would also be higher in a flat-cutting tax model (EUR 5.9 million > EUR 4.2 million). On the basis of the above-mentioned arguments, the preparation led to a uniform choice of a taxi model for all medicinal products. The model was in line with the objective of budgetary savings, all patients would benefit from the model and the incentives for pharmacies to keep stock of the stock of medicines required by the normal customer base would not be weakened.

Proposed amendments to pharmacy taxation

It is proposed that the pharmacy tax be constructed on the basis of the profit margin term used in the tax system to be based on the margin on sales of medicinal products. As an alternative to that taxable amount, the pharmaceutical road map proposed to base the pharmacy tax on the operating profit of the pharmacy. The good side of profit-based taxation compared to the current turnover-based taxation would be that the model would take better account of the costs and investments of the pharmacy and would also be fairer. However, this option would require an assessment of whether there would be a risk of optimising the operating profit. Monitoring of taxation would be more difficult and there would be a break in the comparability of data over several years. It would also be much more difficult to make deductions than the turnover-based model (STM 2019:5, Fimea 1/2021 p. 41).

Pharmacy taxation based on operating profits was not examined during the preparation of the presentation. The option was abandoned because the taxable amount would be lower and therefore the tax rates would have to be higher than in the pharmacy tax model based on the margin. In addition, in the pharmacy tax model based on profits, there would be more items deducted from the taxable amount than under the margin-based tax model. The taxable person would be able to deduct from the taxable amount all business expenses and would have an incentive to increase costs in order to reduce the taxable share. The deduction items in the profit and loss account by type of expense are laid down in the Accounting Regulation (1336/1997). A profit-based tax would also be more vulnerable to market changes, as EBIT could fluctuate strongly from one year to the next and this would undermine the predictability of the State’s tax revenue from the pharmacy iver.

The preparation examined two models of pharmacy tax based on a margin, a progressive tax model and a flat-rate tax model. In both models, the so-called zero tax differential is EUR 250000 below which pharmacies would not pay the pharmacy tax. If the pharmacy’s margin was entirely below zero, it would not pay any pharmacy tax. For all pharmacies, the tax rate for all pharmacies would be 35.5 % of the margin over nollaporta under the flat-rate model. Impact assessments were produced for both tax models. The impact assessments are summarised in Table 10 below.

Table 10. A comparison of the progressive pharmacy tax model and the flat rate model based on 2023 data, taking into account all changes proposed in the government proposal.

Number of pharmacies (n=640)	**Progressive pharmacy tax**	**Flat-rate tax**
Negative tax impact	138	268
Positive tax impact	502	372
Average net effect, i.e. margin -34 790 and tax sum/pharmacy, EUR		—36 037
Notional profit average	195288 after actions/pharmacy,	203 813

EUR		
Imputed income & EUR 0 N= 33		**N= 40**
Number of prescriptions submitted on average (excluding University of Helsinki pharmacy)	150074	122 626
Average result of loss-making pharmacies proposed actions, EUR	—166 996 after the	—122 766
Imputed activity before loss making actions	20 proposed	20
Notionally new loss making	13	20
Number of branch pharmacies (conditions)	9 (2)	12 (4)
Limited Company	12	16

The comparison found that a progressive tax model would have positive tax effects on several pharmacies and less negative tax effects than the flat-rate model. However, under the flat-rate tax model, pharmacies would, on average, have a slightly higher notional profit after intervention than under the progressive tax model. Under the flat-rate model, the notional cut would be smaller for larger pharmacies, leaving them a bigger profit after the measures.

A progressive tax model would make it possible to reduce income disparities between pharmacies, unlike a flat-rate tax model. However, the disadvantage of a progressive model would be that, as sales grow, tax progression would also increase, which would discourage work, business or development. On the other hand, under the proposed amendments, the pharmacy tax would only target the taxable person's sales of medicinal products. Neither of the proposed tax models is expected to reduce incentives, e.g. for the development of pharmaceutical services aimed at improving the efficiency of services responsible for organising wellbeing services, e.g. by optimising pharmaceutical treatments and reducing avoidable drug harm.

It was decided to proceed with a progressive tax model. In comparison with the flat-rate model, the loss-making pharmacies are estimated to be slightly higher than in the progressive tax model and, moreover, these pharmacies are estimated to be smaller in size (based on the prescriptions supplied) than in the progressive tax model. As a result, it would probably be more difficult for these pharmacies to adapt their commercial activities than for larger pharmacies. In addition, the comparison found that loss-making pharmacies in the flat-rate model had more branch pharmacies (and contingent pharmacies) than in a progressive tax model. Under the flat-rate model, loss-making pharmacies would be located not only in urban municipalities, but also in densely populated and rural municipalities. In a progressive tax model, all loss-making pharmacies were located in urban municipalities. With the progressive tax model, any negative effects appear to be directed at larger pharmacies and pharmacies located in areas where other pharmacies also exist.

In practice, a progressive tax model would offset income differences between pharmacies more effectively than the flat-rate model. A flat-rate tax model could operate better in a more competitive market. . On the other hand, a highly regulated market, such as the current state of pharmacy, appears to be more justified as a progressive model.

5.1.3 A range of self-treatment products which would also be allowed to be sold outside pharmacies

It is proposed that the so-called "limited range of self-pharmaceuticals", which could also be sold outside pharmacies, should be based on category 2 of the Fimea study (with some exceptions) and on the list 1 defined by the self-medication team. Since only the

pharmaceutical substances included in the list of the 30 most commonly used pharmaceutical substances are included in List 1, the subsequent preparation of the presentation has considered the indications of the list 1: starvation, constipation, pancreatic enzyme substitution therapy, vitamin and mineral substitution treatment, treatment of small skin lesions and artificial penes, and assessed the possibilities of complementing the range with recommended medicines used for the same indication with a low level of risk. Substitution treatment of pancreatic enzymes has been removed as an inappropriate group of medicines and has been supplemented by mono-pharmaceuticals, including for vitamins, in addition to combination products.

The range of self-pharmaceuticals to be extended to sales outside pharmacies could also have been wider than proposed in the presentation. The options 2 and 3 defined by the Self-therapy Working Group included, among others, diarrhoea, allergy and self-treatment products for the treatment of pain. The inclusion of those categories of medicinal products would have improved the accessibility of those products and would have lowered the threshold for their use. However, there would have been a risk of increasing the risks associated with the use of those products, such as misuse, interaction with other products, or the protraction or obscuration of any serious symptoms.

For the medicinal substance loperamide used on diarrhoea in List 2, the report of the Self-Medicinal Products Working Party mentions the risks of incorrect long-term use, potential for abuse and overdose due to severe heart and central nervous system disorders. On the other hand, allergic medicines in List 2 would not pose such a high risk for patient safety, but a wide range of products authorised for self-treatment would make it difficult to choose an appropriate individual product independently. Allergic medicines also have adverse interactions with other medicines, and according to the treatment recommendations, priority products are local products, e.g. medicines that are administered to the eye and the nose.

Option 3 defined by the Working Party on Self-therapy Medicinal Products included medicinal substances commonly used for pain and fever. These products are included in the national classification of risk medicinal products. The classification includes medicinal products which do not necessarily lead to more hazardous situations than other medicinal products, but which, if used incorrectly, may lead to more serious consequences or more serious consequences than usual. A particular risk is that of multipharmaceuticals and older people, who are more vulnerable to serious adverse reactions to medicines. For medicines sold as self-treatment medicines, ibuprofen is at risk of gastrointestinal harm and, for paracetamol, the risk of life-threatening overdose. Taking into account the potentially serious harm of high-risk medicinal products to certain groups of customers, it is not proposed that the range of products be included in a limited range of self-pharmaceuticals.

The extension of the sales channel for certain self-medication medicinal products takes place in a context where the development of pharmacy and pharmaceutical services and, for example, quality standards for medical advice, are not determined at national level. In addition, information management solutions for drug advisory services have not yet been designed and defined as part of the long-term development of information management in pharmaceutical care. For this reason, it is not possible to authorise the sale outside pharmacies of medicinal products which, in order to be sold in a medico-safe manner, would require medical advice by a pharmacy (alternatives 2 and 3) or which include self-medication products on the national list of risky medicinal products (Choice 3).

It is also proposed to do so in parallel with taxiing of prescription-only medicines and changes to the pharmacy tax, which have an impact on the pharmacy’s finances. The estimated impact of Option 1 on the economy of pharmacies compared to the liberalisation of larger selections was also an important factor in the assessment.

It should also be noted that treatment practices and the criteria for classifying a medicinal product as a self-treatment medicinal product have changed. Some of the most commonly used self-medicines have been authorised as self-medication products at a time when the EU criteria currently in place were not applied, so not all self-medicines on the market have undergone a similar assessment. The criteria for self-treatment medicinal products have also changed in general, meaning that not all self-care medicines currently sold in pharmacies may meet current efficacy and safety proof requirements and are not treatments in line with up-to-date standard of practice. As a result, there are also self-treatment products on the market which, on the basis of today's knowledge, are no longer in line with the recommended treatment. These risk factors should be taken into account in the extension of the sales channel.

5.2. Legislation of foreign countries and other means used abroad

[To be completed after consultation]

6 Opinion feedback

[To be completed after consultation]

7 Detailed explanatory memorandum

Act amending the Medicines Act

ARTICLE 2. This section sets out the scope of application of the Medicines Act. According to paragraph 1, the Act covers medicinal products, their manufacture, importation, distribution, brokering and sale and other releases for consumption, pharmaceutical factories carrying out the abovementioned activities, wholesale medicine shops, brokers and pharmacies of medicinal products, laboratories carrying out pre-clinical safety studies of medicinal products, and the manufacture and distribution of medicinal products in hospitals and health centres. It is proposed to add to this article that the law should also cover the retail sale outside the pharmacy of certain self-medication and nicotine products. The proposal would be based on the legislative changes proposed in this proposal. It is also necessary to add a reference to the separate regulation of nicotine products which has not been included. Paragraphs 2 to 5 are not proposed to be amended.

ARTICLE 9. This section regulates the responsible manager and qualified person of the pharmaceutical plant. According to the provision in paragraph 2, the general manager may not at the same time be in the position of the general manager of another company which has obtained an industrial authorisation to manufacture medicinal products. In addition, the accountable manager may not be a responsible director in the wholesale distribution of medicinal products by another company, or a pharmacist, a hospital pharmacy or a pharmaceutical centre manager, a military pharmacy manager, a pharmacy manager or a branch pharmacy manager. It is proposed to add that the accountable manager should also not be the holder of a retail licence for self-treatment medicinal products, his manager or the person responsible for self-medication. It is not proposed to amend subsections 1, 3-4.

Article 23b. This section provides for data protection for large pre-clinical or clinical trials carried out by the marketing authorisation holder to remove the prescription of a medicinal product. The prescription condition referred to in the section, i.e. the condition that a medicinal product for human use may only be supplied on the basis of a prescription, is one of the conditions of the marketing authorisation. The Centre for Safety and Development of Medicinal Products is entitled to attach conditions to the marketing authorisation for a medicinal product in order to ensure the correct and safe use of the medicinal product on the basis of Section 21(2) of the Medicinal Products Act. The decision of the Centre for Safety and

Development of Medicinal Products on the classification of the supply of a medicinal product, i.e. whether the medicinal product may be sold or otherwise released for consumption as a prescription-only medicinal product or as a self-treatment medicinal product, is governed by Article 9 of the Medicinal Products Regulations.

It is proposed that the rules on the classification of the supply of a medicinal product be merged with the same article so that Article 9(1) and (2) of the Medicinal Products Decree would be moved into a new paragraph 1 and 2 of Article 23b of the Medicinal Products Act. A reference to the terms of the marketing authorisation for a medicinal product as set out in Section 21(2) of the Medicinal Products Act would be added to the proposed subsection 1. For the rest, the regulation would not be changed. The current provision in Section 23b on data protection would be moved unchanged into a new paragraph 3 of the article.

Article 23d. The proposed section would be new. It would define the categories of medicinal products included in a limited range of self-medication products. According to the proposed subsection 1, a limited range of self-medication products would consist of a number of categories of medicinal products which are assessed to present low risks and for which it is estimated that the treatment can be carried out safely without advice. A defined range of self-medication products would have two legal effects. The categories of medicinal products in the range would be subject to different price regulation from other self-medication products and would be exempt from the pharmacy. Secondly, for medicinal products in the range of medicinal products, an extension of the sales channel could be requested under the proposed Article 23e for sales outside pharmacies.

The limited range of self-pharmaceuticals would be based on the above-mentioned Option 1, as defined by the Self-medicine Working Group, which would have been subject to the changes described above in the further preparation of the proposal.

These categories of medicinal products are combined by the fact that the risks associated with them are generally assessed as low and that they can be treated safely without medical advice.

The assessment of the low-risk range is based on the fact that several products corresponding to the range of medicinal products are already sold as food supplements or medical devices outside pharmacies. In addition, medicinal products in the range have been assessed as low-risk in relation to their potential adverse effects and possible interactions with other medicines used at the same time.

The assessment of the safe use of a group of medicinal products without advice is partly related to the low-risk nature of the product. In addition, the consumer has been assessed as being able to use self-care medicinal products in the range for their purposes independently, without any significant risk of error as to the underlying cause of those symptoms and without a significant risk to the safety of medicinal products and medication due to the misuse or inappropriate use of medicinal products.

It is also proposed to provide in subsection 2 that the limited range of self-medicines referred to in subsection 2 be further defined by Government decree. The proposed article, together with the general conditions for a range, would constitute the basic provision for the proposed list of categories of medicinal products in Article 11 of the Medicinal Products Decree. The actual power to adopt regulations would be in the second paragraph of the proposed article. The range would be defined in the proposal to amend the Medicinal Products Regulation contained in this proposal by identifying the categories of medicinal products by ATC group. The ATC classification refers to the anatomic-therapeutic-chemical classification (ATC) groups *of*the World Health Organisation (World Health Organisation) system for the*classification of medicinal products for anatomical-therapeutic-chemical purposes*. Under the ATC classification system, the active substances of medicinal products are classified on the

basis of the indication and pharmacological and chemical properties. There are five levels of classification. The Medicinal Products Regulation would use the most accurate possible level of classification.

Article 23e. The proposed section would be new. It proposes that the classification of a medicinal product as a self-treatment product should, in principle, entitle the medicinal product to be sold only in a pharmacy. However, for medicinal products within the limited range of self-medication medicinal products, an extension of the sales channel could be requested for sales outside pharmacies in accordance with the section.

According to the proposed subsection 1, if, in accordance with Paragraph 23b(1) or (2), the Finnish Medicines Agency has attached to the marketing authorisation for a medicinal product a condition that the medicinal product may be sold or otherwise released for consumption without prescription (as a self-medicated medicinal product),the medicinal product may only be sold in a pharmacy. The reference to Paragraph 23b(1) would refer to a situation in which Fimea classified a medicinal product as a self-treatment medicinal product when marketing authorisation was granted. The reference to Paragraph 23b(2) would mean that a change in the supply classification of a medicinal product as a self-treatment product would be made by means of an application for variation of a marketing authorisation.

Under the proposed subsection 2, the marketing authorisation holder could apply to the Finnish Medicines Agency for an extension of the sales channel for his own-care medicinal product to sales outside pharmacies. Thus, self-care medicinal products would not automatically be sold outside pharmacies, but the decision to apply for an extension of the sales channel would, in principle, be at the discretion of the marketing authorisation holder. Fimea would have to grant an extension of the sales channel if the self-treatment medicinal product met the conditions laid down in the subsection. Under the conditions, the self-treatment product should fall within the categories of medicinal products referred to in Section 23d, which constitute a limited range of self-medication products, the risks associated with the self-medication product should be low and the medicinal product should be able to be treated safely without advice.

Under the first condition, a self-treatment medicinal product should fall within the categories of medicinal products referred to in Paragraph 23d which constitute a limited range of self-medication products. The medicinal product for which an extension of the sales channel is requested should belong to one of the ATC groups defined in the Government Decree issued under the Section, which would constitute a limited range of self-medication medicines.

The second condition is that the risks associated with the self-treatment product should be low. The level of risk has already been assessed for each category of medicinal product when determining the categories of medicinal products referred to in Article 23d. This assessment would ensure that the product for which an extension of the sales channel is requested would meet the low-risk criterion for its own category of medicinal product and would not contain any specific elements that would result in a higher level of risk than the ATC group. The level of risk of the medicinal product should be assessed, for example, in relation to the potential harm to the medicinal product and possible interactions with other medicines used at the same time.

The third condition is that treatment with a self-treatment product should be safe without advice. The assessment would have been carried out on a group-by-category basis when the self-treatment product was part of the self-treatment range limited in accordance with the first condition. In the case of a medicinal product, it should be assessed whether it would meet the condition relating to the low-risk nature of its category of medicinal product and the condition that the consumer should be able to use the product without a significant risk of error as to the underlying cause of its symptoms and without a significant risk to the safety of medicinal

products and medication due to misuse or inappropriate use of the medicinal product. It would be necessary to carry out the assessment on a medicinal product-by-product basis, as described in the subsection, since there may be differences between products belonging to the same category of medicinal products.

Paragraph 3 of the proposed article would provide that the provisions of paragraphs 1 and 2 above would not apply to the products referred to in Sections 22, 22a or 54a. The reference would refer to traditional herbal medicinal products and homeopathic products whose registration determines where they are sold. Nicotine products which, under Section 54a of the Medicinal Products Act, are also directly available for sale outside the pharmacy if they are not classified as medicinal products subject to medical prescription would also not be subject to the application procedure.

The subsection would also provide that self-care medicinal products which are supplied to the purchaser of the medicinal product as reimbursed in accordance with the Health Insurance Act (1224/2004) would only be sold in pharmacies. A limited range of self-pharmaceuticals could include products that would be eligible for reimbursement under the Health Insurance Act. Those products may be supplied to the user of the medicinal product either as self-treatment products without a prescription, so that the price of the medicinal product is paid in full by the user himself or by prescription, with the sickness insurance covering part of the price of the medicinal product. In the latter situation, these medicinal products should only be supplied from the pharmacy, as only pharmacies would have the capacity to supply prescription-only medicines. In so far as a self-medication medicinal product, which would have been granted an extension of the sales channel in accordance with paragraph 2, was supplied to the user of the medicinal product as a self-treatment medicinal product without reimbursement, it could also be sold from an outlet outside the pharmacy.

Paragraph 4 of the proposed article would provide that the Medicinal Products Safety and Development Centre could amend the decision referred to in paragraph 2 on the basis of new information received on the basis of a marketing authorisation holder’s application or on its own initiative, which affects the sales channel. For example, for safety reasons, a decision could be taken if the Centre became aware of an increase in the misuse of a self-medication product due to sales outside pharmacies. Moreover, since it would be for the marketing authorisation holder to decide whether or not to apply for an extension of the sales channel for his product, he would also be entitled to seek the annulment of the decision and the return of the self-treatment medicinal product to pharmacy distribution only.

In addition, the extension of the sales channel for a self-treatment medicinal product would depend on the validity of the classification of the self-treatment medicinal product under Paragraph 23b. If the classification of the supply of a self-treatment medicinal product were changed within the meaning of Paragraph 23b, so that the medicinal product could in future be sold or otherwise released for consumption only on prescription, the decision referred to in paragraph 2 of this article would be annulled and the medicinal product would have to be removed from the sale outside the pharmacy.

ARTICLE 26. Under that section, the marketing authorisation holder and the registration holder referred to in Section 22 must ensure that the medicinal product authorised and the registered traditional herbal medicinal product are available on an ongoing basis to wholesalers and pharmacies of medicinal products, in accordance with the needs of patients and other users. It is proposed that self-medication products from the so-called ‘limited self-care’ range could also, under the conditions laid down by law, be sold by holders of retail licences for self-pharmaceuticals authorised outside pharmacies. Holders of retail licences for self-treatment medicinal products need to be added to the section as the number of operators to whom such self-medication products should be made available. A change would be possible

under the Medicinal Products Directive under Article 81(2), which requires medicinal products to be made available at all times to pharmacies and persons authorised to supply medicinal products to the public.

30 **Article U.** This section regulates the operators for which Finland requires, pursuant to Article 23 of the EU Regulation on the safety features of medicinal products, that the wholesale distribution of medicinal products checks the safety features of the medicinal product and removes the unique identifier of the medicinal product. **According to Article 23(a) of the EU Regulation on the safety features of** medicinal products, Member States may require, where necessary to take into account the specificities of the supply chain in their territory, that the wholesaler verify the safety features and decommission the unique identifier of the medicinal product before supplying the medicinal product concerned to one of the following persons or institutions: (a) persons authorised or entitled to supply medicinal products to the public who do not operate in a healthcare establishment or pharmacy. In view of the extension of the sales channel for certain self-medication medicinal products proposed in this proposal, it is proposed to add holders of retail licences for self-treatment medicinal products to the section. They would fulfil the conditions of Article 23(a) of the EU Regulation on safety features for medicinal products. The addition would be necessary in case self-care medicines with safety features were sold outside pharmacies.

31 **§§.** This section sets out to whom a pharmaceutical plant may sell or otherwise supply pharmaceutical substances and proprietary medicinal products. In the case of traditional herbal medicinal products classified as medicinal products and traditional homeopathic products and nicotine products sold outside pharmacies, paragraph 1 provides that medicinal products which are not prescribed or prescribed for sale only from pharmacies may, in addition, be sold or otherwise disposed of from a pharmaceutical factory to retailers of those products.

It is proposed to add the missing title ‘Försäljning från läkemedelsfabrik’ in the Swedish version, which corresponds to the heading ‘Sale from a pharmaceutical factory’ in the Finnish-language version.

It is proposed to amend subsection 1 in order to allow pharmaceutical factories to sell self-treatment medicinal products for human use for which the extension of the sales channel referred to in Article 23e(2) has been granted to holders of retail licences for self-treatment medicinal products. The current wording of this paragraph does not cover products belonging to a limited range of self-medication products, as their sales channel would not be the subject of a legislative or regulatory act of general application. On the other hand, self-medication products in the range would, in principle, be sold only in pharmacies. The marketing authorisation holder could choose to apply for an extension of the sales channel for his product. Fimea would grant the extension by means of a separate administrative decision if the conditions laid down in Paragraph 23e(2) were met. Subsections 2 and 3 would not be amended.

32 **§§.** This section regulates the definition of wholesale distribution of medicinal products and the wholesale distribution authorisation. Under Article 38(2), wholesale distribution of medicinal products does not constitute, inter alia, the sale of medicinal products and medicinal products to the general public under Article 38. It is necessary to amend the paragraph to refer to Article 38a instead of Article 38. The former Section 38 of the Medicinal Products Act has become Article 38a and Section 38 of the Medicinal Products Act now provides for the definition of concepts relating to pharmacy activities. The reference would also cover the sale of a limited range of self-medication products outside the pharmacy. That solution would be justified on the basis of Article 1(17) of the Medicinal Products Directive,

according to which the distribution of medicinal products to the public is not the wholesale distribution of medicinal products. Paragraphs 1 and 3 to 4 would not be amended.

33 §§. The section provides for a responsible manager in the wholesale trade of medicinal products. According to the provision in subsection 2, the general manager may not be at the same time a general manager of another company authorised to engage in the wholesale distribution of medicinal products. In addition, the accountable manager may not be a responsible director of another company's pharmaceutical plant, nor a pharmacist, a hospital pharmacy or a pharmaceutical centre manager, a military pharmacy manager, a pharmacy manager or a branch pharmacy manager. It is proposed to add that the accountable manager should also not be the holder of a retail licence for self-treatment medicinal products, his manager or the person responsible for self-medication. Subsections 1 and 3 are not proposed to be amended.

34 §§. This section sets out to whom the wholesale distribution of medicinal products may sell or otherwise supply medicinal products. In addition, under the first paragraph of that section, medicinal products which are not regulated or ordered to be sold only from pharmacies may be sold or otherwise disposed of to retailers of those products. It is proposed to amend the subsection in line with Article 31(1) above. According to the proposed addition, self-care medicinal products which have been granted the extension of the sales channel referred to in Paragraph 23e(2) would also be allowed to be sold to holders of retail licences for self-treatment medicinal products. As proposed in this proposal, the self-care medicinal products referred to in the Appendix would be exclusively self-medicines for human use. However, EU law and the Veterinary Medicinal Products Regulation would make it possible that self-care veterinary medicinal products would also be delivered to retail licence holders if these medicines were included in a limited range. Therefore, unlike Paragraph 31 of the Law on medicinal products, it is not necessary to state explicitly in the Addendum that it applies only to medicinal products for self-treatment for human use. Subsections 2 and 3 would not be amended. Subsection 3 would also apply where medicinal products from the new self-pharmaceutical range are sold to their retail licence holders.

35 §§. Under paragraph 1, medicinal products may be supplied free of charge from the pharmaceutical plant and from the wholesale distribution of medicinal products to doctors, dentists, veterinary surgeons and pharmacists, hospital pharmacies and medical centre operators for sample and standby purposes. Accordingly, medicinal products which are not prescribed or prescribed for sale only from pharmacies may be supplied to retailers of those products.

It is proposed to amend subsection 1 to reflect the ruling of the Court of Justice of the European Union of 11 June 2020 in Case C-786/18, according to which only samples of non-prescription medicinal products may be distributed to pharmacists. Prescription-only medicinal products could also be supplied to those qualified to prescribe a medicinal product. The judgment in that case did not rule on the supply of samples of a self-treatment medicinal product to the persons authorised to prescribe the medicinal product. However, the CJEU based its decision on the fact that the use of prescription-only medicinal products is particularly dangerous, so that the distribution of samples of those medicinal products would be permitted only to those qualified to prescribe the medicinal product. However, recital 51 in the preamble to the Medicinal Products Directive could allow samples of self-treatment medicinal products to be distributed to pharmacists in order to be familiar with them under restrictive conditions laid down by national law. A similar right to self-treatment samples could also be envisaged for the persons authorised to prescribe the medicinal product, subject to the limitations laid down by national law. This section should take into account pharmacists and pharmacists, as Finland has a two-tier university degree in pharmacy.

The last paragraph of paragraph 1 provides that medicinal products which are not prescribed or prescribed for sale only from pharmacies may, by analogy, be supplied to retailers of those products. It is proposed to replace this provision with a more specific provision in Article 25f of the Medicinal Products Decree, according to which sample packages of registered homeopathic products and traditional herbal medicinal products which are not prescribed for sale only in pharmacies may be supplied from the pharmaceutical factory and the wholesaler to retailers of those products. Under this provision, holders of retail licences for nicotine products and holders of retail licences for self-treatment medicinal products should not receive samples of medicinal products. Subsections 2-3 would not be amended.

ARTICLE 37. In accordance with subsection 1, the wholesale distribution of medicinal products must seek to ensure that it has the necessary quantity of medicinal products on sale. Subsections 2 and 3 provide for the obligation to notify the wholesale distribution of medicinal products in the event of a supply disruption. Subsection 1 is not proposed to be amended. Subsections 2-3 would be amended to include holders of retail licences for self-medical products as part of the group of operators for which the wholesale distribution of medicinal products would be obliged if the conditions laid down in the paragraphs are met. This section would be based on Article 81(1) to (3) of the Medicinal Products Directive for medicinal products for human use.

37 **section A.** This section provides for a uniform wholesale price for a medicinal product and for derogations therefrom. Under subsection 1, the wholesale price of a medicinal product must be the same for all pharmacies and branch pharmacies. The wholesale price shall take into account all discounts, rebates and other benefits granted to pharmacies and branch pharmacies. The wholesale price shall be notified to the entities providing information on the prices of medicinal products. Wholesale price restrictions do not apply to the wholesale prices of medicinal products which may also be sold outside pharmacies. According to the legislation in force, this refers to nicotine products, registered homeopathic products and traditional herbal medicinal products.

It is proposed to amend subsection 1 to reflect the limited range of self-medicines defined in the proposed Section 23d. It is proposed that wholesale price discounts, rebates and other benefits prohibited by subsection 1 of this article be allowed for products in this range, whether they have been requested to extend the sales channel or are sold only in a pharmacy. However, the retail prices of self-medical products in the limited range would be subject to a maximum price in accordance with the formula for self-treatment medicinal products in the Medicinal Tariff Regulation, and the Medicinal Tariff Regulation would also apply to the products in the range, for example with regard to the addition of VAT and the prohibition of quantity discounts. However, the application of the Medicinal Tariff Regulation would require a uniform national wholesale price for the products in the limited range, even if separate discounts and rebates on that wholesale price were allowed in practice. It is therefore proposed to add a provision in paragraph 1 according to which, in the case of a limited range of self-care as defined in Article 23d, the restrictions would not apply to that range. However, the wholesale price of these medicinal products used nationally should be communicated to the entities maintaining the price information. Subsection 2 is not proposed to be amended.

38 **section A.** That section provides that medicinal products may be sold to the general public only from a pharmacy, a branch pharmacy, a pharmacy service facility and an online pharmacy service within the meaning of this Law. In addition, the traditional herbal medicinal products and homeopathic products referred to in Paragraphs 22 and 22a above may also be sold elsewhere unless the Finnish Medicines Agency has decided otherwise at the time of registration. In addition, nicotine products may also be sold elsewhere in accordance with the provisions of Article 54a below.

It is proposed to amend this section so that the first provision on the right to sell pharmacies would constitute a paragraph 1 and the derogating provisions would be transferred to a new paragraph 2 in a specified form. A new derogation would be added to the proposed subsection 2 for self-care medicinal products that would have been granted the extension of the sales channel referred to in Article 23e(2). It would also state that nicotine products and self-care medicinal products which have been granted the extension of the sales channel referred to in Paragraph 23e(2) may also be sold outside a pharmacy, as provided for in Paragraphs 54a to 54i below.

Article 52b. The section regulates the online services of a pharmacy. This section is based on Article 85c of the Medicinal Products Directive. **According to** subsection 1 of this section, the pharmacist, the pharmacy of the University of Helsinki and the pharmacy of the University of Eastern Finland may also provide pharmacy services through the pharmacy's online service. The operator of the pharmacy's online service must have a website where medicinal products are offered for sale at a distance. These websites shall contain a link to the list of legal online pharmacies services kept by the Centre for Safety and Development of Medicinal Products and clearly display the common logo in the European Union in accordance with Article 85c of the Medicinal Products Directive.

It is proposed to amend subsection 1 in order to include the right of the holder of a retail licence for self-treatment medicinal products to offer self-medication products for which the extension of the sales channel referred to in Section 23e(2) has been granted through an online service. The online services of pharmacies and holders of retail licences for self-treatment medicinal products would be referred to as 'distance sales services of medicinal products'. The definition would cover information society services under Directive 1535/2015/EU offering medicinal products for sale. Holders of retail licences for self-treatment medicinal products would be subject to similar requirements in terms of website maintenance and content for pharmacies. In addition, linguistic changes are proposed to this article. The proposed change would be possible under Article 85c(1a) of the Medicinal Products Directive, which requires a natural or legal person offering medicinal products for sale to be authorised or entitled to supply medicinal products to the public, including at a distance, in accordance with the national law of the Member State in which that person is established. Member States have been left with national regulatory discretion as to which operators are entitled to supply medicinal products to the public.

Subsection 2 lays down rules on the prior notification of the operation of the pharmacy's online service, on the plan for medical advice contained therein, on the notification procedure, on the obligation to notify the commencement of operations, on termination and on the substantial modification, and on the grounds on which the Centre may prohibit the commencement of the activity or order the termination of the service. It is proposed to amend this article to make the obligation of prior notification and other reporting obligations also applicable to the holder of a retail licence for self-medical medicinal products. The obligations would be changed to all distance sales services of medicinal products. However, the obligation to provide advice on medicinal products would only apply to pharmacies. The proposed change would be possible under Article 85c(1b) and (d) of the Medicinal Products Directive.

Under subsection 2 of this section, the Centre may prohibit the commencement of an activity or order the termination of an online service if the pharmacy's online service does not meet the conditions laid down in this section, in the provisions referred to in paragraph 6, in Sections 55(3), 56, 57 or 57, or in the orders issued pursuant to Sections 49(2), 50, 51 or 80b.

The conditions laid down in the second paragraph and in the provisions referred to in paragraph 6 would also apply to the holder of a retail licence for self-medical medicinal products, in so far as the operating requirements applicable to the online service of a pharmacy

would not be concerned alone. It is also proposed to add the operating conditions applicable only to the holder of a retail licence for self-treatment medicinal products. Fimea could prohibit the commencement of an activity or order the termination of the online service if the holder of a retail licence for self-medical medicinal products does not meet the conditions laid down in section 54h or is subject to measures under the proposed section 79.

According to subsection 3, a pharmacy operating a pharmacy's online service should ensure that the marketing of a medicinal product is lawful in the State to which the medicinal product is sold. Prescription-only medicinal products should only be supplied on the basis of an electronic prescription under the ePrescription Act (61/2007) for the pharmacy's online service. The first provision of the subsection should also be extended to holders of retail licences for self-treatment medicinal products who must ensure that the self-treatment product is covered by a marketing authorisation valid in Finland. The provision would be based on Article 85c(1c) of the Medicinal Products Directive. On the other hand, the second provision of that paragraph would apply to prescription-only medicinal products and therefore only to an online pharmacy service which would have the exclusive right to sell prescription-only medicinal products at a distance.

Subsection 4 lays down the responsibility of the pharmacist, the obligation to carry out inspections and the provision of appropriate storage and transport conditions. In addition, the pharmacy's online service should have an adequate range of therapeutic groups, and the cheapest available medicinal products should also be available. It is proposed to amend this article in order to extend the obligations laid down therein, with the exception of the range of medicinal products, to holders of retail licences for self-treatment medicinal products and to use the joint name of the obligated entities. This would refer to the operators of distance sales services for medicinal products referred to in the preceding paragraph. Holders of retail licences for proprietary medicinal products would not be subject to the obligation as regards the range of medicinal products, since it would be for the holder of the marketing authorisation for self-treatment medicinal products to consider whether to apply for an extension of the sales channel for his product in accordance with the proposed Article 23e(2). The amendment would be based on Article 85c(2) of the Medicinal Products Directive, which allows Member States to lay down conditions for the retail supply within their territory of medicinal products offered for sale at a distance to the public by means of information society services.

Subsection 5 concerns the rights of a pharmacist to operate a pharmacy's online service when the pharmacy licence is transferred to a new pharmacy. Under that subsection, a new pharmacy licensed to operate a pharmacy must notify the Centre for Safety and Development of Medicinal Products pursuant to paragraph 1 if he continues to operate the pharmacy's online service. It is possible that the business of a retail licence for self-medical medicinal products will be sold to a new trader or that control of the company will change as set out below. These material changes should be notified to Fimea. Similarly, a new authorisation holder should be required to inform Fimea if he would continue to provide a distance sales service for medicinal products.

Otherwise, according to subsection 6 of the section, the provisions of Chapter 6 of the Consumer Protection Act (38/1978) on distance selling apply to the online service activities of a pharmacy. The provisions on the pharmacy's online service shall also apply to the sale of medicinal products by other means of distance communication. More detailed provisions on advice provided in connection with the use of an online service and on fees charged to customers in connection with online service activities may be issued by government decree. The Centre for Safety and Development of Medicinal Products may issue orders to pharmacies concerning the content and submission of prior notification, as well as the provision of advice on medicinal products, the packaging and checking of consignments of medicinal products, transport, outsourcing of activities, returns, handling of product defects, information to be

provided by the pharmacy's online service on the medicinal product, storage of medicinal products, delivery of medicinal products via the web service, premises, technical implementation, the range of medicinal products, treatment, and the performance and documentation of the inspection of online service activities.

It would be necessary to extend this paragraph to holders of retail licences for self-treatment medicinal products. Instead of the pharmacy's online service, it is proposed to provide for distance sales services for medicinal products, which would include not only the online services of pharmacies, but also the online services of holders of retail licences for self-treatment medicinal products. For reasons of regulatory convergence, the power to adopt a regulation and the power to issue orders need to be amended to cover the online services of the holder of a retail licence for self-medical medicinal products. In addition, in line with Directive 1535/2015/EU, it is proposed to replace the term 'remote communication' with the term 'information society service'.

Article 52d. According to subsection 1 of this section, the Centre for Safety and Development of Medicinal Products shall maintain and make publicly available on the internet an up-to-date list of legal pharmacies' online services. The provision proposes to replace the online services of a pharmacy by the term 'distance sales of medicinal products', which would include online pharmacy services and online services of holders of retail licences for self-medication medicinal products. Article 85c(4c) of the Medicinal Products Directive implements in part the obligation under Article 85c(4c) of the Medicinal Products Directive to set up a website containing at least the following sections: (C) the list of persons offering medicinal products for sale at a distance to the public by means of information society services in accordance with paragraph 1, together with the addresses of those websites. Under this proposal, holders of retail licences for self-treatment medicinal products would be entitled to sell, at a distance, self-medicines which would have been granted the extension of the sales channel referred to in the proposed section 23e(2). The holders of retail licences would then be 'persons' within the meaning of the Directive. Subsection 2 would not be proposed to be amended.

Article 54a. This section regulates the sale of nicotine products outside a pharmacy. It is proposed that the reference in subsection 1 to Section 38a of the Medicinal Products Act be amended as a result of the proposed amendment to that section, so that reference should be made to Section 38a(1) in the future. For the rest, it is not proposed to amend the section.

Article 54f. The proposed section would be new. It would lay down the conditions and conditions for the retail sale of self-medication medicinal products sold outside the pharmacy. Under paragraph 1, the sale outside a pharmacy of self-medication medicinal products which have been granted the extension of the sales channel referred to in Paragraph 23e(2) would be subject to a retail licence for self-treatment medicinal products issued by the Finnish Medicines Agency for Safety and Development. The authorisation would be per branch. This provision would mean that if the applicant had several offices, they would have to apply for authorisation separately.

Subsection 2 would lay down the conditions for granting the licence. Authorisation should be granted if all the conditions referred to in subsections 1 to 4 are met. According to subsection 1, the applicant should be a sole trader or a legal person registered in the commercial register pursuant to Section 3 of the Trade Register Act (564/2023). The purpose of this paragraph would be to ensure that the applicant would have the legal right to conduct a business in Finland, that the trader would be reliably identifiable and that he had a valid business registration number.

Article 3(1) of the Law on the commercial register governs companies and entities which would be obliged to register in the commercial register. In the case of sole proprietors, the obligation to notify would be incumbent on a sole trader who, under Chapter 3, Section 9(2) of

the Accounting Act (1336/1997), is required to file annual accounts for registration or who has a place of residence outside the European Economic Area. However, in accordance with Article 3(2) of the Commercial Register Act, the notice of incorporation may also be submitted by a sole trader who is not obliged to do so under Article 10(1). The provisions of this Act on an obliged entity shall also apply to a private trader who has voluntarily registered in the commercial register.

According to subsection 2, point 2, the applicant could not be an entity within the meaning of Sections 8, 32 or 34a of the Medicinal Products Act. In order to take account of the vertical integration of the pharmaceutical distribution chain, it was considered justified to provide that a pharmaceutical plant holding a manufacturing authorisation for a medicinal product within the meaning of Paragraph 8 of the Law on medicinal products, the wholesale distribution of medicinal products or an intermediary of medicinal products could not apply for a retail licence for self-treatment medicinal products.

According to subsection 2, point 3, the applicant should appoint a responsible person who would have been familiar with the legislation and procedures for self-care medicinal products. Holders of retail licences for self-treatment medicinal products could take different business forms and presumably have no prior knowledge or experience in the marketing of medicinal products. It would require the authorisation holder to appoint a responsible person who could be subject to legal obligations, e.g. to monitor the activity. The responsible person would also act as the contact person for the licence holder vis-à-vis the authorities. The responsible person could be a person employed by the licensee. If the applicant was a sole trader, he could act as the responsible person himself. For example, if the applicant were a grocery chain, a person in the chain who would be responsible for the duties of the responsible person at several sites could act as the responsible person.

Paragraph 2(4) requires that the applicant's sales and storage facilities and the training given to staff meet the conditions laid down in this Act and the regulations adopted on the basis thereof. This paragraph would refer to the conditions set out in the proposed section 54h below and the Government Decree adopted on the basis thereof.

54 g §. The proposed section would be new. It proposes to provide for the application for a retail licence for self-treatment medicinal products, notification of variations, validity and withdrawal of the authorisation.

According to the proposed subsection 1, a retail licence for a self-treatment medicinal product should be applied for in writing or electronically to the Finnish Medicines Agency. The application or the accompanying documents should include the applicant's name or business name, the business identification number and contact details of the applicant and, where applicable, the name and contact details of the applicant's contact person. This information could also be provided by attaching an extract from the applicant's business register to the application. In addition, the application should include the address and contact details of the office, the name and contact details of the responsible person, and a declaration that that person would have been familiar with self-treatment products within the meaning of Paragraph 54f(2)(3). In addition, the application or its annexes would include a description of the applicant's sales and storage facilities and the planned induction for staff.

According to the proposed subsection 2, the licence holder should inform the Medicinal Products Safety and Development Centre of any material changes in the operation. The Centre could require the authorisation to be re-applied if, as a result of a change in activity, the conditions for authorisation under section 54 septies would have to be re-assessed. Substantial changes would mean changes in matters relevant to the fulfilment of the conditions for authorisation. This would include, for example, the cessation or sale of the entire business of the licensee to another trader, or the transfer to another undertaking of the control referred to

in Chapter 1, Section 5 of the Accounting Act (1336/1997), the filing of the licence holder for bankruptcy or the change of the responsible person, the change of establishment to the new premises or the change of contact details if these were contact details used in the communication with the authorities. However, not all changes in activity would be required to be notified.

Under the proposed paragraph 3, a retail licence for a self-treatment medicinal product would be valid indefinitely. The authorisation holder could withdraw the authorisation by notifying the Finnish Medicines Agency. The authorisation could also be revoked by a decision of the Centre for Safety and Development of Medicinal Products pursuant to Article 79(2). The proposed Article 79(2) would lay down the grounds on which Fimea should withdraw the retail licence for self-treatment medicinal products.

Article 54h. The proposed section would be new. It proposes to lay down the conditions for the operation of a retail licence for self-treatment medicinal products. According to subsection 1, point 1, of the proposed section, the holder of the authorisation should only sell self-care medicinal products of sound quality which have been authorised in Finland and which have been granted the extension of the sales channel referred to in Section 23e(2). That condition would in part correspond to the obligations imposed on pharmacies. In addition, only the sale of self-treatment medicinal products for which an extension of the sales channel has been granted would be a specific condition.

According to point 2 of subsection 1 of the proposed article, self-care medicinal products should be handled and stored appropriately. This would mean that self-care medicines should be dealt with taking into account their storage conditions and the integrity of their packaging. For example, they should not be stored at a temperature that could compromise their usefulness.

According to point 3 of subsection 1 of the proposed article, self-care medicines should be sold in complete sales packages and should be subject to product-specific restrictions and to ensure that sales are always carried out under the supervision of staff. Holders of retail licences for self-treatment medicinal products would not be pharmacy graduates and would therefore not be entitled to distribute packaging for medication safety reasons. Product-specific sales restrictions would mean the maximum purchase volume for the product in question in the supply classification of the self-prepared medicinal products to be sold in a single purchase. Sales of self-treatment medicines should always take place under the supervision of staff. This would make it possible for self-services to sell, but the seller should be present to ensure that the buyer has complied with the sales restrictions in force.

According to subsection 1(4) of the proposed article, self-care medicinal products should be sold and stored in a business premises at the authorised establishment, which should meet the storage conditions of the medicinal products. Particular attention should be paid to ensuring that the temperature of the rooms is right.

According to point 5 of subsection 1 of the proposed article, staff should be given appropriate training and instructions on self-medication. In order to be authorised, the presence of persons trained in pharmacy would not be required. However, staff should be required to be familiar with, for example, the specific characteristics of self-medication medicinal products, their sale, marketing, pricing, sales restrictions and the fact that staff should not provide medical advice to customers.

According to paragraph 1(6) of the proposed article, the sale, pricing and marketing of self-treatment medicinal products should comply with the provisions of this Act, the regulations adopted on the basis thereof and the Consumer Protection Act. This would refer, for example,

to the regulation of pricing and marketing in the Medicines Act, which would be applicable to holders of retail licences for self-treatment medicinal products.

Under point 7 of subsection 1 of the proposed article, a retail licence holder should, when ordering self-care medicinal products from a pharmaceutical factory or from a magazine, reliably demonstrate that he is entitled, as the holder of a retail licence for self-medical medicinal products, to receive self-care medicinal products. That requirement could be demonstrated by means of a specific identifier obtained at the time of authorisation, which would allow a wholesaler of medicinal products or a pharmaceutical manufacturer to check the validity of a retail licence from a public register.

According to subsection 2 of the proposed article, neither the retail licence holder nor the person working at the site should give medical advice or disclose without authorisation any private or family secret of which they have become aware in the course of their duties. Neither the holder of a retail licence for self-treatment medicinal products nor his staff would be required to be pharmacy graduates or pharmacists. In order to ensure the safety of medicinal products and medication, it would therefore be prohibited for customers to be given advice on medicinal products when self-care medicinal products are sold. The obligation of professional secrecy would be equivalent to the duty of professional secrecy incumbent on the pharmacy's staff under the Medicines Act.

According to subsection 3 of the proposed section, further provisions on the premises of the licence holder, the induction and guidance of staff, control arrangements, storage, treatment of self-treatment medicinal products and the resulting waste of medicinal products could be laid down by Government decree. The basic rule for the power to issue regulations would be contained in subsection 1 of the section.

Article 54i. The proposed section would be new. It proposes to provide for the tasks of the person in charge appointed by the retail authorisation holder for self-treatment medicinal products at a higher level. Further regulation would be contained in a government decree under the section. According to the proposed subsection 1, the responsible person would be responsible for regularly monitoring the storage conditions and sales of self-care medicinal products, acting as the contact person for the holder of the authorisation vis-à-vis the authorities, and carrying out an annual inspection of the office. According to the proposed subsection 2, further provisions on the tasks of the responsible person could be laid down by Government decree.

Article 57f. The proposed section would be new. It would lay down the conditions under which a pharmacist or pharmacist working at a pharmacy, a branch pharmacy or an online pharmacy service could derogate from the prescription. Under the first provision of the proposed paragraph 1, when supplying an industrially prepared medicinal product based on a prescription to the user of a medicinal product, a pharmacist or pharmacist working at a pharmacy, a branch pharmacy or an online pharmacy service may depart from the prescription as regards the pack size, the pharmaceutical form, the strength, the dosage instructions and the trade name of the prescribed medicinal product.

A derogation from the prescription would mean a procedure applicable in exceptional situations. As a general rule, prescription-only medicinal products would be supplied by a pharmacy, as has been the case until now. The pharmacy's right to exchange medicinal products, which is governed by Article 57b of the Law on medicinal products and is based on a list of interchangeable medicinal products drawn up by Fimea, would be part of the normal supply of medicinal products and would always be the preferred approach to the proposed derogation from the prescription. If the supply of the medicinal product could be solved by substitution, a derogation from the prescription would not be possible.

In order to ensure the safety of medicinal products, it is proposed that the decision to derogate from the prescription should be taken by a pharmacist or pharmacist working in the pharmacy. As a health professional, this would be responsible for ensuring the safety of medicines and medication. A pharmacist or pharmacist serving the patient would also have first-hand knowledge of the relevant circumstances in the event of supply. A pharmacist working in a pharmacy could, of course, also be a pharmacist serving the patient, a university pharmacy or a branch pharmacy. However, this could not be a pharmacy student or other member of the pharmacy's staff.

The possibility of derogation would apply to a prescription issued to the user of a medicinal product which imposes on him an industrially manufactured medicinal product. A prescription would mean both a domestic prescription and a European prescription. It would only be possible to derogate from prescriptions for industrially manufactured medicinal products for human use which the patient or anyone acting on behalf of the patient would collect from the pharmacy. This would not be possible in the case of a pro auctore prescription or prescription under which the pharmacy would manufacture the medicinal product or if the prescription concerned veterinary medicinal products.

A pharmacist or pharmacist working in a pharmacy could deviate from the prescription as regards the pack size, pharmaceutical form, strength, dosage instructions and trade name of the medicinal product prescribed for the user of the medicinal product. The list of ways in which the prescription could be derogated from would be exhaustive. This would mean that no derogation from the prescription is permitted in any other way, nor could it concern other information contained in the prescription.

Deviations from the dosage form could, for example, mean replacing the eye drop bottle with eye drops in the pharmacy in the pipette. An exchange between strengths and dosage instructions could mean, for example, that 10 mg tablets, taken one per day, are replaced by 5 mg into tablets taken two per day or 20 mg into a tablet taken half a day. A deviation from the pack size would mean situations where, for example, the quantity of the medicinal product indicated on the prescription differs from the packaging available. In case of deviation from strength, there would also be a need to deviate from the dosage instructions of the medicinal product. An indication of the abnormal dosage should be recorded for the supply of the medicinal product.

When deviating from the trade name, priority should be given to the supply of a medicinal product of a different strength or another pharmaceutical form that is interchangeable with the prescribed medicinal product. If the exchange had to be made to another medicinal product which is not interchangeable with the prescribed medicinal product, it would be necessary to ensure, on the basis of pharmaceutical considerations, that the safety of the medicinal product or medication would not be compromised as a result of the incident. A medicinal product may also be defined in a prescription only by reference to the active substance. For example, in European prescriptions, as a general rule, a medicinal product is defined by the active substance only. Where that is the case, the application of the prescription to the brand name of the medicinal product is part of the normal supply of a pharmacy and, in such situations, there would be no departure from the prescription. The deviation could then concern only the strength, pack size and dosage of the medicinal product.

Under the second provision of the proposed subsection 1, a derogation from the prescription could be made if all the conditions laid down in that paragraph were met.

Under the first condition of subparagraph 1(1), a medicinal product prescribed and a medicinal product which can be exchanged with it would not be available at a pharmacy because of a national shortage or the withdrawal of the medicinal product from the market. For the purposes of this condition, a pharmacist or pharmacist working in a pharmacy should check

whether the prescribed medicinal product and its interchangeable medicinal products are affected by a nationwide shortage or whether the marketing authorisation holders have indicated that the products are no longer marketed. As a matter of priority, the exchange of medicinal products under Section 57b of the Medicinal Products Act should apply and a derogation from the prescription would only be possible where normal delivery of the medicinal product would not be possible.

According to the second condition in point 2 of the proposed subsection 1, a prescribed medicinal product and a medicinal product that can be exchanged with it would not be possible to order from the wholesale distribution of medicinal products and the user of the medicinal product could not be redirected to another pharmacy. For example, the condition could be met if, due to a national shortage or withdrawal of the medicinal product from the market, the medicinal product would be stopped from the wholesale trade in medicinal products and from other pharmacies. The condition would also be met if there was an individual shortage of stock of a pharmacy within the meaning of paragraph 2 below, but the time needed to order the medicinal product from the hour would not be timely because of the customer's acute need for a medicinal product. The condition would also be met if the medicinal product was available in another pharmacy, but the customer could not be referred to that pharmacy because of, for example, a long distance or the customer's state of health. If, on the other hand, it were possible for the customer to wait for the order for the medicinal product to be received or for him to go to another pharmacy, then the deviation could not be made. There could be a variety of possible situations and the assessment should be made on a case-by-case basis, on the basis of a pharmaceutical judgement.

According to the third condition in point 3 of the proposed subsection 1, the derogation would not alter the intended effects of the medicinal treatment. The dispensation of a non-prescription medicinal product would ensure continuity of treatment by supplying a medicinal product that meets the therapeutic objective of the prescriber. For example, in the case of a derogation from the prescription for the strength of a prescribed medicinal product and the supply of twice a higher dose, the dosage instruction should be amended to halve the dosage in order to maintain the effect of the treatment. When deviating from the trade name of a medicinal product in the absence of an interchangeable medicinal product, priority should be given to the supply of a prescribed medicinal product or an interchangeable medicinal product in a different pack size, pharmaceutical form or strength, so that, as regards the similarity of the medicinal products, it could be ensured that the effect of the treatment would not change.

According to the fourth condition in point 4 of the proposed subsection 1, there would be no derogation from the particulars of the prescription by the prescriber and the prescription would not have to be issued or maintained by telephone, or a prescription for a medicinal product with a special authorisation, a narcotic drug containing a medicinal product, a medicinal product primarily active on the central nervous system or a medicinal product containing alcohol.

When prescribing a medicinal product, the prescriber may include, for example, a ban on exchange, a patient-specific medical or therapeutic justification for not prescribing the cheapest, comparable and alternative biological medicinal product, a SIC mark, an iterative indication or an indication of the limitation of the period of validity of the prescription. In addition, the prescription could have been invalidated or the medication stopped. There is always a special reason for adding labelling to the prescription. Since the prescriber is responsible for the patient's entire medical treatment, a pharmacy would not be entitled to depart from those particulars provided by the prescriber. If the prescription contained such a specific indication, an exemption in the pharmacy could not constitute an exception to it. For example, if the prescriber has issued a prescription ban, it would not be possible to change the

trade name of the medicinal product or if the prescription bears the SIC indication, the medicine should be supplied accordingly.

It would also require that it should not be subject to a prescription by telephone or to a prescription for a medicinal product which is compulsorily authorised, a medicinal product containing a narcotic substance, a medicinal product primarily active on the central nervous system or a medicinal product containing alcohol. The above-mentioned special prescriptions and the prescribing of certain medicinal products suitable for misuse have specific characteristics and risks which do not justify deviations from the prescription.

Point 5 of the proposed subsection 1 would provide, as a fifth condition, that the total amount of the prescription should not be exceeded. The limit on the total amount of the prescription is based on the government programme. For example, a restriction could be relevant for deviations from strength, pack size, dosage instructions or pharmaceutical form. In these situations, care should be taken not to change the initial total quantity of medicinal products. The quantity of the medicinal product remaining after delivery should also be consistent with the initial overall adequacy of the medicinal product, e.g. taking into account a change in the dosage instruction. For example, in situations where 200 tablets are left on prescription, the dosage guide is one 10 mg tablet per day and, due to a lack of availability, 5 mg tablets are supplied with a double dosage guide. If 200 pieces of 5 mg tablets are supplied, then the corresponding quantity of 100 tablets at 10 mg is still indicated on the prescription.

However, the proposed paragraph would allow the total quantity of medicinal products to be exceeded to a limited extent if the quantity of medicinal product not supplied was lower than the lowest available packaging or the cheapest package of medicinal products, if it was cheaper than the smallest available package per dose, or in the case of a pharmaceutical form such as a cream which would make it impossible to distribute the pack. In addition, a derogation from the total amount of the medicinal product could be made in the situations referred to in subsection 3 of the proposed article, where the medicinal product is regularly used on a finished or outdated prescription, which would allow the supply of up to three months of use of the medicinal product.

According to the sixth condition set out in point 6 of the proposed subsection 1, any derogation from the prescription should not compromise the safety of medication and should be necessary on the basis of pharmaceutical judgement. The safety of medicinal products should be ascertained on the basis of a case-by-case assessment by a pharmacist or pharmacist, which should determine whether a derogation from the prescription can be made in a medico-secure manner. When making a decision, the pharmacist or pharmacist should assess the harm that delays in treatment would cause to the patient, taking into account that the medicine is intended to cure, alleviate or prevent the disease or its symptoms. A relevant factor could also be the commitment to the treatment of the user of the medicinal product if the treatment was interrupted or would result in an additional burden. This assessment of harm should be weighed against the potential harm caused by non-prescription. The assessment should also take into account the health and cognitive status of the user of the medicinal product and assess whether it would be possible for the user of the medicinal product to remember and understand the changes made to the medication used on a regular basis. The client should always be referred to healthcare if the pharmacy could not solve the situation in a medication safe manner. The need to contact the pharmacy should be assessed on a case-by-case basis.

The pharmacist and pharmacist should also assess whether, on the basis of pharmaceutical judgement, a derogation would be necessary in order to ensure the continuity of the patient’s medical treatment. If the continuity of medical treatment would not necessarily require an incident, the customer should be given instructions for further action. For example, if the customer were to collect a medicinal product which he would have started to use only at a

later stage and the medicinal product would have left the market. The customer should be asked to liaise with the prescriber to change the prescription.

It would be proposed, in paragraph 2, to provide that a pharmacist or pharmacist working in a pharmacy may also derogate from the prescription for a specific reason, as provided for in paragraph 1, in a specific exceptional situation in which, for other reasons, a prescribed medicinal product or a medicinal product that can be exchanged with it is not available in the pharmacy's warehouse and the client would necessarily have to take the medicinal product immediately with him, as a delay in the treatment of the patient's condition would be detrimental to the treatment of the patient's disease or its symptoms. The derogation could then be made if the conditions laid down in subparagraph 1, points 2 to 6, were met and if, despite the attempt, the prescriber of the medicinal product would not be reached.

In the situations referred to in that paragraph, there would be a very exceptional situation in which the customer would have an acute need to obtain the medicinal product immediately from the pharmacy, failing which he would be inconvenient if his treatment were delayed. The threshold for the application of this paragraph should be set at a high level. The derogation would be subject to the condition that the conditions laid down in subparagraph 1, points 2 to 6, were met. Particular attention should then be paid to whether the customer could be redirected to another pharmacy in order to obtain a medicinal product. In addition to satisfying the conditions set out in subparagraph 1, points 2 to 6, it would be necessary to attempt to reach the prescriber for changing the prescription before departing from the pharmacy and to fail to contact the pharmacy. This could be the case, for example, if the prescriber could not be contacted, or the client would appear in a pharmacy, for example, so late in the evening or during a weekend that the prescriber could not be reached when the healthcare institution was closed. Derogations in these situations should not be due to the financial interests of the pharmacy or the patient or be based on grounds other than those set out in the subsection.

The proposed subsection 3 would provide for situations in which the prescription of a medicinal product regularly used by the customer would have expired or been exhausted less than three months earlier. In such a case, a pharmacist or pharmacist working at a pharmacy, a branch pharmacy or an online pharmacy service could, in a specific exceptional case, deviate from the period of validity of the prescription or the total quantity of the medicinal product and provide the customer, on the basis of a prescription, with up to three months' dose of the prescribed medicinal product or a medicinal product that can be exchanged with it. A different supply would be subject to compliance with the conditions laid down in subparagraph 1, points 3 to 6, and to the condition that the dissimilar supply of the medicinal product would be evaded in order to ensure the continuity of the medical treatment of the customer.

The regular use of a medicinal product by a customer would mean a prescription under which the customer has already regularly used a prescribed medicinal product or an interchangeable medicinal product over a longer period of time and there should be no change in the regular use of the medicinal product.

A non-conforming supply would entail the supply of a quantity of medicinal product up to three months' dose on prescription. In terms of the quantity of medicinal products, the pharmacy should take into account the pack sizes available in the supply, the customer's need to receive the medicinal product and its possibilities for re-prescription. Account should also be taken of the provisions on reimbursement of the medicinal product to be supplied, in particular the provision in Chapter 5, Paragraph 9(5), of the Health Insurance Act on the reimbursement of medicinal products for which the retail price, subject to VAT, at the time of delivery is higher than EUR 1000 and for which the purchaser of the medicinal product is paid a health insurance allowance up to the same amount as the one-month period of treatment purchased, subject to special circumstances.

In order for a derogation to be made, the conditions laid down in subparagraph 1, points 3 to 6, would have to be met. In such a case, in accordance with point 4 of the proposed subsection 1, the specific indications provided by the prescriber on the prescription, such as the limitation of the period of validity of the prescription, the iteration of the prescription, the invalidation of the prescription and the indication of the discontinuation of the prescription, would prevent a dissimilar dispensation under subsection 3 on the basis of an outdated or used prescription. A different supply would also require it to be necessary in order to ensure the continuity of the medical treatment of the customer. This would mean, for example, that the prescription would not be renewed before the end of the customer's medicinal products. On the other hand, if the customer had, for example, the amount of one month left at home, no abnormal delivery should be made.

Article **57 g.** The proposed section would be new. It would provide for a procedure in the event of a derogation from a prescription in accordance with the proposed Paragraph 57f of the pharmacy. According to the proposed paragraph 1, the derogation from the prescription referred to in Article 57f should be made in agreement with the purchaser of the medicinal product and in accordance with Article 57. Any derogation from the prescription should be subject to restrictions based on the marketing authorisation. The purchaser of the medicinal product should be provided with a dosage guide for the medicinal product and should be invited to contact the prescriber if necessary.

The agreement would mean that the user of the medicinal product should accept deviations from the prescription and understand the risks and possible additional costs involved. In addition, the pharmacist or pharmacist should assess, for example, whether the user of the medicinal product would be able to understand the change and remember the new instructions for the use of the medicinal product given to him or, if another person were to act on behalf of the user at the pharmacy, whether the change could be implemented safely. In the case of a mechanised medicinal product, the purchaser of the medicinal product in the subsection would mean a care unit which would be the primary contact of the pharmacy. In such cases, the user of the medicinal product should be informed in the dosage information of the dispensing bags and the medication card. A derogation from the prescription could only be made if the conditions laid down in the section are met. The agreement would not mean that it could be concluded at the request of the purchaser of the medicinal product in any other situation.

The proposed reference to compliance with Section 57 of the Medicinal Products Act would mean that, even in the case of a disparate supply of medicinal products, the advice and guidance of the pharmacist's pharmacist should, in accordance with Article 57, be aimed at ensuring that the user of the medicinal product is aware of the correct and safe use of the medicinal product in order to ensure the success of medical treatment. When dispensing a prescription medicinal product, the pharmaceutical staff of the pharmacy and the branch pharmacy must offer the purchaser of the medicinal product the cheapest actually priced medicinal product. In addition, the purchaser of the medicinal product should be informed of the prices of the cheapest available medicinal products and other factors influencing the choice of the medicinal products. That obligation would mean that, in the event of a different supply, a pharmacy would have to ensure the overall economy of the medicinal product by supplying the purchaser of the medicinal product with the most favourable price.

In the case of a derogation from a prescription, the purpose of medical advice would be to ensure that the purchaser of the medicinal product understands what is involved in the procedure and that the medicinal product supplied would replace the medicinal product prescribed for the user of the medicinal product. Medical advice would also ensure that the user of the medicinal product would be able to use the medicinal product supplied to him correctly and safely and that he would understand how the change would affect the use of the medicinal product. As part of the drug advice to the purchaser of the medicinal product, he should also be given a dosage instruction for the medicinal product to be supplied which, due

to the deviation, may differ from the original dosing instruction in the prescription if, for example, the strength or pharmaceutical form would have had to be changed. Any derogation from the prescription should be subject to restrictions based on the marketing authorisation.

Where appropriate, the purchaser of the medicinal product should be invited to communicate with the prescriber and should be given a dosage guide for the supplied medicinal product taking into account the changes made. There would be a need for contact with the prescriber or healthcare to ensure successful follow-up treatment, e.g. with a view to renewing a prescription. The pharmacy could also pass on the buyer's request for renewal of healthcare. The request for renewal should take into account that renewal is not done for the same product, but for a product that replaces a previously prescribed product. The need to refer the purchaser of a medicinal product to healthcare would also be in situations where no derogation from the prescription could be made.

The proposed subsection 2 would provide that, where a pharmacist or pharmacist working in a pharmacy, branch pharmacy and pharmacy's online service derogates from a medical prescription within the meaning of section 57f, the pharmacist or pharmacist would record in the prescription centre the dispensing information on the supply of the medicinal product, the reason for it and any contact with the prescriber. Information about the deviation and the reason for it would be recorded in the data on purchases of medicinal products submitted to the Social Insurance Institution. The recording of the data referred to in the subsection would take place before 1 October 2027, with the data being entered in the prescription centre in the information on the supply of the medicinal product and the Social Insurance Institution's data on the purchase of medicinal products with the so-called 'DP' mark, and the reason for the discrepancy recorded separately. Instead, after 1 October 2027, nationally defined cause codes would also be in place to allow structured recording of the medicinal product in the prescription centre.

ARTICLE 58. According to subsection 1 of this section, the retail sale of a medicinal product must be carried out at a price in accordance with the pharmaceutical tariff laid down by Government decree. The price of the medicinal product shall consist of the retail selling price of the medicinal product and, in the cases referred to in subparagraphs 2 and 3, an item-by-item delivery fee to be added to the retail price, and VAT. The retail price of a medicinal product shall be based on the wholesale price notified by the holder of the marketing authorisation for the medicinal product in accordance with Paragraph 37a and on the margin calculated on the basis of the wholesale price. The margin calculated on the basis of the pharmaceutical tax may be proportionally lower than the pharmacy tax levied on that medicinal product under Section 6 of the Act on the taxation of pharmacies (770/2016). The difference shall not exceed EUR 6 for an individual medicinal product.

It is proposed to amend this subsection in order to delete the last provision according to which the margin calculated on the basis of the pharmaceutical tax rate for a medicinal product may be proportionally lower than the pharmacy tax levied on that medicinal product under Section 6 of the Act on the taxation of pharmacies (770/2016). The difference shall not exceed EUR 6 for an individual medicinal product. This proposal proposes that the taxable amount of the pharmacy tax be converted into a taxable person's profit margin on the taxable person's sales of medicinal products, based on the profit margin of pharmacies. The proposed amendment would remove the so-called negative margin problem. The last provision of subsection 1 has been attempted by the current law to resolve the problem, which would now be removed as superfluous. Subsections 2-3 are not proposed to be amended.

Subsection 4 governs the pricing of self-medical products. According to the current paragraph, the price of a medicinal product which may be supplied from a pharmacy without a prescription shall consist of the retail price of the medicinal product and VAT. If the medicinal

product referred to in this paragraph is supplied on the basis of a prescription, the retail price shall be increased by the delivery fee and VAT per consignment. The retail selling price of a medicinal product supplied from a pharmacy without prescription shall be no more than the retail price at the retail price of the medicinal product and shall not be less than the wholesale price of the medicinal product available at national level in accordance with Paragraph 37a. The price must be the same for all pharmacies and online services. However, by way of derogation from the above, the retail selling price of self-prescription medicinal products requiring additional advice shall be the retail price of the medicinal product in accordance with the tariff and the retail price of a medicinal product supplied from a pharmacy without prescription shall be the retail price of the medicinal product, provided that the nationally uniform price is justified in the light of the medical advice required for the use of the medicinal product, any adverse effects of the medicinal product or public health.

It is proposed to amend subsection 4 so that for medicinal products which may be supplied from a pharmacy without prescription, the term ‘self-medicine’ would be used. A definition of the term would be included in the proposed Section 23e. In addition, the term ‘self-care medicinal product’ would be used in the provision allowing discounts in the subsection, so that the retail price of the self-treatment medicinal product is to be no more than the retail price of the medicinal product at the retail level and not less than the nationally available wholesale price of the medicinal product in accordance with Paragraph 37a. In addition, the provision that the retail price of self-prescription medicinal products requiring additional advice is the retail price of the medicinal product and that the retail price of a medicinal product supplied from a pharmacy without a prescription is, however, the retail price of the medicinal product, provided that the nationally uniform price is justified in the light of the medical advice required for the use of the medicinal product, the possible adverse effects of the medicinal product or public health, is proposed to be linguistically edited. As a result of the amendments to subsection 4 described above, the existing legislation would not be substantively altered.

It is also proposed to add a provision on the retail price of a self-medication product within the limited range of Section 23d proposed. Pricing would change for these products. According to the proposed provision, by way of derogation from paragraph 1 and this paragraph, the maximum retail price of a self-treatment medicinal product within the limited range of self-medication products referred to in Article 23d would be the sum of the national wholesale price notified by the marketing authorisation holder in accordance with Paragraph 37a and the margin calculated on that basis. On the other hand, the maximum price in accordance with the price of a medicinal product would be the maximum retail price, plus VAT, as set out above. VAT should always be added to the retail price of a medicinal product in a limited range. If a product in the range is supplied on prescription, a delivery fee per batch is also added to the price.

This provision means a derogation from the provision in paragraph 1, according to which the retail price of a medicinal product should in all cases be based on the wholesale price notified by the holder of the marketing authorisation for the medicinal product in accordance with Paragraph 37a and on a margin calculated on the basis of the wholesale price. On this basis, the maximum retail price for products in the limited range of self-medication products would continue to be established. However, separate wholesale discounts would be allowed for self-pharmaceutical products in the range under Paragraph 37a and the retail price of the product could be lower than the uniform wholesale price. In all cases, however, the price should consist of a retail price plus VAT and a delivery fee per batch of prescriptions.

In accordance with subsection 5 of the section, further provisions on the price of the medicinal product, the exemptions from the maximum price and the discounts to be granted shall be laid down by Government decree. It is proposed to amend the subsection so that instead of exceptions to the maximum price, exceptions to the price could be provided for by

Government decree more broadly. It would be necessary to provide for a different pricing of self-medical products from a limited range. Paragraph 6 would not be amended.

Under subsection (7), the provisions of subsections (1) to (6) do not apply to medicinal products which may also be sold outside pharmacies, branch pharmacies, pharmacy service outlets and online pharmacy services. It is proposed to amend this paragraph to identify the categories of medicinal products to which it does not apply. The proposed wording would be as follows: The provisions of subsections 1 to 6 shall not apply to registered homeopathic products, registered traditional herbal medicinal products and nicotine products which may also be sold outside pharmacies, branch pharmacies, pharmacy outlets and online pharmacy services. This clarification would be necessary because medicinal products falling within the limited range of self-medication products under Paragraph 23d of this proposal could also be sold outside the pharmacy if they had been granted an extension of the sales channel. However, the pricing of these medicinal products would be governed by this section and the Medicinal Duty Regulation. Paragraph 8 would not be amended.

ARTICLE 77. This section lays down the right of inspection of the Centre for Safety and Development of Medicinal Products. Paragraph 1 sets out the operators to be inspected by Fimea. It is proposed to amend this article to allow Fimea to check also holders of retail licences for self-treatment medicinal products. From the point of view of the supply of medicinal products, their activities are assimilated to a pharmacy service where only self-care medicines can be sold, so it is proposed to add them to the article as one of the operators that Fimea has the right to inspect without the time limits laid down by law.

It is also proposed to correct this article by reintroducing the system for recording the safety features of medicinal products and the operator of the recording system mentioned previously in the subsection among the operators to be checked. Fimea's right of inspection for these operators was deleted from the paragraph by mistake in the context of the parallel amendments to the section (Act 985/2021 vp amending the Medicines Act).

With the addition of the paragraph, the provisions of paragraphs 2 and 3 of the article on the conduct of the inspection would also apply to the new operators referred to therein. Article 78 of the Medicines Act would also be suitable for new operators. Paragraphs (2) to (4) are not proposed to be amended.

ARTICLE 79. The proposed section would be new. It would provide for penalties to be imposed on the holder of a retail licence for self-medical medicinal products, the conditions for the withdrawal of a retail licence and an order for temporary cessation of sales.

It is proposed to provide in subsection 1 that the Finnish Medicines Agency may issue an oral or written warning to the holder of a retail licence for self-medication medicinal products if the licence holder is acting in breach of this Act or the provisions adopted pursuant to it, and the act is not of such a nature that the holder of the authorisation should be prosecuted in court. An oral or written warning would be the primary measure. This paragraph would be in part equivalent to Article 51 of the Law on medicinal products, which contains a similar provision for pharmacists. However, that paragraph would not impose on the retail licence holder a penalty for unfair conduct, which must be interpreted as relating to the special confidential position of a pharmacist in society.

According to the proposed subsection 2, the Centre for the Safety and Development of the Finnish Medicines Agency should withdraw the retail licence for self-treatment medicinal products if one of the conditions set out in points 1 to 5 is met. Points 1 to 3 would relate to changes in business activity. The authorisation should be revoked if (1) the licensee's entire business is terminated, (2) his entire business is sold to another trader, or the control of the licensee's undertaking referred to in Chapter 1, Section 5, of the Accounting Act (1336/1997)

is transferred to another undertaking and no appeal has been lodged; or (3) the holder of a retail licence for self-medical medicinal products is declared bankrupt and no assets are regained possession within one year from the beginning of the bankruptcy.

Points 4 to 5 of the proposed subsection 2 would relate to situations where the authorisation holder has failed to comply with the provisions of the Medicinal Products Act or has failed to comply with an order issued to him. The authorisation should be revoked if (4) the holder of a retail licence for self-pharmaceutical medicinal products would receive a written warning as referred to in paragraph 1 or an order from an inspector as referred to in Article 78, and would not correct his procedure within the prescribed period or, failing that, within a reasonable period, or if (5) the holder of a retail licence for self-medical medicinal products would materially abuse his rights under the retail licence for self-medication medicinal products or would fail to comply with this Act or the provisions adopted pursuant thereto in a manner that would seriously jeopardise patient safety. In the case of the latter particularly serious actions which would endanger patient safety, the retail licence could be withdrawn immediately without prior warning or order by an inspector.

The proposed paragraph 3 would provide that the Finnish Medicines Agency could provisionally order the cessation of the sale of self-treatment medicinal products if the conditions laid down in paragraph 2 are met. The order could be issued for a maximum period of one year or until a decision has been taken on the withdrawal of the authorisation. Should the suspicion of irregularities prove to be unfounded, the Centre should revoke the order without delay.

Article 84b. According to subsection 1 of this section, pharmacies, including the pharmacy of the University of Helsinki and the pharmacy of the University of Eastern Finland, wholesalers and manufacturers of medicinal products shall carry out an inspection relating to the monitoring of trade in medicinal products and pharmaceutical substances to the Finnish Medicines Agency, two thousands of the difference between the price of the sale and purchase of medicinal products, exclusive of VAT (quality control fee). The pharmacy tax or the pharmacy fee is deducted from the corresponding margin for pharmacies before the charge is imposed. Manufacturers of medicinal products pay a fee for the supply of goods directly to a pharmacy or any other person entitled to purchase, without brokering medicinal products. It is proposed to add holders of retail licences for self-pharmaceuticals as a group of operators for which a quality control fee would also be collected. It is proposed to provide for the disclosure of the information required for the payment of the fee in Article 89(2) below.

In accordance with subsection 2 of this section, the Centre for the Safety and Development of Medicinal Products shall fix the fee referred to in paragraph 1 each year and shall be entitled to receive the information necessary for the calculation of the fee free of charge. The Centre for Safety and Development of Medicinal Products shall lay down more detailed rules on the levying of the fee. It is not proposed to amend this article. It would also apply to holders of retail licences for self-treatment medicinal products. The power to order contained in the subsection could also apply to retail licence holders.

ARTICLE 89. Subsection 1 lays down the obligation for pharmaceutical operators to provide the Centre for Safety and Development of Medicinal Products, free of charge and without prejudice to the confidentiality provisions, to provide the Centre with information and explanations relating to medicinal products which are necessary for the performance of the tasks laid down in the Medicines Act, in another law or in an act of the European Union. It is proposed to amend this article to include in the list of operators required to provide information the holders of retail licences for self-treatment medicinal products. Extending the obligation to provide information to those operators would help to enable Fimea to monitor them effectively.

According to subsection 2 of this section, the pharmacist, the pharmacy of the University of Helsinki and the pharmacy of the University of Eastern Finland shall provide the Finnish Medicines Agency with the information necessary for the purposes of its development, planning and supervision tasks, the determination of the quality control fee and the compilation of statistics, of the identification, income and expenditure and otherwise of the financial status of the pharmacy and of other business activities carried out in the same premises as the pharmacy. Further provisions on the information to be provided may be laid down by Government decree. The Centre for Safety and Development of Medicinal Products may issue further provisions on the procedure to be followed for the provision of information.

It is proposed to add to this article the obligation to provide information to holders of retail licences for self-medication medicinal products, so that the retail licence holder should provide the Centre for Safety and Development of Medicinal Products with the information necessary for its development, planning and supervision tasks and for setting the quality control fee for the self-sales of medicinal products. Holders of retail licences for self-treatment medicinal products would be a new group of operators supervised by Fimea, for which it would be necessary to develop, plan and supervise the activities. It is also proposed that the quality control fee referred to in section 84b be collected from this group of operators. The data to be collected would be necessary for these tasks of Fimea. The power to make regulations and orders provided for in the section would continue to apply to this information.

Article 91b. Under the first subparagraph of Paragraph 91a(1), medicinal products within the meaning of Paragraph 91a(1) may also be marketed to persons qualified to prescribe or supply a medicinal product. It is proposed to specify the person entitled to supply the medicinal product referred to in that provision as a pharmacy, hospital pharmacy or pharmaceutical centre authorised to supply medicinal products, since they would be entitled to supply medicinal products subject to medical prescription within the meaning of Paragraph 91a(1) and medicinal products containing narcotic drugs or psychotropic substances. On the other hand, the person authorised to supply the medicinal product would not refer to holders of retail licences for self-treatment medicinal products or to sellers of nicotine products which sell, outside pharmacies, self-medication products which have been granted an extension of the sales channel or nicotine products.

Subsection 2 lays down the content of advertising targeted at persons qualified to prescribe or supply a medicinal product. It is not proposed that the definition of the person entitled to supply a medicinal product referred to in the subsection be amended in accordance with subsection (1), since this paragraph may be interpreted as referring more broadly to advertising to all persons entitled to supply the medicinal product, including, for example, advertising of self-treatment medicinal products.

ARTICLE 97. The section provides that breaches of confidentiality obligations under the Medicinal Products Act are punishable under Chapter 38, Section 1 or 2 of the Criminal Code, unless the offence is punishable under Chapter 40, Section 5 of the Criminal Code or a more severe penalty is laid down elsewhere in the Act. It is proposed to add a reference to Section 54h(2) which would provide for a confidentiality obligation for the retail marketing authorisation holder of self-medical medicinal products and their staff. Failure to comply with this obligation could also be punished under the Criminal Code.

ARTICLE 102. This section provides for appeals against decisions under the Medicines Act. It is proposed to amend this section to take into account decisions on the extension of the sales channel of a self-medicine medicinal product and decisions on retail licences for self-treatment medicinal products.

Under subsection 1 of this section, an inspector’s order referred to in section 78 may be subject to rectification by the Finnish Medicines Agency. The decision of the Centre for Safety

and Development of Medicinal Products in the cases referred to in Sections 2, 6, 8, 12a, 15a, 15c, 17a, 30e, 30 l, 30n, 32, 48, 51, 52a, 52b, 53, 57c, 61, 62, 67, 76a, 84b, 87 and 87a may also be challenged. The objection is governed by the Administrative Procedure Act (434/2003).

It is proposed that the Finnish Medicines Agency should also be able to check holders of retail licences for self-treatment medicinal products under section 77. In such a case, orders issued by the inspector under section 78 could also be issued to the holder of a retail licence for self-medical medicinal products. Those orders could also be the subject of appeal proceedings under the current paragraph 1.

It is also proposed to amend subsection 1 to include the decisions of the Centre for Safety and Development of Medicinal Products on the basis of Article 54f concerning the authorisation for the retail sale of self-medication medicinal products. Given the potentially large number of applicants and the limited range of self-medication products, it is proposed that the authorisation procedure be as straightforward as possible in this presentation and that the application for authorisation would contain only limited information on the applicant's activities. The review procedure could be a necessary appeal stage to ensure the correction of applications for permits that have been rejected, for example due to incomplete or unclear data. In view of the potentially large number of applicants, it would not be justified in procedural economy for all rejected decisions to be brought directly before the Administrative Court. Under the current section, the objection procedure would also be the first stage of appeal in cases concerning, for example, pharmacy service points. Since the first paragraph does not refer to decisions relating to the marketing authorisation or classification of medicinal products, it would not propose to mention the decision to extend the sales channel under the proposed Article 23e(2). The first instance of appeal would be an administrative court.

Under section 29(2), an administrative court decision in a case referred to in sections 29(2), 49, 50, 66, 80, 80a, 80b, 87c, 88a, 93, 101 and 101a may be appealed to the Korkein hallinto-oikeus (Supreme Administrative Court) without leave to appeal. It is proposed to amend the subsection to include also the decisions referred to in subsections 2-3 of the proposed Article 79 which would withdraw the retail licence for self-treatment medicinal products or issue a temporary injunction prohibiting the sale of self-medical products. The proposal would be comparable to the decision to withdraw a pharmacy licence under Section 50 of the Medicinal Products Act referred to in the current section and to the decision on the temporary closure of a pharmacy under Section 80b.

It provides that, in the case referred to in Article 29(2) of the Law on medicinal products, an appeal against a decision of an administrative court may be brought before the Korkein hallinto-oikeus (Supreme Administrative Court) without leave to appeal. This section refers to decisions on the withdrawal and expiry of a marketing authorisation. On the other hand, the decision to change the classification of deliveries, for example, is not mentioned in the list. If the MA holder's application for an extension of the sales channel under the proposed section 23e(2) were rejected, the decision would mean that the marketing authorisation holder could still sell his product on the pharmacy channel. The legal effect would therefore not be as high as that of a decision withdrawing a marketing authorisation, which would completely prevent marketing on the market. It would therefore not be justified to add the decision to extend the sales channel to the list provided for in paragraph 2. In the case of an appeal against an administrative court decision, leave to appeal should be sought.

According to the first paragraph of paragraph 3, the decisions referred to in Articles 2(4), 6, 23c, 30 l, 30n, 59, 66, 80, 80a, 80b, 87, 87c, 88a, 93 and 101 of the Centre for Safety and Health, the decisions referred to in Sections 68 and 71 of the Regional State Administrative Agency and the National Supervisory Authority for Welfare and Health and the orders of the inspector are to be complied with notwithstanding the lodging of an appeal, unless otherwise ordered by the appeal authority. It is proposed to add a temporary injunction on the retail sale of self-medication medicinal products, as provided for in the proposed section 79(3). The current provision refers to the temporary lockdown of pharmacies in accordance with Article 80b of the Law on medicinal products. There is a similar situation in the temporary ban on the retail sale of self-treatment

medicinal products, in which sales should be stopped immediately due to identified medication safety incidents. In such a case, it would be justified not to wait for the decision to become final in the execution.

It is also proposed to add Fimea's decisions in the proposed section 23e(3). Under Article 23e(3), the Medicinal Products Safety and Development Centre could amend the decision referred to in paragraph 2 on the basis of new information received on the basis of a marketing authorisation holder's application or on its own initiative, which affects the sales channel. The subsection refers to the decision in subsection 2 by which the marketing authorisation holder's medicinal product would have been granted an extension of the sales channel. The proposed subsection 3 could concern a situation in which, because of the risks of medicinal product or medication safety identified in a medicinal product, its sale should be immediately restricted to the pharmacy channel only. From the point of view of the protection of the health of users of the medicinal product, it should be possible to enforce such a decision immediately.

According to the second paragraph of paragraph 3, decisions of the Centre for the Safety and Development of Medicinal Products pursuant to Sections 21, 21a and 21c of the marketing authorisation for a medicinal product may be enforced before they have become final, unless otherwise ordered by the appeal authority. The second provision would not be proposed to be amended. The decision to extend the sales channel of a self-medication medicinal product would comply with the rules on the enforcement of the decision under the Administrative Procedure Act.

According to the third paragraph of paragraph 3, decisions of the Centre for the Safety and Development of Medicinal Products pursuant to Articles 40, 41, 52, 53 and 54 may not be enforced until they have become final. It is proposed to amend the provision to include decisions on retail licences for self-medical medicinal products under the proposed Article 54 s. The granting decision would mean that the authorised trader would undertake various economic investments. It would therefore be justified that, in all circumstances, the commencement of the activity should be subject to a final decision. Paragraphs (4) to (5) would not be amended.

7.2. Act amending the Act on the taxation of pharmacies

ARTICLE 1. Scope. Under the current article, a taxable person is required to pay pharmacy tax to the State in respect of a pharmacy which he operates. This proposal proposes to change the taxable amount of the pharmacy tax to the profit margin obtained by the pharmacy on the turnover of the pharmacy on the sales of medicinal products, which would be calculated on the basis of the profit margin of the pharmacy's sales of medicinal products. The taxable amount would be set out in more detail in Article 5 below. In line with the changed taxable amount, it is proposed to clarify the scope provision in such a way that the taxable person would have to pay pharmacy tax to the State on the sale of medicinal products by his pharmacy.

ARTICLE 5. Taxable amount. This section lays down the taxable amount. Paragraph 1 provides that, for the purposes of calculating the amount of pharmacy tax for a tax year, VAT is deducted on the turnover of a pharmacy, a branch pharmacy, a pharmacy service, an online pharmacy service and a medical cabinet.

It is proposed to amend subsection 1 so that the pharmacy tax would be based not on the taxable person's turnover but on the total profit margin for pharmaceutical sales of the taxable person's pharmacies, excluding VAT. The taxable persons would be a private pharmacist, the University of Helsinki and the University of Eastern Finland under Section 3 of the Act on the Tax on Pharmacy. The taxable person's pharmacies would mean a pharmacy, branch pharmacies, pharmacy outlets and an online pharmacy service.

Paragraph 1 would regulate how the profit margin for pharmaceutical sales is calculated and what items are included in it. Under the proposed paragraph, the profit margin for the sale of medicinal products would be the difference between the consideration received at the taxable pharmacy office for the sale of medicinal products free of VAT and the purchase price,

exclusive of VAT, of the medicinal products sold immediately, plus the delivery fee per consignment of the medicinal product referred to in Article 58 of the Medicines Act (395/1987).

The consideration for the sale of medicinal products would be the retail price, exclusive of VAT, for the sale of medicinal products under the Regulation. The profit margin for the sale of medicinal products would be the difference between the consideration received for the sale of medicinal products free of VAT by pharmacies and the purchase price, exclusive of VAT, of the medicinal products sold immediately, plus the delivery fee per consignment of the medicinal product referred to in Article 58 of the Medicines Act (395/1987). The consideration, that is to say the retail price, and the purchase price would be determined at the time of sale of the medicinal product sold in the same way as the retail price of a medicinal product in accordance with the pharmaceutical tariff. The purchase prices, exclusive of VAT, of medicinal products sold immediately would mean deducting the purchase price of the products sold from the consideration received. Thus, a pharmacy would not be able to deduct, for example, medicinal products purchased in stock at the end of the year. The purchase prices of immediately sold medicines, exclusive of VAT, would mean the purchase price of the medicinal products sold to customers at the time of sale.

According to paragraph 1 of the proposed article, in the case of a medicinal product prepared on prescription in a pharmacy, the purchase price of the substances used, packaging materials and media used in the administration of the medicinal product would be deducted from the consideration received for the sale of medicinal products before the price of delivery is increased.

The amounts to be deducted from the consideration for medicinal products produced in a pharmacy would be based on the Annex to the Government Decree on the Medicinal Tariff, which sets the prices of prescriptions. According to the Annex 1. The purchase price of the substance used in the manufacture of the medicinal product shall be multiplied by a factor of 2,0. The lowest price of a substance used in the manufacture of a medicinal product is EUR 0.84. 2. The price of a medicinal product or substance is added as a manufacturing charge for making the medicinal product ready for use (contains water in antibiotic winds) and weighing an individual substance EUR 1.68, for sterile manufacture EUR 13.46 and 3. For other medicinal products, EUR 6,73 4. The prices calculated in points 2 to 3 shall be added, in addition to the manufacturing quantity, to EUR 1,68 for the manufacture in excess of the following amounts: the preparation of creams, gels, solutions and powders per distribution unit, the preparation of portion powders, anft-hoots and pills per 10 units, the manufacture of capsules per 20 units and the manufacture of tablets per 100 units. 5. The prices of packaging materials and equipment used to administer medicinal products are determined by multiplying the selling price invoiced by the wholesaler or producer by 2.0.

The pharmacy tax base could be deducted from the pharmacy tax base for items based on the Annex to the Medicinal Products Tax Regulation which a pharmacy has to obtain from elsewhere in order to be able to manufacture the medicinal product. The items would be reduced in simple form. The manufacturing levies and coefficients referred to in the annex may be regarded as constituting elements of the pharmacy’s margin for recipes and could not therefore be deducted from the consideration as a purchase price.

In addition, the proposed paragraph 1 would provide that the delivery fee per consignment referred to in Article 58 of the Law on medicinal products should be included in the profit margin on the sale of medicinal products. The delivery fee is charged to the customer for the supply of prescription-only medicinal products and is an integral part of the sale of prescription-only medicinal products and should therefore also be included in the calculation of the profit margin for pharmaceutical sales by pharmacies.

Paragraph 2 of the current article lays down the items to be deducted from the taxable amount. In addition, the VAT-exempt turnover is to be deducted from the VAT-exempt proportions of (1) the value of sales of contract manufacturing within the meaning of Paragraph 12(2) of the Medicines Act (395/1987) and sales of medicinal products to social and healthcare establishments; (2) the value of sales of nicotine-reimbursable medicinal products which, under the Medicines Act, may also be sold outside a pharmacy; (3) sales of products other than medicinal products, up to a maximum of 20 % of turnover subject to deductions pursuant to paragraphs 1 and 2; and (4) the proportion of sales of medicinal products with a wholesale price above EUR 1500, to the extent that the retail price, exclusive of VAT, of each such medicinal product exceeds EUR 1683,92.

It is proposed to amend subsection 2 in order to provide, in paragraphs 1 to 4, for sales of medicinal products by a taxable person for which the consideration received and the purchase price could be disregarded when determining the taxable amount for pharmacy tax in accordance with paragraph 1. In accordance with points 1 and 2 of the proposed subsection 2, the taxable amount is not to be taken into account for the purposes of the taxable person's contractual preparation within the meaning of Paragraph 12(2) of the Law on medicinal products (395/1987) or the sale of medicinal products to social and health care establishments. Point 1 and 2 would be in line with the first subparagraph of the second paragraph in force, with the difference that, where taxation is based on the profit margin on the sale of medicinal products, the purchase price and other related costs of the sale of medicinal products referred to in that paragraph should also be disregarded.

It is proposed to transfer paragraph 2 of the current section, as amended, into a new paragraph 3. According to the proposed paragraph 3, when determining the taxable amount, the taxable person's sales of nicotine-reimbursable medicinal products which, under the Medicines Act, may also be sold outside a pharmacy, would not be taken into account. The paragraph would be amended so that, where taxation is based on the profit margin on sales of medicinal products, not only the value of sales but also the purchase price of the pharmaceutical sales referred to in paragraph should be excluded.

It is proposed to repeal points 3 and 4 of subsection 2. The basis for the pharmacy tax would be the profit margin for pharmaceutical sales, so that it would not be necessary to provide for other products to be taken into account for the purposes of pharmacy taxation, as in the case of paragraph 3. The proposed tax model would eliminate the problem of negative mark-up, so paragraph 4 would also be superfluous.

It is proposed to add as a new paragraph 4 the deletion of the limited range of self-medicines referred to in Section 23d of the Medicines Act proposed in this proposal from the taxable amount for pharmacy tax. Since the products in the range could also be sold outside pharmacies in the future, it is proposed to remove them from the pharmacy tax base in order to ensure as equal conditions as possible of competition. The entire range defined in Section 23d of the Medicinal Products Act and the decree adopted on the basis thereof, whether or not an extension of the sales channel has been requested for the product, should be disregarded when determining the basis for the pharmacy tax.

ARTICLE 6. Tax scale. This section lays down the scale of the pharmacy tax to be calculated by turnover group. There are ten steps in the tax scale. The pharmacy tax rate varies between 6.10 % and 11.20 %. In addition, pharmacy operators whose total turnover would be less than EUR 871393 would not pay any pharmacy tax.

It is proposed that this section be amended so that the pharmacy tax would be calculated on the basis of the total profit margin for pharmaceutical sales made by the pharmacies of the taxable person. The proposed new tax scale would consist of six profit margins for pharmaceutical sales. The first so-called zero step would cover the profit margin of pharmaceutical sales of

pharmacies in the range of EUR 0-250 000. The pharmacy tax at the lower mark-up threshold for pharmaceutical sales would be EUR 0 and the tax rate of the lower limit, i.e. the profit margin for pharmaceutical sales above EUR 0, up to EUR 250000, would be 0 %.

The second step would consist of a profit margin for pharmaceutical sales of between EUR 250000 and EUR 500 000. The pharmacy tax at the lower profit margin threshold for pharmaceutical sales, i.e. EUR 250000, would be EUR 0. The tax rate for the profit margin on pharmaceutical sales above the lower threshold up to EUR 500000 would be 22 %.

The third step would consist of a profit margin for pharmaceutical sales of EUR 500000-750 000. The pharmacy tax at the lower profit margin threshold for pharmaceutical sales, i.e. EUR 500000, would be EUR 55000 and the tax rate for pharmaceutical sales above the lower threshold up to EUR 750000 would be 37 %.

The fourth step would consist of a profit margin for pharmaceutical sales of between EUR 750000 and EUR 1000 000. The pharmacy tax at the lower profit margin threshold for pharmaceutical sales, i.e. EUR 750000, would be EUR 147500. The tax rate for the profit margin on pharmaceutical sales above the lower threshold up to EUR 1000000 would be 39 %.

The fifth step would consist of a profit margin for pharmaceutical sales of between EUR 1000000 and EUR 1500 000. The pharmacy tax at the lower profit margin threshold for pharmaceutical sales, i.e. EUR 1000000, would be EUR 245000. The tax rate for the profit margin on pharmaceutical sales above the lower threshold up to EUR 1500000 would be 41 %.

The sixth step would consist of a profit margin on pharmaceutical sales of more than EUR 1500000. The pharmacy tax at the lower profit margin threshold for pharmaceutical sales, i.e. EUR 1500000, would be EUR 450000. The tax rate on the profit margin on pharmaceutical sales above the lower threshold would be 43 %.

ARTICLE 7. Calculation of the amount of the tax. The current article provides for the calculation of the pharmacy tax. According to subsection 1, the pharmacy tax is calculated for each taxable person separately. It is not proposed to amend this article.

Under Paragraph 6(2), if the pharmacy does not have a branch pharmacy, the pharmacy tax is to be calculated on the basis of the combined taxable amount of the pharmacy, the pharmacy's service centre, the pharmacy's online service and the medical cabinet, on the basis of the tax scale laid down in Paragraph 6. It is proposed to amend this article to take account of the changes in pharmacy taxation proposed in this proposal. For the reasons set out in the general statement of reasons, it is proposed to waive the special tax treatment of branch pharmacies. It is therefore proposed to amend this paragraph so that the pharmacy tax would be calculated on the basis of the combined taxable amount of the pharmacy, branch pharmacy and online pharmacy services on the basis of the scale laid down in Paragraph 6. If a pharmacy had more than one branch pharmacy or more pharmacy outlets, they would be taken into account in the taxable amount.

Subsections 3 to 7 provide for the special treatment of branch pharmacies in the field of pharmacy taxation. It is proposed to delete the articles. The profit margin for sales of medicinal products by branch pharmacies would be taken into account as part of the taxable person's profit margin on pharmaceutical sales, like other pharmacies.

7.3 Act amending the Act on electronic prescription

Paragraph **10 Correction, annulment and renewal of the prescription and the indication of the cessation of use of the medicinal product.** Subsection 1 provides for the correction of a prescription. According to this subsection, if the prescription in the centre of prescription is incorrect, the prescriber of the prescription may make the necessary corrections to the prescription. In addition, pharmacists and pharmacists supplying the medicinal product from a pharmacy may make the necessary technical corrections at the time of delivery. If the content of the prescription is unclear or incomplete, the oral consent of the prescriber shall be obtained. Subsection 2 provides for the annulment of a prescription, subsection 3 provides for the renewal of the prescription and paragraph 4 provides for the cessation of the use of the medicinal product. In accordance with paragraph 5 of that article, the repair, cancellation, non-renewal or termination of a medicinal product in use referred to in paragraphs 1 to 4 must be justified. In accordance with subsection 6 of this section, more detailed provisions may be laid down by decree of the Ministry of Social Affairs and Health concerning the rectification, annulment, renewal and non-renewal of an electronic prescription and the indication of cessation of use of the medicinal product.

Subsections 1 to 4 are not proposed to be amended. It is proposed to add, as a new paragraph 5, provisions allowing a pharmacist or pharmacist working in a pharmacy to correct manifest errors in the prescription. Under the proposed provision, a pharmacist and pharmacist supplying an industrially manufactured medicinal product from a pharmacy would be able to correct an obvious error in the prescription addressed to the user of the medicinal product in relation to the trade name, pack size, pharmaceutical form, strength or dosage instructions of the prescribed medicinal product. A correction should be necessary on the basis of pharmaceutical judgement. It should not jeopardise the safety of medication, indicate that the total quantity of the medicinal product is exceeded or deviate from the particulars of the prescription by the prescriber. In the case of a prescription or prescription issued or stored by telephone for a compassionate medicinal product, a medicinal product containing a narcotic substance, a medicinal product primarily active on the central nervous system or a medicinal product containing alcohol, the repair should be subject to the consent of the prescriber. The repair should be made in agreement with the purchaser of the medicinal product and in accordance with Article 57 of the Medicines Act. The purchaser of the medicinal product should be invited to communicate with the prescriber if necessary. Information on how to correct the prescription, the person who issued it, the reason, and any contact with the prescriber should be recorded in the prescription centre.

According to the proposed provision, the repair could be carried out by pharmacists and pharmacists supplying the medicinal product in the pharmacy. As a healthcare professional, this would be responsible for ensuring patient safety when the prescription is corrected and when the medicinal product is supplied. A pharmacist or pharmacist serving the patient would have first-hand knowledge of the relevant circumstances in the event of supply. A pharmacist working in a pharmacy could, of course, also be a pharmacist serving the patient, a university pharmacy or a branch pharmacy. That condition would contribute to ensuring that medication safety is achieved when a prescription is corrected in a pharmacy.

The correction of the prescription as proposed would be an exceptional procedure. As a general rule, medicinal products would be supplied as before. The correction of the prescription could only concern a manifest error in the prescription addressed to the user of the non-delivered medicinal product.

The prescription should cover an industrially prepared medicinal product addressed to the user of the medicinal product. This would only allow a correction to be made to prescriptions for industrially manufactured medicinal products for human use which are addressed to the user

of the medicinal product. That would not be possible if there were a pro auctore prescription or a prescription under which the pharmacy would manufacture the medicinal product or if the prescription concerned veterinary medicinal products. The prescription to be corrected could be a domestic or European prescription.

The independent right of a pharmacist or pharmacist working in a pharmacy to correct a prescription under the proposed paragraph 5 would be limited to manifest errors. In addition, the prescription should not be provided, i.e. it would not have previously provided the customer with any packet of medicinal products. If an error were to be found in the prescription submitted, that would be an indication that the error was not obvious and that, in order to correct the prescription, there would have to be contact with the prescriber in accordance with the first paragraph of the section. The obviousness of the error would always be assessed by a pharmacist or pharmacist working in a pharmacy. A manifest error should be deduced from the information available in the pharmacy. An obvious error could, for example, be that the previously used dosage of a medicinal product used on a regular basis would have changed significantly, e.g. tenfold or the pharmaceutical form changed in the past without the customer being informed of this.

If the prescription were so ambiguous or incomplete that it is not possible to determine which medication or by what instructions the prescriber intended to prescribe, it would be clear that a pharmacist or pharmacist working in a pharmacy would not be able to correct the prescription without contacting the prescriber from the point of view of medication safety. If it is suspected that a defect is possible but the error is not obvious, the pharmacist or pharmacist should, if necessary, lock the prescription and contact the prescriber to correct the prescription in order to ensure medication safety.

The obvious error should concern the trade name, pack size, pharmaceutical form, strength or dosage instructions of the prescribed medicinal product. For example, a prescription could be corrected if, unlike a previous medication, the customer had been prescribed a medicinal product in a different pharmaceutical form, a medicinal product of different strengths, or a manifest error in the dosing instructions.

A pharmacist or pharmacist working in a pharmacy would also have the right to remedy a manifest error in the brand name of the medicinal product. However, particular care should be taken to ensure that the correct repair is done and that the correct medicinal product containing the active ingredient is supplied to the client. A medicinal product may also be defined in a prescription only by reference to the active substance. For example, in European prescriptions, as a general rule, a medicinal product is defined by the active substance only. Where that is the case, the application of the prescription to the brand name of the medicinal product would be part of the normal supply of the medicinal product and, in such situations, it would not constitute a ‘prescription’. The repair could then be limited to the strength, pack size and dosage of the medicinal product.

In the proposed subsection 5, the list of information that a pharmacist or pharmacist working in a pharmacy could correct could be exhaustive. This would mean that other information on the prescription could not be corrected. The list would correspond to the prescription information under Paragraph 57f(1) of the Medicinal Products Act proposed in this proposal, from which a pharmacist or pharmacist working in a pharmacy could derogate under the conditions laid down in that section.

The correction of the prescription would require that all the conditions laid down in the proposed subsection 5 be met. According to the proposed paragraph, the correction of a manifest error should be necessary on the basis of pharmaceutical judgement. The pharmacist and pharmacist should assess whether, on the basis of pharmaceutical judgement, the repair is necessary in order to ensure the continuity of the medical treatment of the customer.

The subsection also requires that the repair should not compromise the safety of medication, indicate that the total quantity of the medicinal product is exceeded or deviate from the particulars prescribed by the prescriber. The safety of medication should be ascertained on the basis of a case-by-case assessment by a pharmacist or pharmacist, which should determine whether the repair can be carried out in a medication-safe manner. The assessment should take into account the health and cognitive status of the user of the medicinal product. The client should always be referred to healthcare if the pharmacy cannot solve the situation in a medication safe manner. The need to contact the pharmacy should be assessed on a case-by-case basis. When repairing, the pharmacy should always provide the patient with the necessary medical advice and ensure the success of the follow-up treatment;

The repair should not mean that the total prescribed quantity of the medicinal product has been exceeded. That limitation would mean that a pharmacist or pharmacist working in a pharmacy would not be able to correct manifest errors relating to the period of validity of the prescription or the quantity of the medicinal product. If a pharmacist or pharmacist working in a pharmacy were able independently to correct the period of validity of the prescription or the total number of medicinal products prescribed under it, that correction would necessarily alter the total quantity of the medicinal product prescribed. Therefore, it is not proposed to allow a correction in these situations. If necessary, the pharmacy could have the right to make a different supply under Paragraph 57f(3) of the Medicinal Products Act, as proposed in the draft, in order to ensure the continuity of medical treatment for the customer if the conditions laid down in that paragraph were met.

The paragraph would also require that the repair should not constitute a departure from the particulars made by the prescriber on the prescription. For example, if the prescriber had imposed a prescription ban, the trade name of the medicinal product should not be corrected without the consent of the prescriber. If the brand name were considered to be manifestly incorrect, the pharmacy would have to communicate with the prescriber in order to clarify the lack of clarity under Paragraph 10(1) of the Law on electronic prescription. The same would apply to other specific indications, such as iteration of prescriptions and SIC labelling.

In the case of a prescription or prescription issued or stored by telephone for a compassionate medicinal product, a medicinal product containing a narcotic substance, a medicinal product primarily active on the central nervous system or a medicinal product containing alcohol, the repair should be subject to the consent of the prescriber. That condition would be based on the specific nature of those prescriptions and the associated risks of misuse of medicinal products.

In addition, the repair would have to be made in agreement with the purchaser of the medicinal product and in accordance with Article 57 of the Medicinal Products Act. The purchaser of the medicinal product should be invited to communicate with the prescriber if necessary.

The subsection would also require that information on the rectification of the prescription, the person who issued it, the reason for the prescription and any contact with the prescriber be recorded in the prescription centre.

However, it would not be possible to record that information in the customer’s prescription before 1 October 2027, in accordance with the nationally defined causal codes, and therefore the proposed amendment to Article 10 would apply from 1 October 2027.

It is proposed to transfer the existing paragraph 5 into a new paragraph 6. It is proposed to amend this article to include a reference to a new paragraph 5. According to the amended provision, the repair, cancellation, non-renewal or termination of a medicinal product in use, as referred to in paragraphs 1 to 5, should be justified.

The current paragraph 6 would be transformed unchanged into a new paragraph 7. According to that provision, more detailed provisions may be laid down by decree of the Ministry of Social Affairs and Health concerning the rectification, annulment, renewal and non-renewal of an electronic prescription and the indication of cessation of use of the medicinal product. After the entry into force of the proposed legislative amendment, the power to adopt a regulation would also apply, with effect from 1 October 2027, to the correction of obvious defects in prescriptions in a pharmacy under the new paragraph 5.

Section **13 Patient's right to order the disclosure of information. In accordance with** subsection 1 of this section, information from the National Medical List in the prescription centre on medicinal products prescribed for the patient and the related labelling may be disclosed, without prejudice to confidentiality regulations, to healthcare and social care providers and to the prescriber for the organisation and implementation of the patient's health and medical care. However, the patient may refuse the disclosure of the information relating to the medicinal product prescribed to the persons and pharmacies referred to above. The issuing and revocation of the prohibition is governed by Section 58 of the Customer Information Act.

Paragraph 3 provides that, notwithstanding subsection 1, the information referred to in subsection 1 may be disclosed, inter alia, if the provision of information or the right to be informed is expressly provided for by law, information on all prescriptions prescribed for a patient and narcotic drugs and related labelling, on the medical or social service provider responsible for the renewal of a prescription or on the prescriber's prescription, the details of the prescriptions requested by the patient for renewal and, in accordance with paragraph 4, information on the prescriptions stored by the prescriber in the prescription centre and on the medical relationship, irrespective of the changes to the prescription in accordance with Article 12(3) of the pharmacy, the prescriptions in the medical prescription centre and the recording of the prescription in the medical prescription centre.

In this presentation, it is proposed that information on deviations from the prescription by pharmacies and the correction of a manifest error in the prescription be recorded in the prescription centre. A derogation from the prescription would take effect on 1 January 2026 and a wider correction of obvious errors would apply from 1 October 2027. Prior to that, under Paragraph 10(1) of the current Law on electronic prescriptions, pharmacies would have an independent right to make technical corrections to the prescription and, with the consent of the prescriber, to make other repairs.

It is proposed to amend subsection 3(4) to take into account the derogation from the prescription and the ePrescription provided for in Article 10 of the Law on medicinal products by a pharmacist and pharmacist working in a pharmacy, within the meaning of Article 57f of the Law on medicinal products, which, before 1 October 2027, would mean technical repairs and other corrections made with the consent of the prescriber and, in addition, corrections of manifest defects within the meaning of Article 10(5) of the proposed Article 10 on 1 October 2027. According to the proposed provision, the prescriber would have the right to be informed of these deviations and corrections to prescription deliveries, irrespective of the therapeutic relationship, even in situations where the patient would have refused to provide the information if the prescriber is labelled as the prescriber. Subsections 1-2 and 3-3 and 5-9 would not be amended.

7.4 Act amending the Health Insurance Act

Chapter 5 Reimbursement of medicinal products

ARTICLE 1. ***Medicinal product to be reimbursed.*** Paragraph 1 provides that the insured person is entitled to reimbursement of the costs of a medicinal product prescribed by a doctor and a dentist and by a nurse entitled to prescribe a limited or fixed-term medicinal product. In

addition, the insured person is also entitled to reimbursement of an interchangeable medicinal product listed by the Centre for Safety and Development of Medicinal Products for which the medicinal product prescribed for the patient has been exchanged in a pharmacy in accordance with Section 57b of the Medicines Act.

It is proposed to add that the insured person would also be entitled to reimbursement of a medicinal product supplied to the patient under Section 57f of the Medicinal Products Act or in a pharmacy on the basis of a corrected prescription under Section 10 of the Act on electronic prescription (61/2007). The addition would mean that if a pharmacy were to deviate from the prescription in accordance with Paragraph 57f proposed in this presentation and the medicinal product to be supplied to the insured person would have to be reimbursed, he would be entitled to reimbursement of the medicinal product supplied. Similarly, if the insured person were to be supplied with a pharmacy under Article 10 of the Law on electronic prescription on the basis of a revised prescription, the insured person would be entitled to reimbursement of the medicinal product supplied and which should be reimbursed.

The reference to repairs under Article 10 of the Law on electronic prescription would mean, before 1 October 2027, technical repairs carried out independently by a pharmacy or other repairs carried out with the consent of the prescriber and, as from 1 October 2027, corrections made by the pharmacy independently under Article 10(5) of the Law on electronic prescriptions or, with the consent of the prescriber, in special prescriptions. Reimbursement would always require that the medicinal product supplied to the customer as a result of an incident or repair should be reimbursed. The last provision of the paragraph, which provides that the reimbursement of a medicinal product approved by the Medicinal Products Pricing Board is valid and that the price charged to the insured person for the medicinal product does not exceed the reasonable wholesale price fixed or the maximum wholesale price referred to in Chapter 6, Paragraph 22, plus, at most, a margin for the supply of a pharmacy in accordance with the pharmaceutical tariff referred to in Article 58 of the Law on medicinal products and VAT, would apply to the additional elements. Subsections 2-3 would not be amended.

Chapter 18 Health insurance *fund and insurance premiums*

ARTICLE 10. State contribution. The section provides for a state contribution. According to the current article, 51.4 % of the total cost of health insurance costs under Article 8(1)(1) to (4), (2) and (3) of the Act is financed from State resources. In addition, the costs of medical treatment referred to in Section 8(1)(5) are financed from State resources in so far as they are not covered by reimbursements received from abroad on the basis of health care benefits provided in Finland. In addition, it is proposed to provide that the refund fee referred to in Chapter 6, Section 6a, subsection 2 of the Act should be fully allocated to the reduction of the State contribution.

8 Sub-statutory regulation

Section 23d of the Medicines Act proposes a new power to issue regulations. It would further define by Government decree the limited range of self-treatment medicinal products referred to in subsection 1 of the section. According to the new regulatory power proposed in Section 54h of the Medicinal Products Act, more detailed provisions on the premises of the licensee, the induction and guidance of the staff, the control arrangements, the storage, treatment and waste of medicinal products for self-treatment could be laid down by Government decree. In addition, Section 54i of the Medicines Act proposes a new power to issue regulations, which would allow more detailed provisions on the duties of the responsible person to be laid down by government decree. The draft Government Decree amending the Medicinal Products Decree, which is to be adopted at the Government General Session after the proposed adoption, is attached to the draft. The draft shall contain the provisions referred to in Articles 23d, 54h and 54i above.

It is proposed to amend Sections 2(1), 9(2), 32(2), 33(2), 34(1), 35, 52b, 58, 77, 84b(1) and 89 of the Medicinal Products Act. These articles include the power to issue decrees granted to the Government and/or the power to issue directions granted to the Centre for the Safety and Development of Medicinal Products. It is not proposed that the powers to issue regulations or directions in the sections be amended in the proposal, with the exception of the amendment broadening the wording of the power to issue regulations in Section 58 of the Medicinal Products Act. The Government Decree amending the Government Decree on the Tariff of Medicinal Products (annexed to the proposal), based on Section 58 of the Medicinal Products Act, is to be adopted after the adoption of the proposed Acts at the General Session of the Government.

However, it can be seen that at least the power to make regulations and/or to issue directions contained in Articles 34, 52b, 58, 77, 84, 89b of the Medicinal Products Act could, in the future, be directed at a new group of operators, that is to say, holders of retail licences for self-treatment medicinal products. In addition, the power to issue regulations under Article 77 of the Law on medicinal products could also apply to the recording system for the safety features of medicinal products and to the operator of the recording system. The draft Medicinal Products Regulation annexed to the proposal contains a provision based on the power to issue a regulation in Section 52b of the Medicinal Products Act, which is proposed to be amended to include the distance sales of self-treatment medicinal products by the holder of a retail licence for self-treatment medicinal products. On the basis of the amendments to Section 58 of the Medicinal Products Act, it is proposed to add to the draft Decree on pharmaceuticals annexed to the proposal a regulation on the pricing of a limited range of self-pharmaceuticals. The proposed amendment to Section 35 of the Medicinal Products Act has already been taken into account in the provision of the Medicinal Products Regulation, which is based on the power to issue regulations in that section.

It is proposed to amend Article 10 of the ePrescription Act. The power to issue decrees of the Ministry of Social Affairs and Health in this section would not be proposed to be amended. According to the power to issue a decree, more detailed provisions may be laid down by decree of the Ministry of Social Affairs and Health concerning the rectification, annulment, renewal and non-renewal of an electronic prescription and the indication of cessation of use of the medicinal product. However, with the proposed amendment to the Act, the power to adopt a regulation could also extend to the correction of obvious errors in prescriptions.

The proposed amendments to the Act on the taxation of pharmacies and the Health Insurance Act would not provide for sub-statutory regulation. The amended articles in force do not contain any power to issue regulations or orders.

9 Entry into force

The laws proposed in the draft, i.e. the Act amending the Medicines Act, the Act amending the Act on Pharmacy Tax, the Act amending Chapter 5, Section 1 and Chapter 18, Section 10 of the Health Insurance Act and the Act amending Sections 10 and 13 of the Electronic Medical Prescription Act, as well as the proposals for amendments to the Regulations which are part of the package, which would be adopted after the parliamentary examination of the Act, i.e. the Government Decree amending the Government Decree on the Medicinal Products Tariff and the Government Decree amending the Medicinal Products Decree, are all intended to enter into force as of 1 January 2026.

The pharmaceutical tax cut for prescription medicines and the full allocation of conditional reimbursement refund payments to the State aim at permanent savings from the beginning of 2026. It is proposed that the entry into force of the Government Decree amending the Decree on Medicinal Products provides for the application of Section 3(1) of the Decree on the tariff

of medicinal products subject to medical prescription from 1 January 2026. The Act amending the Health Insurance Act would also apply from its entry into force on 1 January 2026.

The Act amending the Act on the taxation of pharmacies proposes to provide that the provisions of the Act should apply for the first time to the pharmacy iver to be collected for the year 2026. The tax period for the pharmacy tax is the calendar year. With the entry into force of the Act on the taxation of pharmacies from the beginning of 2026, the 2025 tax period has just ended and, pursuant to the Act on the Procedure for Taxation of Own-initiative Taxes (768/2016), the tax return for the tax period is to be submitted and the tax paid by the end of February 2026 at the latest. The proposed amendments to the pharmacy tax law would then already be in force. In order to prevent the retroactive entry into force of the law, it should be applied for the first time in the 2026 tax period.

It is proposed that the sale of certain self-medication medicines outside pharmacies should start one year after the entry into force of the Medicines Act, i.e. as of 1 January 2027, due to the time needed to implement the law by public authorities, electronic authorisation systems and internal processes. The provisions proposed in the Law on medicinal products concerning the sale outside pharmacies of self-treatment medicinal products would apply in such a way that marketing authorisation holders could apply for an extension of the sales channel for their own-care medicinal product from 1 October 2026 and traders could apply for a retail licence for self-pharmaceutical medicinal products from 1 January 2027. In accordance with that timetable, the provisions proposed in the Law on medicinal products concerning retail licences for self-medical medicinal products would apply from 1 January 2027 and the regulation on the extension of the sales channel for self-medical medicinal products in a limited range would apply from 1 October 2026.

However, it is proposed that a limited range of self-medication products could already be established after the entry into force of the Medicines Act as from 1 January 2026 and that the exceptional pricing applicable to it could be applied in pharmacies from the entry into force of the Act. It is also proposed to remove from the taxable amount of pharmacy tax for the first time in the tax period to be collected for the year 2026, self-medication products from the limited range. Pharmacies would thus benefit from the sale of a limited range of self-pharmaceuticals one year before sales outside their pharmacies started. Article 23d of the Law on medicinal products concerning the limited range of self-medication products and the proposed regulation concerning samples of medicinal products (Article 35(1)), the pharmacy's right to derogate from the prescription (Articles 57f to 57 g), retail pricing (Article 58) and, as regards the operator of the system for recording and recording the safety features of medicinal products, the inspection provision (Article 77(1)) would apply from the entry into force of the Act, that is to say, from 1 January 2026.

The Government Decree amending the Medicinal Products Decree would apply in such a way that Section 11 on the formation of a limited range of self-medication medicinal products would apply from the entry into force of the Decree on 1 January 2026. However, it is proposed that Article 9, which is repealed by the proposed decree, apply until 30 September 26 to the classification of medicinal products for supply, since Article 23b of the Law on medicinal products, which concerns the classification of supplies of medicinal products, would not apply until 1 October 2026. The other proposed Articles 12, 12a and 21b of the Medicinal Products Regulation and the heading to be inserted before Article 13 would relate to holders of retail licences for self-medical medicinal products and it is therefore proposed that their application be applied at the same time as the retail licences for self-treatment medicinal products, that is to say, from 1 January 2027.

The Government Decree amending the Medicinal Products Tax Decree would become applicable as soon as it enters into force. It would provide for a tariff for prescription-only

medicinal products and a different pricing of self-medicines within the limited self-care range, which is proposed to be applied only in pharmacies during 2026 and in pharmacies and in the sale of self-care medicinal products by holders of retail licences for self-care medicinal products as from 1 January 2027.

The proposed amendment of Article 13 of the Law on electronic prescription would apply from the entry into force of the Act on 1 January 2026, since the right of pharmacies to derogate from the prescription under Article 57f of the Law on medicinal products would apply from 1 January 2026. However, Article 10 of the Law on electronic prescription, as amended, would not apply until 1 October 2027. Before that date, it would not be possible for the pharmacy to record non-technical corrections to the prescription. Therefore, it should be possible for pharmacies to correct obvious errors only after 1 October 2027, allowing corrections to the prescription to be recorded in the customer's prescription data in accordance with nationally defined cause codes.

10 Toimeenpano ja seuranta

[To be completed after consultation]

11 Relationship with other presentations

11.1.Reliance of the proposal on other presentations

This presentation proposes to give pharmacists and pharmacists working in a pharmacy the right to derogate from the prescription in certain situations and to correct certain manifest errors in the prescription. It is proposed that the right to repair enters into force on 1 October 2027. These amendments to the Medicines Act and the ePrescription Act relate to the same subject matter as the Government's proposal to amend the ePrescription Act and certain related laws (HE xxx/2025 vp).

11.2 Relation to the draft budget

The proposal is linked to the draft state budget for 2026 and is intended for consideration in the context of the draft state budget for 2026.

12 Relationship with the Constitution and order of enactment

12.1. Regulation of pharmaceutical prices and taxation of pharmacies

It is proposed to cut the retail price of prescription medicines and to amend the pharmacy tax. In addition, the Medicines Act proposes to define a limited range of self-medication products, which would not be included in the pharmacy tax base and would be subject to a different price regime for other self-medication products. In the case of self-medication medicinal products in a limited range, pharmacies and, as from 1 January 2027, holders of retail licences for self-medication medicinal products could also conclude separate wholesale price reduction agreements with pharmaceutical companies in derogation from Article 37a of the Law on medicinal products and grant discounts to the consumer for those products below the uniform national wholesale price level. However, the Medicinal Tariff Regulation would lay down, for those products, a maximum retail price based on the tariff and some other pricing rules.

The proposed regulation is relevant to the right to property guaranteed by Article 15 of the Constitution of pharmacies, pharmaceutical companies and holders of retail licences for self-medical medicinal products. In its opinion (PeVL 49/2005 vp), the Constitutional Committee stated that "the right to *property includes not only the power to use its property as it sees fit (control power) but also the power to dispose of it (disponse power), for example by selling it.*

In principle, pharmaceutical manufacturers are entitled to sell their products to pharmacies at the price they wish. Pharmaceutical manufacturers are not considered to have a legitimate expectation that the system will remain unchanged. However, sudden and exceptional changes in the system may lead to a conflict with the protection of the legitimate expectation that the parties to the contract must be able to rely on the permanence of the law governing the rights and obligations which are essential to the contractual relationship, so that such matters cannot be regulated in such a way as to unreasonably prejudice the legal position of the parties to the contract (PeVL 36/2004 vp, p. 3/I and PeVL 25/2005 vp, p. 3/I). However, since it does not follow from the entry into force of the draft law that the law is intended to apply retroactively also to procurement and cooperation contracts concluded before the entry into force of the Act, the price regulation can only apply to contracts concluded after the entry into force of the Act. Therefore, in the opinion of the Constitutional Committee, regulation is not problematic from the point of view of the right to property."

The impact assessment shows that some new pharmacies would become notionally loss-making as a result of the proposed changes. This is relevant to the right to property, since imputed loss-making appears to stem from the proposed changes in the system and since, under the Medicinal Products Act, the holder of a pharmacy licence can only give up a pharmacy if a new pharmacy is taken over by a new pharmacy. However, it should be noted that the profitability of a pharmacy is influenced by a number of factors, such as the place of business, the location of the location, competing pharmacies and the structure of sales. The proposed amendments represent only some of the factors affecting the overall pharmacy business and it is possible for the pharmacy to take various adjustment measures to take account of price cuts in its business. It should also be borne in mind that, in order to ensure the provision of medicinal products to the public in the region, it is legitimate to require that the pharmacist may not unilaterally, with immediate effect, abandon the pharmacist. In addition, as a trader, the pharmacist bears a certain business risk in relation to its business activities, which include various regulatory changes.

The proposed regulation must be adopted on the basis of general requirements for restrictions on fundamental rights (PeVM 25/1994 vp and HE 309/1993 vp). Restrictions on fundamental rights must be based on a law adopted by Parliament and be precise and sufficiently precise. In its opinion PeVL 19/2002 vp on the regulation of the prices of medicinal products, the Constitutional Committee stated that*"price regulation is aimed at the protection of property guaranteed by Article 15 of the Constitution. The draft law must therefore contain sufficiently precise provisions on the criteria for determining the retail price of a medicinal product so that it can be dealt with in the ordinary legislative procedure.'* The regulation of the price of medicinal products is based on Articles 37a and 58 of the Law on medicinal products. More specifically, price regulation is laid down in the Government Decree on the Medicinal Product Tax. The pharmacy tax in its entirety is governed by the Act on the taxation of pharmacies, which defines the taxable amount, the items to be deducted from the taxable amount and the tax scale. The regulation meets the requirements of strict and precise regulation at the legal level.

The second requirement is that the grounds for restriction must be acceptable and proportionate to a pressing social need. The proposed amendments fulfil these conditions. In its opinion (PeVL 56/2005 vp), the Constitutional Committee stated that "*The aim of the regulation is to ensure that the population has equal access to medicines needed to treat the disease at affordable prices. For its part, it implements the obligation imposed on the public authorities by Article 19(3) of the Constitution to promote the health of the population. The proposal is therefore justified by the fundamental rights system (see also PeVL 49/2005 vp, p. 2/I).*' The changes to the pharmaceutical tariffs for prescription medicines and the

amendments to the Law on the taxation of pharmacies are based on a government programme which provides for an overall reform of the pharmaceutical economy aiming at savings of EUR 30 million per year in public finances and a more cost-effective retail distribution system for medicinal products. The reforms will be implemented in a way that ensures regional access to medicines and pharmaceutical services, as well as safety of medicines and medication. The reform of the pharmacy economy takes into account the pharmacy tax and the pharmaceutical tariff together, taking into account the actual profitability of the pharmacies and securing a nationwide network of pharmacies, pharmaceutical support (including medical advice), medication safety and access to medicines for rational pharmaceutical treatment.

In addition, in its opinion (PeVL 49/2005 vp), the Constitutional Committee has drawn attention to the problem of the so-called negative margin and considered that the regulation on it under Article 58 of the Medicines Act was not entirely problematic. The proposed pharmacy tax regime in this proposal, based on the profit margin for pharmaceutical sales, proposes to remedy the problem of negative margins.

For a limited range of self-medication medicinal products, it is proposed to provide for exceptional pricing whereby separate wholesale price reductions would exceptionally be allowed under Section 37a of the Medicinal Products Act. Provision would also be made for those products to be removed from the taxable amount for pharmacy tax and for a different retail price regime. The proposals are based on a government programme entry to enable the sale of certain self-medication medicines outside pharmacies. The aim of the amendment is to improve the accessibility of self-medication medicines and to create price competition between self-medicines in a limited range. It should be noted that the Constitutional Committee has ruled on Article 37a of the Medicines Act when it was enacted (PeVL 56/2005 vp and PeVL 49/2005 vp). In the case of a limited range of self-medicines, the proposed amendment to the section would partly revert to the period prior to the 2006 amendment. The difference would, however, be that the range of medicinal products could be subject to discounts for consumers, which would allow the benefits of wholesale discounts to be channelled to the user of the medicinal product. The proposed amendment seeks to create price competition to the benefit of the consumer and the proposal can therefore be considered to be in line with a strong social objective.

The regulation proposed in the proposal would not constitute restrictions that go beyond the core of the fundamental right. The Act on the taxation of pharmacies and the Law on pharmaceuticals provide for adequate legal protection arrangements. Moreover, the restrictions would not conflict with Finland’s international human rights obligations. Member States have been recognised as having the right to regulate the pricing and taxation of medicinal products.

New basis for pharmacy tax

It is proposed that the taxable amount of the pharmacy tax be changed. The pharmacy tax would be based on the taxable person’s profit margin on pharmaceutical sales, as provided for in Article 5 of the Law on the taxation of pharmacies. It would also provide for items for the sale of medicinal products which would not be taken into account in the taxable amount. It is proposed to amend the scale of taxation in Article 6 of the Law on the taxation of pharmacies so that the pharmacy tax would be calculated on the basis of the six-stage scale for the calculation of the pharmacy tax by category of profit margin for pharmaceutical sales. It is proposed to amend Section 7 of the Act on the Tax on Pharmacy in order to remove the special tax treatment of branch pharmacies.

According to Article 81(1) of the Constitution, the State tax is to be governed by a law containing provisions on the basis of which the tax is payable and the amount of the tax, as well as on the legal protection of the taxpayer. In its opinion PeVL 37/2009 vp, the Committee on Constitutional Law has stated that, in accordance with the established practice of the

Constitutional Committee, the tax law becomes an unequivocal class of tax liability. The provisions of the Act must also be so precise that the discretion of the authorities applying the law when determining the tax is tied (e.g. PeVL 36/2005 vp, p. 3/II), PeVL 67/2002 vp, p. 3/II, PeVL 3/2003 vp, p. 2/I.

The proposed amendments to the Act on the taxation of pharmacies fulfil the constitutional requirements. Pursuant to Section 3 of the Act on the taxation of pharmacies, which is not proposed to be amended, pharmacists, the University of Helsinki and the University of Eastern Finland are obliged to pay the pharmacy tax. The proposed Article 5 would specify precisely that the tax would in future be based on the taxable person's profit margin on pharmaceutical sales. It would specify how the profit margin is calculated in the case of industrially manufactured medicinal products and medicinal products manufactured by a pharmacy. In addition, Paragraph 5(2) would provide for sales of medicinal products to be disregarded for the purposes of determining the taxable amount. The amount of the tax would be determined on the basis of the proposed Articles 6 and 7, in particular on the basis of the scale of the tax in Article 6. By virtue of the articles, the discretion of the tax authorities would be bound by the law. The legal protection of the taxpayer is not proposed to be amended in this proposal. The provisions on legal protection would be contained in Section 8 of the Act on the taxation of pharmacies, in the Act on Own-initiative Tax Procedure (768/2016) and in the Tax Collection Act (11/2018).

Authorisation requirement for the sale of non-pharmaceutical medicinal products

It is proposed that a marketing authorisation holder who would like to sell his own medicinal product outside pharmacies should apply for an extension of the sales channel for his product under Section 23e(2) of the Medicinal Products Act. It is also proposed that a trader wishing to retail self-care medicinal products to consumers should apply for a retail licence for self-treatment medicinal products under Sections 54f and 54 g of the Medicines Act. The law would lay down the conditions for the extension of the sales channel and the right of the marketing authorisation holder and Fimea to withdraw the extension of the sales channel. In addition, it is proposed to lay down the conditions for authorisation for the retail sale of self-medication medicinal products, the content of the application for authorisation, notification of variations, the validity of the authorisation, withdrawal of the authorisation, the operating requirements of the holder of the authorisation, the duties of the responsible person, the penalties to be imposed on the licence holder, inspections, information obligations and appeals.

The proposed regulation would be relevant to the freedom to conduct a business guaranteed by the Constitution. According to Article 18 of the Constitution, everyone has the right, in accordance with the law, to obtain his or her means of subsistence through an employment, profession or trade of his or her choice. In its opinion on the Medicines Act (PeVL 19/2002 vp), the Constitutional Committee stated that: "the*Committee has considered the freedom to conduct a business as a general rule in accordance with the Constitution, but considered it possible, by way of exception, to require authorisation to conduct a business. However, the requirement for authorisation must be laid down by law, which must satisfy the general requirements of a law which restricts a fundamental right. The restrictions on the freedom to conduct a business laid down by law must not only be precise and precise, but also the substance of the restrictions, such as the extent of the restriction and the conditions under which it is imposed, must be apparent from the law. As regards the content of the regulation, the Committee has considered it important that the provisions on the conditions and durability of the authorisation provide sufficient predictability as to the action taken by the authorities. What matters in this regard is, inter alia, the extent to which the authority's powers are*

determined by 'tied' or 'appropriateness' (see e.g. PeVL 28/2000 vp, pp. 1-2 and PeVL 28/2001 vp, p. 6/II).'

In the light of the fundamental rights system, the Constitutional Committee considered the wholesale authorisation of medicinal products, which it assessed, to be acceptable when it had "criteria relating to the safety of*medicinal products and thus to the promotion of the health of the general public. In Section 102, the legal protection arrangements are also appropriate. However, the draft law does not contain any provisions on the conditions for granting a permit and the power of the authority to decide on the conditions of authorisation is not proposed in any way to be restricted or guided by the provisions of the Act. Provisions on these matters must be included in the draft law in sufficient detail to enable it to be dealt with in the ordinary legislative procedure'*(PeVL 19/2002 vp). In its opinion (PeVL 49/2005 vp), the Constitutional Committee has also assessed the regulation of the Medicines Act on nicotine products. The committee considered that the provisions were sufficiently precise and that the permit assessment was a legal consideration, as the authorisation had to be granted if the conditions proposed to be laid down by law were met. The Constitutional Committee did not consider the authorisation system to be problematic in the light of Article 18(1) of the Constitution.

The extension of the sales channel for self-medical medicinal products and the system of retail licences for self-medical medicinal products must be regarded as satisfying the general requirements of a law which restricts a fundamental right. The Medicinal Products Act (Sections 23e(2) and 54f to 54i) proposes to lay down precisely and precisely the scope and conditions of authorisations. The authorities' discretion would be bound by the law. If the conditions are met, the authority should grant the requested authorisation.

Restrictions shall not be deemed to extend to the core of the fundamental right. Medicinal products are special goods, the sale of which is, to a large extent, restricted to the exclusive rights of pharmacies, in a generally accepted manner. The sale of certain self-treatment medicinal products outside the pharmacy constitutes an exception to that general rule and a relaxation of the specific rules on the sale of medicinal products in a limited range. Nor is the restriction incompatible with Finland's international human rights obligations. The regulation includes a right of appeal and is part of the obligation of the public authorities, in accordance with Article 19(3) of the Constitution, to provide everyone with adequate social and health services and to promote the health of the population.

The Constitutional Committee has ruled on the withdrawal of the licence as follows: '*The withdrawal of an authorisation, as an act of public authority which interferes with the legal position of the individual, has a more severe effect than the refusal to grant the authorisation applied for (PeVL 28/2001 vp, p. 7/I). It is therefore essential, in the interests of proportionality, that the possibility of withdrawal of an authorisation be linked to serious or material infringements or omissions. Such a review of the legislation is a prerequisite for the examination of a draft law in the ordinary legislative procedure.'* (PeVL 19/2002 vp – HE 46/2002 vp).

Under Article 23e(3) of the proposal, the Medicinal Products Safety and Development Centre may amend the decision referred to in paragraph 2 (extension of the sales channel) on the basis of new information received on the basis of a marketing authorisation holder's application or on its own initiative, which affects the sales channel. The provision refers to information affecting the sales channel, for example, which would eliminate the previously low-risk character of a medicinal product and which should require the consumer to have access to advice on medicinal products at the time of sale of the medicinal product. However, the amendment of the decision would not involve the withdrawal of the marketing authorisation of

the marketing authorisation holder, which is expressly provided for in the current Medicines Act. Amending the decision could return the medicinal product to the pharmacy channel only. Given the diverse nature of possible situations, it is proposed to proceed with a transparent formulation in this respect.

The proposal proposes a new Article 79 of the Medicinal Products Act, paragraph 2 of which requires the Centre for Safety and Development of Medicines to revoke a retail licence for self-treatment medicinal products if one of the conditions laid down in the subsection is met. The proposed Article 79 is assessed to be in line with the requirements of the Constitutional Committee. The withdrawal of an authorisation would be linked to situations where other business activities are discontinued and to situations where there is a material breach or omission that would endanger patient safety.

The Constitutional Committee ruled on the conduct of inspections (PeVL 19/2002 vp) as follows: '*In practice, taking into account the premises and operators subject to the checks, the checks cannot be carried out in respect of the home peace guaranteed by Article 10 of the Constitution. In this respect, the inspection provisions do not affect the order in which draft laws are dealt with. However, it is appropriate to exclude from the scope of inspection the premises which are covered by the home by means of specific references to the laws*.' Article 77 of the Law on medicinal products excludes from the right of inspection holdings which are limited to permanent housing. In addition, according to the proposed section 54h, the premises of the holder of a retail licence for self-medical medicinal products must be for business purposes. The proposed amendments to the articles would be allowed on these grounds.

12.4. Right to process information on waivers and repairs to prescription

The proposal proposes to amend the Medicines Act so that pharmacies would have a limited right to derogate from prescriptions. It is proposed to amend the ePrescription Act so as to give pharmacies the right to remedy manifest errors in prescriptions independently. Pharmacies' access to prescription information would be based on Article 11 of the ePrescription Act, which would not be proposed to be amended. In those situations, it would also be necessary to safeguard the right of the prescriber to be informed of any deviations and corrections made to his prescriptions. The information rights of the prescriber are laid down in Section 13 of the ePrescription Act, for which it is proposed that the prescribing person's right to information be safeguarded without prejudice to the medical relationship.

In addition, under Article 54 g, Fimea, as the licensing authority, would have the right to process the personal data of applicants for authorisation and the responsible persons they designate in connection with applications for authorisation under Article 54 g of the Law on medicinal products, and would have a right to information under Article 89 of the Law on medicinal products, which would also apply to holders of retail licences for self-medical medicinal products.

The proposed regulation is relevant to the protection of private life provided for in Article 10 of the Constitution. Everybody's private life, honour and home peace are safeguarded. The protection of personal data is further regulated by law.

However, the regulation would meet the general requirements of restrictions on fundamental rights. The regulation would be based on the ePrescription Act and the Medicines Act and would be precise and precise. The Constitutional Law Committee has drawn attention to what and to whom the right of access extends and how the right of access is linked to the necessity of the data. According to the Committee, the authority's right of access to information and the possibility to disclose information may have been linked to 'information necessary' for a specific purpose, provided that an exhaustive list of the data content in question has been sought in the law. If, on the other hand, the data content is not listed in the same way, the

requirement of ‘indispensability of the information’ for a specific purpose must have been included in the regulation (PeVL 42/2016 vp and referred to in PeVL 17/2016 vp).

Section 54 g of the Medicines Act would set out in detail the information to be included in the application for authorisation. Section 57f of the Medicinal Products Act and Section 10 of the ePrescription Act would set out precisely to what extent a pharmacist and a pharmacy working in a pharmacy could correct or deviate from the prescription. It is proposed to provide, in Article 13(3)(4) of the Law on electronic prescriptions, that the prescriber of a medicinal product, irrespective of the relationship of treatment, would be entitled to receive information under Article 10 on the rectification of prescriptions made by a pharmacist and pharmacist and on the derogation from prescriptions made under Article 57f of the Law on medicinal products, in which he is identified as the prescriber of the medicinal product and the labelling relating to those prescriptions. Article 89 of the Medicinal Products Act governs Fimea’s right of access to information necessary for its statutory tasks.

Restrictions must be acceptable and based on a pressing social need. This condition is fulfilled with regard to the processing of data. The purpose of the aforementioned Articles 54 g and 57f of the Medicinal Products Act and Article 10 of the Law on electronic prescription is to ensure that the safety of medicinal products and medication is achieved when the user of a medicinal product purchases self-care medicinal products from outside the pharmacy and in situations where it is necessary to derogate from or correct the prescription and the prescriber would need, for the purposes of further treatment, to be informed of the prescription actually delivered to the user of the medicinal product. The purpose of Article 89 of the Law on medicinal products is to ensure that operators comply with their obligations under the Medicinal Products Act.

The proposal on the right of pharmacies to derogate from prescriptions in specific exceptional situations contributes to the fulfilment of the obligation of public authorities laid down in Article 19(3) of the Constitution. The legislative amendment makes it possible to prevent delays in the treatment of medicines in situations where the prescriber cannot be apprehended and the patient needs a pack of medicines from the pharmacy immediately. However, the contribution to the realisation of a fundamental right depends on a proper assessment by the pharmacy that the deviation does not compromise the safety of medication and on the provision of the necessary medical advice to the customer.

Restrictions must be considered proportionate. Under Articles 54 g and 89 of the Medicinal Products Act, Fimea would only have access to the information necessary to assess the application for authorisation and to carry out Fimea’s official function. The prescriber, who would receive information on any deviations or repairs made, would have been named in that prescription as the prescribing entity with overall responsibility for the patient’s medicinal treatment. The prescriber and Fimea are subject to a duty of professional secrecy under a separate regulation.

There is no restriction at the heart of a fundamental right. The patient’s right to order the processing of information contained in a medical prescription has already been restricted on legal grounds. Nor can the restrictions be considered incompatible with Finland’s international human rights obligations when it is intended to support the patient’s medical treatment and to ensure the safety of the patient’s medicinal products and medication.

12.5 powers to adopt regulations

It is proposed to add a new Sections 23d, 54h and 54i to the Medicines Act, which would include the power to adopt regulations. In addition, it is proposed to amend the power to issue regulations in Section 58 of the Medicinal Products Act and to extend the scope of the powers to issue regulations in Sections 52b, 77 and 89 of the Medicinal Products Act to include

holders of retail licences for self-medical medicinal products and, in Section 77, holders of retail licences for self-medical medicinal products, as well as the system for recording the safety features of medicinal products and the operator of the recording system. In addition, it is proposed to amend Article 10 of the ePrescription Act, which would, however, allow the power to issue decrees contained therein to be extended to the correction of obvious errors in prescriptions.

The power to issue decrees must be assessed in accordance with Article 80(1) of the Constitution, according to which the President of the Republic, the Council of Ministers and the Ministry may issue decrees on the basis of the powers provided for in this Constitution or in another law. However, the law must lay down the grounds for individual rights and obligations, as well as matters which, according to the Constitution, otherwise fall within the scope of the law. Where there is no provision specifying who is to issue a decree, it is issued by the government.

In its evaluation of the Medicines Act (PeVL 19/2002 vp), the Constitutional Committee has stated that *"the power to legislate in the law has been subject to requirements of precision and precision in the opinion practice of the Constitutional Committee (see e.g. PeVL 16/2002 vp, pp. 2-3). The Constitutional Committee has repeatedly stressed that the provisions of Article 80(1) and (2) of the Constitution directly limit the interpretation of the enabling provisions as well as the content of the delegated acts (see e.g. PeVL 48/2001 vp, p. 4). Thus, neither a decree nor an order of a public authority may lay down general rules of law, for example on the basis of individual rights or obligations, or on matters which, according to the Constitution, otherwise fall within the scope of a law (PeVL 16/2002 vp, p. 2/II).'*

In its assessment of the draft animal welfare law (PeVL 106/2022 vp), the Constitutional Committee has noted, for example, because of the regulatory detail and technical nature of environmental legislation, that a significant part of the detailed regulation remains in sub-statutory acts. The imposition of obligations at the level of the regulation, which vary by sector and activity, may then be justified, as otherwise the regulation at the level of the law would be unnecessarily detailed. However, the committee has drawn attention to the fact that, even in this case, powers cannot remain fully transparent, including as regards the grounds for obligations.

Pursuant to the proposed Article 23d of the Medicinal Products Act, the so-called 'limited self-care' range of medicinal products consists of a number of categories of medicinal products which are assessed to present low risks and which are assessed as capable of safe treatment without medical advice. According to the section, the limited range of self-treatment medicinal products referred to in subsection 1 shall be further defined by Government decree. The proposed new Article 11 of the Medicinal Products Regulation, which is annexed to the proposal, would provide for a limited range of self-medication products by ATC group.

The proposed regulation must be regarded as permissible under Article 80(1) of the Constitution. Article 23d(1) of the Medicinal Products Act would form the basic provision for the power to issue regulations and the detailed rules would be laid down in the regulation. In practice, a limited range would be defined on the basis of the ATC groups of the Regulation. This is because it is possible that there are other low-risk self-treatment groups on the market than those currently proposed to be included in Article 11 of the Medicinal Products Ordinance. In that case, it could be argued that the regulation affecting individual rights would be partly at the level of the regulation. However, the regulatory solution is considered justified because it is necessary to have a very detailed and technical regulation on the definition of a limited range based on the most accurate ATC classification. Such regulation at the level of the law would be exceptionally detailed and would therefore justify its adoption in the Regulation.

Regulation-level regulation would also allow for a more flexible update of the categories of medicinal products in the future. The proposal proposes to start with the now defined range and could be supplemented or narrowed in the light of experience at a later stage by amending the Government Decree on Medicinal Products.

The proposed new Sections 54h and 54i of the Medicines Act, as well as the proposed section 58 for the amendment of the Medicinal Products Act, provide for a clear division into law and lower regulation. The legal article would at the top level lay down individual rights and obligations and a more detailed and technical regulation would be in the Regulation. It is proposed to include in the current Section 52b of the Medicines Act on distance sales of medicinal products also holders of retail licences for self-treatment medicinal products. In Section 77 of the Medicinal Products Act, it is proposed to add to the list of operators checked by Fimea the holders of retail licences for self-treatment medicinal products, as well as the system for recording the safety features of medicinal products and the operator of the recording system. In addition, it is proposed that holders of retail licences for self-treatment medicinal products be added to Section 89 of the Medicines Act as entities to provide information to Fimea. With the proposed amendment to Section 10 of the ePrescription Act, the power to make regulations contained therein would also apply to the correction of obvious errors. In these articles, the addition of new entities to the section would not alter the existing powers to adopt regulations, even if their scope would be altered by the proposed legislative amendments. Existing authorisations shall be deemed to comply with Article 80(1) of the Constitution.

The proposal proposes to amend the articles of the Medicines Act, which include the power to prescribe;
Fimea. The amendments would also include holders of retail licences for self-treatment medicinal products (Sections 34, 52b, 77, 84b and 89) and the system for recording the safety features of medicinal products and the operator of the recording system (Section 77). The power to issue orders must be assessed in accordance with Article 80(2) of the Constitution, according to which another authority may also be empowered by law to adopt rules on specific matters where there are special reasons relating to the subject-matter of the regulation and the material importance of the regulation does not require that the matter be regulated by law or regulation. Such authorisation must be strictly limited in scope. However, the proposed amendments to the sections of the Medicines Act would not alter the powers of order already contained therein. Existing authorisations shall be deemed to meet the conditions laid down in Article 80(2) of the Constitution.

On the basis of the above, draft laws may be dealt with under the ordinary legislative procedure—

in twist.

Ponsi

Based on the foregoing, the following bill is submitted to be passed by Parliament:

Law

amending the Medicines Act

In accordance with the Parliamentary resolution,

Articles 2(1), 9(2), 23b, 26, 30u, 31, 32(2), 33(2), 34(1), 35(1), 37(2) and (3), 37a(1), 38a, 52b, 52d(1), 54a(1) of the Medicines Act (395/1987), Articles 58, 77(1), 84b(1), 89, 91b, 97 and 102 as *amended* by Articles 2(1), 9(2) and 33(2) of Law 1200/2013, Articles 23b, 26, 32(2) and 35(1) of Law 853/2005, Articles 30u, 52b, 52d(1), 97 and 102 of Law 1258/2021, Article 31, Acts 1112/2010 and 1200/2013, Section 34(1) of Act 978/2013, Section 37(2) and (3) of Act 553/2020, Section 37a(1) of Act 22/2006, Section 38a and Section 54a(1) of Act 1112/2010, Section 58 of Acts 1258/2021 and 1233/2022, Section 77(1) and Section 89 of Act 985/2021, Section 84b(1) of Act 789/2016 and Section 91b of Acts 700/2002 and 853/2005 and *insert* new Sections 23d, 23e, 54f to 54f, 57 g and the new Article 79 thereof by Act 1039/2015
in place of Article 79, which has been repealed, as follows:

Scope

ARTICLE 2

This Law applies to medicinal products, their manufacture, importation, distribution, brokering and sale and any other release for consumption, pharmaceutical factories carrying out the abovementioned activities, wholesale medicinal products, brokers and pharmacies, laboratories carrying out pre-clinical safety studies of medicinal products, and the manufacture and distribution of medicinal products in hospitals and health centres. That law also applies to the retail sale of certain self-medication and nicotine products outside the pharmacy.

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ARTICLE 9

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The responsible manager of a pharmaceutical plant must be a qualified pharmacist or other relevant master’s degree. In addition, the accountable manager is required to have been active in a pharmaceutical plant for a sufficient period of time in the manufacturing or quality assurance of medicinal products. The general manager shall not be at the same time a director of another company authorised to manufacture medicinal products on an industrial basis. In addition, the accountable manager may not be a responsible director in the wholesale distribution of medicinal products by another company, or a pharmacist, a hospital pharmacy or a pharmaceutical centre, a manager of a military pharmacy, a manager of a pharmacy or a branch pharmacy, or a holder of a retail licence for self-medical medicinal products, a member of his management or a person responsible for the sale of self-medical medicinal products. The qualifications of the accountable manager may, if necessary, be laid down in more detail by Government decree.

— —..... – Article 23b

When granting a marketing authorisation for a medicinal product, the Centre for Safety and Development of Medicinal Products shall decide, as part of the terms of the marketing authorisation for a medicinal product referred to in Article 21(2), whether the medicinal product may be sold or otherwise released for consumption only on the basis of a prescription.

The Medicinal Products Safety and Development Centre may amend the decision referred to in paragraph 1 on the basis of new information received on the medicinal product which affects the classification of the supply.

If a condition attached to a marketing authorisation, according to which a medicinal product for human use may only be supplied on the basis of a prescription (prescription condition), has been removed on the basis of extensive pre-clinical or clinical trials carried out by the marketing authorisation holder, the marketing authorisation holder of another medicinal product containing the same active substance may apply for the waiver of the prescription on the basis of those studies at least one year after the change of the term of the marketing authorisation for the reference medicinal product.

Article 23d

A limited range of self-medicines consists of a number of categories of medicinal products which are assessed to present low risks and which are assessed as capable of safe treatment without advice.

The limited range of self-treatment medicinal products referred to in subsection 1 shall be further defined by Government decree.

Article 23e

If, in accordance with Paragraph 23b(1) or (2), the Finnish Medicines Agency has attached to the marketing authorisation a condition that the medicinal product may be sold or otherwise released for consumption without prescription (as a self-treatment product), *the* medicinal product may only be sold in a pharmacy.

The marketing authorisation holder may apply to the Finnish Medicines Agency for an extension of the sales channel for his own-care medicinal product to sales outside pharmacies. An extension of the sales channel shall be granted if:

1) a self-treatment medicinal product is included in the categories of medicinal products referred to in Article 23d which constitute a limited range of self-medication products;
2) the risks associated with the self-treatment product are low; and
3) treatment with the medicinal product can be carried out safely without medical advice.

The provisions of paragraphs 1 and 2 shall not apply to the products referred to in sections 22, 22a or 54a. Self-care medicinal products which are supplied to the purchaser of the medicinal product as reimbursed in accordance with the Health Insurance Act (1224/2004) are only sold in a pharmacy.

The Medicinal Products Safety and Development Centre may amend the decision referred to in paragraph 2 on the basis of new information received on the basis of a marketing authorisation holder's application or on its own initiative, which affects the sales channel.

ARTICLE 26

The marketing authorisation holder and the holder of the registration referred to in Article 22 shall ensure that the authorised medicinal product and the registered traditional herbal medicinal product are available on an ongoing basis to wholesale distributors, pharmacies and retail licence holders of self-medication medicinal products, in accordance with the needs of patients and other users.

Article 30u

Wholesale trade must check the safety features of a medicinal product and remove the unique identifier referred to in the Falsified Medicinal Products Directive and the EU Regulation on the safety features of medicinal products before it is handed over to a military pharmacy, a holder of a retail licence for a self-care medicinal product, a veterinary surgeon, a university, a university or a scientific research institute for research, or a health and welfare institution when it maintains stocks of medicinal products for civil protection or disaster management.

Sales from a pharmaceutical plant

31 § 3A.

Only another pharmaceutical factory, wholesale medicine, pharmacy, branch pharmacy, military pharmacy, hospital pharmacy and pharmaceutical centre may sell or otherwise distribute pharmaceutical substances and proprietary medicinal products. In addition, medicinal products which are not prescribed or prescribed for sale only from pharmacies may also be sold and otherwise disposed of to retailers of those products. In addition, self-care medicinal products for human use which have been granted the extension of the sales channel referred to in Paragraph 23e(2) may be sold to holders of retail licences for self-treatment medicinal products.

Pharmaceuticals and own pharmaceutical products may also be sold or otherwise disposed of by a pharmaceutical plant to a university, a university and a scientific research institute for research purposes. The pharmaceutical factory shall report this to the Finnish Medicines Agency.

Medicinal products outside Finland may only be supplied from a pharmaceutical factory to an operator who is legally entitled in that country to obtain medicines from a pharmaceutical factory. *Practising the wholesale trade of medicines*

32 § 3A.

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However, the wholesale distribution of medicinal products does not constitute the sale to the public of medicinal products and medicinal products in accordance with Paragraph 38a, the supply of medicinal products and medicinal products from one pharmacy to another pharmacy or social and healthcare establishment, the supply of medicinal products and medicinal products from a hospital pharmacy or a pharmaceutical centre in accordance with Paragraph 62, or marketing and billing by the holder of the marketing authorisation or his representative, which does not involve the holding, distribution or storage of the products.

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33 § 3A.

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The responsible manager of the wholesale trade must be a qualified pharmacist. The general manager shall not be at the same time a director in charge of another company authorised to engage in the wholesale distribution of medicinal products. In addition, the accountable manager shall not be a responsible director of another company’s pharmaceutical plant, nor a pharmacist, a hospital pharmacy or a pharmaceutical centre manager, a manager of a military pharmacy, a pharmacy or branch pharmacy, nor a holder of a retail licence for self-medical

medicinal products, a member of his management or a person responsible for the sale of self-medical medicinal products. The qualification requirements of the accountable manager may be laid down in more detail by Government decree.
—.....

34 § 3A.

The wholesale distribution of medicinal products may be sold or otherwise disposed of to a pharmaceutical factory, another pharmaceutical wholesaler, a pharmacy, a branch pharmacy, a military pharmacy, a hospital pharmacy and a pharmaceutical centre, and a veterinarian for veterinary purposes. In addition, medicinal products which are not prescribed or prescribed for sale only from pharmacies may also be sold and otherwise disposed of to retailers of those products. Self-care medicinal products which have been granted the extension of the sales channel referred to in Paragraph 23e(2) may also be sold to holders of retail licences for self-treatment medicinal products. When selling or otherwise dispensing medicines outside the EU/EEA, the wholesaler must ensure that medicinal products are only supplied to an operator that is legally entitled in that country to purchase medicines from the wholesale distribution of medicinal products. When selling or otherwise disposing outside the EU/EEA of medicinal products received by wholesalers from outside the EU/EEA without having been imported into the Union, wholesalers shall ensure that medicinal products are only obtained from persons authorised or entitled to supply medicinal products to the wholesaler in that country.
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35 § 3A.

Medicinal products may be supplied free of charge from the pharmaceutical factory and wholesale medicine to doctors, dentists, veterinarians and non-prescription medicines to pharmacists, hospital pharmacies and medical centre managers for sample and standby purposes. Packages of samples of registered homeopathic products and traditional herbal medicinal products which are not prescribed exclusively for sale in pharmacies may be supplied from the pharmaceutical factory and the wholesaler to retailers of those products.
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ARTICLE 37

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The wholesale distribution of medicinal products must immediately inform the pharmacy, hospital pharmacy, pharmaceutical centre, retail licence holder of self-medication products or veterinary surgeon of the supply of a medicinal product ordered. The wholesale distribution of medicinal products shall include information on the shortage of the medicinal product and an estimate of the duration of the supply disruption.
The wholesale distribution of medicinal products shall immediately inform the Finnish Medicines Agency and all pharmacies, hospital pharmacies, pharmaceutical centres, holders of retail licences for self-treatment medicinal products and veterinarians of any disruption or interruption in the distribution of medicinal products, which has a significant impact on the implementation of the distribution of medicinal products.

37 section A

The wholesale price of a medicinal product shall be the same for all pharmacies and branch pharmacies. The wholesale price shall take into account all discounts, rebates and other

benefits granted to pharmacies and branch pharmacies. The wholesale price shall be notified to the entities providing information on the prices of medicinal products.
Those wholesale restrictions do not apply to the wholesale prices of medicinal products which may also be sold outside pharmacies. Furthermore, the restrictions do not apply to a limited range of self-medication products, as defined in Article 23d. However, the national wholesale price of self-treatment medicines in the range must be communicated to the entities providing the price information.
—.....

38 section A

Medicinal products may be sold to the public only from a pharmacy, a branch pharmacy, a pharmacy service facility and an online pharmacy service within the meaning of this Law.

However, the traditional herbal medicinal products and homeopathic products referred to in Sections 22 and 22a may also be sold outside a pharmacy, unless the Finnish Medicines Agency has decided otherwise at the time of registration. In addition, nicotine products and self-care medicinal products which have been granted the extension of the sales channel referred to in Paragraph 23e(2) may also be sold outside a pharmacy, as provided for in Paragraphs 54a to 54i below.

Article 52b

A pharmacist, a pharmacy at the University of Helsinki and a pharmacy at the University of Eastern Finland can also provide pharmacy services through the pharmacy's online service. The holder of a retail licence for self-treatment medicinal products may also offer, through an online service, self-care medicinal products for which the extension of the sales channel referred to in Paragraph 23e(2) has been granted. These operators of distance sales of medicinal products shall have a website where medicinal products are offered for sale at a distance. The website should contain a link to the Catalogue of Legal Distance Selling Services for Medicinal Products, maintained by the Centre for Safety and Development of Medicinal Products, and clearly display the common logo in the European Union in accordance with Article 85c of the Medicinal Products Directive.

The distance sales service of medicinal products shall be subject to prior notification to the Centre for Safety and Development of Medicinal Products. Pharmacies shall attach to the notification a plan for the organisation of the medical advice provided for in Article 57(2). Operations may be commenced unless, within 60 days of receipt of the notification, the Centre has requested further clarification on the matters referred to in this article or has refused to commence the activity. The Centre shall be notified of the commencement, termination and material changes. The Centre may prohibit the commencement of an activity or order the termination of the service if the distance sales service for medicinal products does not meet the conditions laid down in this section, the provisions referred to in paragraph 6, the pharmacy's online service does not meet the conditions laid down in Paragraph 55(3), Paragraph 56 or 57 or the orders adopted pursuant to Article 57(3), the holder of a retail licence for self-medical medicinal products does not meet the conditions laid down in Article 54h, or the pharmacist is subject to measures under Paragraph 49(2), Paragraphs 50, 51 or 80b, or to the holder of a retail licence for self-pharmaceutical medicinal products under Paragraph 79.

The operator of a distance sales service for medicinal products must satisfy itself that the marketing of the medicinal product is lawful in the State to which the medicinal product is sold. Prescription-only medicinal products may only be supplied on the basis of an electronic prescription under the ePrescription Act (61/2007) from the pharmacy's online service.

The operator is responsible for operating and managing the distance sales service for medicinal products. The latter shall inspect the service annually and ensure appropriate storage and transport conditions for the medicinal products supplied through the service. The

pharmacy’s online service should have an adequate range of therapeutics, including the cheapest available medicinal products.

A pharmacy’s online service may, once a pharmacy licence has been opened, be maintained by a pharmacist who ceases to operate a pharmacy within the meaning of Paragraph 46 or by a pharmacy operator within the meaning of Article 59 until the pharmacy has been taken over by a new pharmacy licensed. A new pharmacy licensed shall submit a notification to the Centre for Safety and Development of Medicinal Products pursuant to paragraph 1 if he continues to operate the pharmacy’s online service. The notification referred to in paragraph 1 shall also be made if the holder of the retail licence for self-treatment medicinal products has changed and the new authorisation holder continues to provide a distance sales service for medicinal products.

Otherwise, the provisions of Chapter 6 of the Consumer Protection Act (38/1978) on distance selling apply to distance sales of medicinal products. The provisions on distance sales of medicinal products also apply to the sale of medicinal products through other information society services. More detailed provisions on advice provided in connection with the use of the service and on fees charged to customers may be laid down by government decree. The Centre for Safety and Development of Medicinal Products may issue orders concerning the content and submission of prior notification, as well as the provision of advice on medicinal products, the packaging and checking of consignments of medicinal products, transport, outsourcing of activities, returns, handling of product defects, information to be provided in the distance sales service for medicinal products, the storage of medicinal products, the supply of medicinal products via an online service, premises, technical implementation, the range of medicinal products on the pharmacy’s online service, the treatment of medicinal products and the conduct and documentation of the inspection.

Article 52d

The Centre for Safety and Development of Medicinal Products shall maintain and make publicly available on the internet an up-to-date list of legal distance sales services for medicinal products.

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Article 54a

By way of derogation from Article 38a(1), nicotine products may also be sold in retail stores, kiosks and service stations and catering establishments selling tobacco on the basis of a retail licence issued by the municipality where the point of sale is located. Nicotine products may only be sold to those aged 18 or over. The seller must be able to monitor the purchase situation. Sales from automatic sales equipment are prohibited.

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Article 54f

The sale outside a pharmacy of self-medication medicinal products which have been granted an extension of the sales channel referred to in Paragraph 23e(2) shall be subject to the issue of a retail licence for self-treatment medicinal products issued by the Finnish Medicines Agency for Safety and Development. The authorisation authorises the retail sale of self-medical medicinal products at the premises specified in the authorisation.

The authorisation referred to in paragraph 1 shall be granted if:

1) the applicant is a sole trader or a legal person registered in the commercial register pursuant to Section 3 of the Trade Register Act (564/2023);
2) the applicant is not an operator within the meaning of Sections 8, 32 or 34a;

3) the applicant appoints a responsible person who is familiar with the legislation and procedures for self-care medicinal products; and
4) the sales and storage facilities and the induction given to staff meet the conditions laid down in this Act and the regulations issued on the basis thereof.

Article 54 g

A retail licence for a self-treatment medicinal product shall be applied for in writing or electronically to the Finnish Medicines Agency. The application or the accompanying documents shall contain the following information:

1) the name or business name of the applicant, the business identification number and contact details of the applicant and, where applicable, the name and contact details of the applicant's contact person;
2) the address and contact details of the branch;
3) the name and contact details of the responsible person and a declaration that that person has knowledge of self-medication products within the meaning of Paragraph 54f(2)(3); and
4) a description of the applicant's sales and storage facilities and the planned induction for staff.

The authorisation holder shall notify the Medicinal Products Safety and Development Centre of any material change in the operation. The Centre may require the authorisation to be re-applied if, as a result of a change in activity, the conditions for authorisation under section 54 septies need to be re-assessed.

The retail licence for the self-treatment product is valid indefinitely. The authorisation may be withdrawn by notification by the holder of the authorisation or by a decision of the Finnish Medicines Safety Agency pursuant to Article 79(2).

Article 54h

The holder of a retail licence for self-treatment medicinal products shall:

1) sell only medicinal products of sound quality which have obtained a marketing authorisation in force in Finland and which have been granted the extension of the sales channel referred to in Section 23e(2);
2) properly handle and store self-care medicinal products;
3) sell self-care medicines in complete sales packages, comply with product-specific restrictions and ensure that sales are always carried out under staff supervision;
4) sell and store self-care medicinal products in a business premises of the authorised establishment that meets the storage condition requirements for the medicinal products;
5) provide staff with training and guidance on self-medicines commensurate with their duties;
6) comply with the provisions of this Act, the regulations adopted on the basis thereof and the Consumer Protection Act in relation to the sale, pricing and marketing of self-treatment medicinal products, and
7) when ordering self-care medicinal products from a pharmaceutical factory or from a magazine, reliably proves that, as holder of a retail licence for self-medical medicinal products, he is entitled to receive the self-care medicinal products.;

The retail licence holder and the person working at the outlet shall not provide medical advice or provide unauthorised disclosure of any private or family secret of which they have become aware in the course of their duties;

Further provisions on the premises of the licensee, on the induction and guidance of staff, on control arrangements, on storage, treatment of self-treatment medicinal products and on the resulting pharmaceutical waste may be laid down by Government decree.

Article 54i

The responsible person appointed by the retail authorisation holder for self-treatment medicinal products shall be responsible for:

1) regularly monitor the storage conditions and sales of self-medicines; (2) Act as the contact person for the authorisation holder vis-à-vis the authorities; and (3) audit the site on an annual basis.

Further provisions on the tasks of the responsible person may be laid down by Government decree.

57 section F

A pharmacist or pharmacist working at a pharmacy, a branch pharmacy or an online pharmacy on the basis of a prescription for a medicinal product may deviate from the prescription as regards the pack size, the pharmaceutical form, the strength, the dosage instructions and the trade name of the prescribed medicinal product. Derogation from the prescription may be made if the following conditions are met:

(1)the medicinal product prescribed and the medicinal product that can be exchanged with it are not available in a pharmacy due to a national shortage or withdrawal of the medicinal product from the market;

2) it is not possible to order a prescribed medicinal product and an interchangeable medicinal product from a wholesale trade and it is not possible to refer the user of the medicinal product to another pharmacy;

3) the deviation does not alter the intended effects of the medicinal treatment;

4) there shall be no derogation from the particulars prescribed by the prescriber and shall not constitute a prescription issued or retained by telephone, or a prescription for a medicinal product which is compassionate, a medicinal product containing a narcotic substance, a medicinal product primarily active on the central nervous system or a medicinal product containing alcohol;

5) the total quantity of the medicinal product prescribed shall not be exceeded unless the quantity of medicinal product not supplied is less than the lowest available package or the most economically advantageous package, if it is cheaper than the smallest available package per dose, the dosage form of the medicinal product makes it impossible to distribute the package, or in the case referred to in paragraph 3, and

6) non-compliance with the prescription does not compromise the safety of medication and is necessary on the basis of pharmaceutical judgement.

The prescription may also be waived for a specific reason, as provided for in paragraph 1, in a specific exceptional case where, for other reasons, a prescribed medicinal product or a medicinal product that can be exchanged with it is not available in the pharmacy's warehouse and the customer necessarily needs the medicinal product immediately, because delay in treatment would be detrimental to the treatment of the patient's illness or its symptoms. In such cases, a derogation may be made if the conditions laid down in subparagraph 1, points 2 to 6, are met and if, despite the attempt, the prescriber of the medicinal product is not reached.

If the prescription of a medicinal product used regularly by the customer has expired or has been exhausted less than three months previously, a pharmacist or pharmacist working in a pharmacy, branch pharmacy or online pharmacy service may, in a specific exceptional case, deviate from the period of validity of the prescription or from the total quantity of the medicinal product and, on the basis of a prescription, provide the customer with up to three months' dose of the prescribed medicinal product or of the medicinal product that can be exchanged with it. An abnormal supply is subject to compliance with the conditions laid down in subparagraph 1, points 3 to 6, and to the condition that the dissimilar supply of the

medicinal product is necessary in order to ensure the continuity of the medical treatment of the customer.

57 section (g)

The derogation from the prescription referred to in Article 57f shall be made in agreement with the purchaser of the medicinal product and in accordance with Article 57. Any derogation from the prescription shall be subject to restrictions based on the marketing authorisation. The purchaser of the medicinal product shall be provided with a dosage guide for the medicinal product and shall be invited to contact the prescriber if necessary.

Where a pharmacist or pharmacist working in a pharmacy, branch pharmacy and pharmacy's online service, in accordance with Paragraph 57f, derogates from a prescription order, records records with the prescription centre of the supply of the medicinal product, the reason for it and any contact with the prescriber. Information about the deviation and the reason for it is recorded in the data on purchases of medicinal products submitted to the Social Insurance Institution.

58 § 3A.

The retail sale of a medicinal product shall be carried out at a price in accordance with the pharmaceutical tariff laid down by Government decree. The price of the medicinal product shall consist of the retail selling price of the medicinal product and, in the cases referred to in subparagraphs 2 and 3, an item-by-item delivery fee to be added to the retail price, and VAT. The retail price of a medicinal product shall be based on the wholesale price notified by the holder of the marketing authorisation for the medicinal product in accordance with Paragraph 37a and on the margin calculated on the basis of the wholesale price.

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The price of a medicinal product for self-treatment is made up of the retail price of the medicinal product and VAT. If the medicinal product referred to in this paragraph is supplied on the basis of a prescription, the retail price shall be increased by the delivery fee and VAT per consignment. The retail price of a self-treatment medicinal product shall be no more than the retail price of the medicinal product and shall not be less than the wholesale price of the medicinal product available at national level in accordance with Paragraph 37a. The price must be the same for all pharmacies and online services. However, the retail price of a self-treatment medicinal product shall be the retail price of a medicinal product in accordance with the tariff if it is a self-medication medicinal product requiring additional advice or if the nationally uniform price is justified by the need to provide medical advice, any adverse effects of the medicinal product or public health. By way of derogation from paragraph 1 and this paragraph, the maximum retail selling price of a self-medication medicinal product within the limited range of self-medication medicinal products referred to in Article 23d shall be the sum of the nationally available wholesale price notified by the marketing authorisation holder in accordance with Paragraph 37a and the margin calculated on that basis, and the maximum price in accordance with the pharmaceutical tariff shall be the maximum retail price plus VAT. VAT must always be added to the retail price of a medicinal product in a limited range. If a product in the range is supplied on prescription, a delivery fee per batch is also added to the price.

More detailed provisions on the price of the medicine, the exemptions from the price and the discounts to be granted are laid down by Government decree.

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The provisions of subsections 1 to 6 shall not apply to registered homeopathic products, registered traditional herbal medicinal products and nicotine products which may also be sold outside pharmacies, branch pharmacies, pharmacy outlets and online pharmacy services.

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ARTICLE 77

The Centre for Safety and Development of Medicinal Products shall ensure that manufacturers of medicinal products and pharmaceuticals and importing advanced therapy medicinal products, units manufacturing advanced therapy medicinal products for individual patients, contract manufacturers and analysers, laboratories carrying out pre-clinical safety studies of medicinal products, the system for recording and maintaining the safety features of medicinal products, wholesale medicine distributors, brokers, pharmacies, branch pharmacies, hospital pharmacies and pharmaceutical centres, and the military pharmacy are inspected as often as is necessary for the proper supervision of medicinal products. In addition, the Centre may check the pharmacovigilance activities and premises of the pharmacy counter, the pharmacy web service, the holder of a retail licence for self-medication medicinal products, the holder of the marketing authorisation for the medicinal product and the registration of the traditional herbal medicinal product, as well as manufacturers of excipients used in the manufacture of medicinal products. The Centre for Safety and Development of Medicinal Products may carry out inspections in cooperation with the European Medicines Agency as agreed.

—..... ARTICLE 79

The Centre for Safety and Development of Medicinal Products may issue an oral or written warning to the holder of a retail licence for self-treatment medicinal products if the authorisation holder is acting in breach of this Act or the provisions adopted pursuant thereto, and the act is not of such a nature that the holder of the authorisation should be prosecuted in court.

The Medicinal Products Safety and Development Centre shall revoke the retail licence for self-treatment medicinal products if:

1) the entire business of the authorisation holder shall be terminated;
2) the entire business of the licensee is sold to another trader or the control of the licensee’s undertaking referred to in Chapter 1, Section 5 of the Accounting Act (1336/1997) is transferred to another undertaking and the authorisation has not been appealed;
3) the holder of a retail licence for self-treatment medicinal products is declared bankrupt and, within one year of the start of bankruptcy, does not regain control of his assets;
4) the holder of a retail licence for self-treatment medicinal products shall receive a written warning as referred to in paragraph 1 or an order from an inspector within the meaning of Article 78 and shall not correct his procedure within the prescribed time limit or, failing that, within a reasonable period;
5) the holder of a retail licence for self-medical medicinal products substantially abuses the rights conferred by the retail licence for self-medical medicinal products or fails to comply with this Act or the provisions adopted pursuant thereto in a manner that seriously endangers patient safety.

The Centre for Safety and Development of Medicinal Products may also provisionally order the cessation of the sale of self-treatment medicinal products where the conditions laid down in paragraph 2 are met. The order may be issued for a maximum period of one year or until a decision has been taken on the withdrawal of the authorisation. If the suspicion of abuse proves to be unfounded, the Medicinal Products Safety and Development Centre shall revoke the order without delay.

Article 84b

Pharmacies, the pharmacy of the University of Helsinki and the pharmacy of the University of Eastern Finland, holders of retail licences for self-pharmaceuticals, including wholesalers and manufacturers of medicinal products, carry out an inspection relating to the monitoring of trade in medicinal products and pharmaceuticals to the Centre for Safety and Development of Medicinal Products two thousands of the difference between the VAT-exempt selling and purchase price of medicinal products (quality control fee). The pharmacy tax or the pharmacy fee is deducted from the corresponding margin for pharmacies before the charge is imposed. Manufacturers of medicinal products pay a fee for the supply of goods directly to a pharmacy or any other person entitled to purchase, without brokering medicinal products.

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ARTICLE 89

A pharmaceutical plant, a licensee manufacturing or importing medicinal products for clinical trials, a laboratory carrying out pre-clinical safety studies of medicinal products, a contract analysis or contract preparation unit and a laboratory, a holder of wholesale, marketing authorisation or registration of medicinal products, a pharmacist, a pharmacy at the University of Helsinki, a pharmacy, a pharmacy, a hospital pharmacy and a pharmaceutical centre at the University of Eastern Finland; the entity which manufactures advanced therapy medicinal products for an individual patient, the holder of a retail licence for self-treatment medicinal products and the Military pharmacy shall, upon request, provide the Centre for Safety and Development of Medicinal Products free of charge, without prejudice to confidentiality provisions, with such information and reports relating to the importation, manufacture, inspection, distribution, sale or other release for consumption of medicinal products which are necessary for the performance of the tasks laid down in this Act, in another law or in a European Union act.

The Centre shall also have the right to obtain from the above-mentioned entities the information necessary for the protection of patients and other persons, as well as for the performance of its supervisory tasks, including medical records.

The pharmacist, the pharmacy of the University of Helsinki and the pharmacy of the University of Eastern Finland shall provide the Centre for Safety and Development of Medicinal Products with the information necessary for the purposes of its development, planning and supervision tasks, the determination of the quality control fee and the compilation of statistics, of the identification, income and expenditure and otherwise of the financial status of the pharmacy and of other business activities carried out in the same premises as the pharmacy. The holder of a retail licence for self-treatment medicinal products shall provide the Centre for Safety and Development of Medicinal Products with the information necessary for its development, design and supervision tasks and for the imposition of a quality control fee on the sales of self-care medicinal products. Further provisions on the information to be provided may be laid down by Government decree. The Centre for Safety and Development of Medicinal Products may issue further provisions on the procedure to be followed for the provision of information.

Article 91b

Medicinal products referred to in Paragraph 91a(1) may also be marketed to persons qualified to prescribe a medicinal product and to pharmacies, hospital pharmacies and pharmaceutical centres authorised to supply a medicinal product. Such marketing shall take place only in presentations and publications for persons qualified to prescribe or supply a

medicinal product, as well as in electronic media. Electronic marketing must be carried out in such a way that it cannot target bystanders.

Advertising of medicinal products to persons qualified to prescribe or supply a medicinal product shall contain relevant information on the medicinal product and its use. The exception is, however, the reminder marketing of the medicinal product. Only the name of the medicinal product, its international non-proprietary name or trade mark and, in addition, the holder of the marketing authorisation or registration may be mentioned in the reminder.

ARTICLE 97

The penalty for breaching the obligation of professional secrecy laid down in Sections 30e(3), 54h(2) and 90 shall be sentenced in accordance with Chapter 38, Sections 1 or 2 of the Criminal Code, unless the offence is punishable under Chapter 40, Section 5 of the Criminal Code or a more severe penalty is provided for elsewhere in the Act.

ARTICLE 102

Rectification of an inspector's order referred to in section 78 may be requested from the Finnish Medicines Agency. The decision of the Centre for Safety and Development of Medicinal Products in the cases referred to in Sections 2, 6, 8, 12a, 15a, 15c, 17a, 30e, 30 l, 30n, 32, 48, 51, 52a, 52b, 53, 54f, 57c, 61, 62, 67, 76a, 84b, 87 and 87a may also be challenged. The objection is governed by the Administrative Procedure Act (434/2003).

An administrative decision in a case referred to in Sections 29(2), 49, 50, 66, 79(2) to (3), 80, 80a, 80b, 87c, 88a, 93, 101 and 101a may be appealed to the Korkein hallinto-oikeus (Supreme Administrative Court) without leave to appeal.

The decisions referred to in Sections 2(4), 6, 23c, 23e(3), 30 l, 30n, 59, 66, 79(3), 80, 80a, 80b, 87, 87c, 88a, 93 and 101 of the Centre for Safety and Development of Medicinal Products, the decisions referred to in Sections 68 and 71 of the Regional State Administrative Agencies and the National Supervisory Authority for Welfare and Health and the orders of the inspector shall be complied with notwithstanding the lodging of an appeal, unless otherwise ordered by the appeal authority. Decisions of the Centre for Safety and Development of Medicinal Products pursuant to Sections 21, 21a and 21c of the marketing authorisation for a medicinal product may be enforced before they have become final, unless otherwise ordered by the appeal authority. The decisions of the Centre for Safety and Development of Medicinal Products pursuant to Sections 40, 41, 52, 53, 54 and 54f shall not be enforced until they have become final.

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This Act shall enter into force on 1 January 2026.

The provisions of Sections 23d, 35(1), 37a(1), 57f, 57 g and 58 of this Act and, with regard to the operator of a system for recording and storing the safety features of medicinal products, Article 77(1) shall apply from 1 January 2026.

The provisions of Section 2(1), Sections 23b and 23e and Section 102(3) of this Act concerning decisions pursuant to Section 23e shall apply from 1 October 2026.

The provisions of Articles 9(2), 26, 30u, 31, 32(2), 33(2), 34(1), 37(2) and (3), 38a and 52b, 52d(1), 54a(1), 54f to 54i, in the case of holders of retail licences for self-health medicinal products, in Articles 77(1), 79, 84b(1), 89, 91b, 97, 102(1) and (2) and (3) on the basis of Articles 54f and 79(3) shall apply from 1 January 2027.

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2.

Law

amending the Act on the taxation of pharmacies

In accordance with the Parliamentary resolution,

sections 1 and 5-7 of the Act on the taxation of pharmacies *(* 770/2016) in the version of Section 5 of the Act 1235/2022 are amended as follows:

PARAGRAPH 1

Scope

The taxable person is required to pay pharmacy tax to the State on the sale of medicinal products by his pharmacy.

ARTICLE 5

Taxable amount

The taxable amount for pharmacy tax for the tax year shall be the combined profit margin of the pharmacies of the taxable person on the sales of medicinal products, net of VAT. The profit margin for the sale of medicinal products is the difference between the consideration received by the pharmacies of the taxable person for the sale of medicinal products free of VAT and the purchase prices, exclusive of VAT, of the medicinal products sold immediately, plus the delivery fee per consignment of the medicinal product referred to in Article 58 of the Medicines Act (395/1987). In the case of a medicinal product prepared on prescription in a pharmacy, the purchase prices of the substances, packaging materials and devices used to administer the medicinal product shall be deducted from the consideration received for the sale of the medicinal product before the abovementioned delivery fee is added.

The taxable person shall not be taken into account in determining the taxable amount:

1) contract manufacturing within the meaning of Section 12(2) of the Medicines Act (395/1987);
2) sales of medicinal products to social and healthcare establishments;
3) the sale of medicinal products for nicotine replacement treatment which, under the Medicines Act, may also be sold outside a pharmacy; nor
4) the sale of self-treatment medicinal products within the limited range of self-treatment medicinal products referred to in Article 23d of the Law on medicinal products.

ARTICLE 6

Tax scale

The pharmacy tax is calculated by profit margin group for pharmaceutical sales as follows:

Profit margin on pharmaceutical sales, EUR	Pharmacy tax at the lower margin on pharmaceutical sales, EUR	Tax percentage of the profit margin on sales of medicinal products above the lower threshold, %

0-250 000	0	0
250000-500 000	0	22
500000-750 000	55 000	37
750000-1 000 000	147 500	39
1000000-1 500 000	245 000	41
1500000 —	450 000	43

ARTICLE 7

Calculation of the amount of tax

The pharmacy tax is calculated for each taxable person separately.

The pharmacy tax shall be calculated on the basis of the combined taxable amount of the pharmacy, branch pharmacy, pharmacy service centre and pharmacy's online service on the basis of the tax scale provided for in Section 6.

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This Act shall enter into force on 1 January 2026.

The provisions of this Act shall apply for the first time to the collection of a pharmacy in 2026.

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3.

Law

amending Sections 10 and 13 of the ePrescription Act

In accordance with the Parliamentary resolution,

sections 10 and 13(3)(4) of the *ePrescription* Act (61/2007) in the version of Section 10 in Acts 251/2014, 786/2021 and 706/2023 and Section 13(3)(4) of Act 706/2023 are amended as follows:

ARTICLE 10

Correction, annulment and renewal of prescriptions and end-of-use labelling

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A pharmacist and pharmacist supplying an industrially manufactured medicinal product from a pharmacy may correct an obvious error in the prescription addressed to the user of the medicinal product which is not supplied, as regards the trade name, pack size, pharmaceutical form, strength or dosage instructions of the prescribed medicinal product. The correction must be necessary on the basis of pharmaceutical judgement. The repair shall not compromise the safety of medication, indicate that the total quantity of the medicinal product is exceeded or deviate from the particulars prescribed by the prescriber. In the case of a prescription or prescription issued or stored by telephone for a medicinal product which is compassionate, a medicinal product containing a narcotic substance, a medicinal product primarily active on the central nervous system or a medicinal product containing alcohol, the repair shall be subject to the consent of the prescriber. The repair must be made in agreement with the purchaser of the medicinal product and in accordance with Article 57 of the Medicines Act. The purchaser of the medicinal product shall be invited to communicate with the prescriber, if necessary. Information on how to correct the prescription, on the person who issued it, on the reason, and on any contact with the prescriber is recorded in the prescription centre.

The repair, cancellation, non-renewal or discontinuation of a medicinal product in use referred to in paragraphs 1 to 5 shall be justified.

More detailed provisions on the rectification, annulment, renewal and non-renewal of an electronic prescription and on the indication of cessation of use of the medicinal product may be laid down by decree of the Ministry of Social Affairs and Health.

ARTICLE 13

Patient's right to order the disclosure of information

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Notwithstanding paragraph 1, the following may be surrendered:

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(4) to the prescriber, in the event of a continuing relationship of treatment, of the prescriptions he has placed in the prescription centre and of the related labelling, and irrespective of the medical relationship, irrespective of the prescriptions placed by the pharmacy at the prescription centre pursuant to Article 12(3) of the Law on medicinal products, the recording of changes to the dosage instructions by a nurse, pharmacist or pharmacist in accordance with Paragraph 5a, of the prescriptions made by pharmacists and pharmacists pursuant to Paragraph 10, and of the prescriptions made by pharmacists and pharmacists pursuant to Article 57f of the Law on medicinal products in respect of which they are registered as prescribers and of the indications relating to those prescriptions;

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This Act shall enter into force on 1 January 2026.
Article 10 of the Act shall apply from 1 October 2027.

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4.

Law

amending Chapter 5, Section 1 and Chapter 18, Section 10 of the Health Insurance Act

In accordance with the Parliamentary resolution,

Chapter 5, Section 1(1) and Chapter 18, Section 10 of the Health Insurance Act (1224/2004) are *amended*.

as it is in Chapter 5, Section 1, subsection 1 of Act 1221/2019 and Chapter 18 Section 10 of Act 693/2024, as follows:

Chapter 5

Pharmaceutical subsidies

PARAGRAPH 1

Medicinal product to be reimbursed

The insured person is entitled to reimbursement of the costs of a medicinal product prescribed by a doctor and a dentist and by a nurse entitled to prescribe a limited or fixed term. The medicinal product shall be reimbursed on condition that it is a medicinal product subject to medical prescription in accordance with the Medicines Act (395/1987) and intended to cure or facilitate the disease or its symptoms, whether used internally or externally. The insured person shall also be entitled to reimbursement in respect of an interchangeable medicinal product listed by the Centre for Safety and Development of Medicinal Products for which the medicinal product prescribed for the patient has been exchanged in a pharmacy in accordance with Section 57b of the Medicines Act and for a medicinal product supplied to the patient under Section 57f of the Medicinal Products Act or in a pharmacy on the basis of a corrected prescription under Section 10 of the Act on electronic prescription (61/2007). It is also required that the reimbursement of a medicinal product approved by the Medicinal Products Pricing Board is valid and that the price charged to the insured for the medicinal product does not exceed the reasonable wholesale price fixed or the maximum wholesale price referred to in Chapter 6, Paragraph 22, plus a margin and VAT up to the price of the supply of a pharmacy in accordance with the pharmaceutical tariff referred to in Article 58 of the Law on medicinal products.

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Chapter 18

Health insurance fund and insurance premiums

ARTICLE 10

State contribution

51.4 % of the total health insurance costs referred to in Article 8(1), points 1 to 4, and Article 8(2) and (3) shall be financed from State resources. In addition, the costs of medical treatment referred to in Section 8(1)(5) are financed from State resources in so far as they are not covered by reimbursements of expenses received from abroad on the basis of medical care benefits provided in Finland. The refund payment referred to in Chapter 6, Section 6a, paragraph 2, fully reduces the State contribution.

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This Act shall enter into force on 1 January 2026.

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Helsinki, x.x.20xx

Premier

Petteri Orpo

Sanni Grahn-Laasonen, Minister for Social Security

1.

Law

amending the Medicines Act

In accordance with the Parliamentary resolution,

Articles 2(1), 9(2), 23b, 26, 30u, 31, 32(2), 33(2), 34(1), 35(1), 37(2) and (3), 37a(1), 38a, 52b, 52d(1), 54a(1) of the Medicines Act (395/1987), Articles 58, 77(1), 84b(1), 89, 91b, 97 and 102 as *amended* by Articles 2(1), 9(2) and 33(2) of Law 1200/2013, Articles 23b, 26, 32(2) and 35(1) of Law 853/2005, Articles 30u, 52b, 52d(1), 97 and 102 of Law 1258/2021, Article 31, Acts 1112/2010 and 1200/2013, Section 34(1) of Act 978/2013, Section 37(2) and (3) of Act 553/2020, Section 37a(1) of Act 22/2006, Sections 38a and 54a(1) of Act No 1112/2010, Section 58 of Acts 1258/2021 and 1233/2022, Section 77(1) and Article 89 of Law 985/2021, Section 84b(1) of Acts 789/2016 and 91b in Acts 700/2002 and 853/2005; and

insert new Sections 23d, 23e, 54f to 54i, 57f and 57 g and a new Section 79 thereof by Act 1039/2015

in place of Article 79, which has been repealed, as follows:

The Act in force	*Proposal*
ARTICLE 2	
Scope	
This Law applies to medicinal products, their manufacture, importation, distribution, brokering and sale and any other release for consumption, pharmaceutical factories carrying out the abovementioned activities, wholesale medicinal products, brokers and pharmacies, laboratories carrying out pre-clinical safety studies of medicinal products, and the manufacture and distribution of medicinal products in hospitals and health centres.	This Law applies to medicinal products, their manufacture, importation, distribution, brokering and sale and any other release for consumption, pharmaceutical factories carrying out the abovementioned activities, wholesale medicinal products, brokers and pharmacies, laboratories carrying out pre-clinical safety studies of medicinal products, and the manufacture and distribution of medicinal products in hospitals and health centres. *That law also applies to the retail sale of certain self-medication and nicotine products outside the pharmacy.*
This Act shall also provide for the marketing authorisation and registration of a medicinal product and for further supervision of the activities referred to in paragraph 1.	This Act shall also provide for the marketing authorisation and registration of a medicinal product and for further supervision of the activities referred to in paragraph 1.
The provisions of this Act shall not apply to preparations used solely for the treatment of ornamental parasites, fungi or bacterial diseases Paragraph 2.	The provisions of this Act shall not apply to preparations used only for the treatment of parasites, fungi or bacterial diseases of ornamental fish.
Scope	

The Act in force

and not only vitamin preparations of cage birds considered as pets, terrary animals or small rodents. Article 55(1) shall not apply to the homeopathic products referred to in Article 22a of the Law.

The provisions of this Act concerning the granting of a marketing authorisation, the modification of a medicinal product, the fees relating to the marketing authorisation, the withdrawal of a marketing authorisation and the prohibition of release for consumption shall not apply to medicinal products for which the granting of a marketing authorisation and any other supervision thereof is decided by the European Medicines Agency or by the Commission of the European Communities or by the Council of the *European Union (an institution* of the European Union), as provided for in legal acts of the European Community. If the protection of human or animal health or the environment so requires as a matter of urgency, the Centre for Safety and Development of Medicinal Products may provisionally prohibit the release for consumption of a medicinal product pending a decision by an institution of the European Union. The fees relating to the importation and monitoring of the medicinal products referred to in this paragraph may be laid down by decree of the Ministry of Social Affairs and Health. The amount of the charge is determined in accordance with the provisions of the Act on Criteria for Charges Payable to the State (150/1992). The Centre for Safety and Development of Medicinal Products may issue more detailed regulations on the marketing and supervision of medicinal products referred to in this paragraph, in so far as the matter is not provided for in European Community legislation or the powers of the institutions of the European Union have not been suspended.

Proposal

This Law also lays down rules on limited stocks of medicinal products for shared use held in social care housing units, their use in medical treatment and their supervision.

ARTICLE 9

and not only vitamin preparations of cage birds considered as pets, terrary animals or small rodents. Article 55(1) shall not apply to the homeopathic products referred to in Article 22a of the Law.

The provisions of this Act concerning the granting of a marketing authorisation, the modification of a medicinal product, the fees relating to the marketing authorisation, the withdrawal of a marketing authorisation and the prohibition of release for consumption shall not apply to medicinal products for which the granting of a marketing authorisation and any other supervision thereof is decided by the European Medicines Agency or by the Commission of the European Communities or by the Council of the European Union (an institution of the European Union), as provided for in legal acts of the European Community. If the protection of human or animal health or the environment so requires as a matter of urgency, the Centre for Safety and Development of Medicinal Products may provisionally prohibit the release for consumption of a medicinal product pending a decision by an institution of the European Union. The fees relating to the importation and monitoring of the medicinal products referred to in this paragraph may be laid down by decree of the Ministry of Social Affairs and Health. The amount of the charge is determined in accordance with the provisions of the Act on Criteria for Charges Payable to the State (150/1992). The Centre for Safety and Development of Medicinal Products may issue more detailed regulations on the marketing and supervision of medicinal products referred to in this

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paragraph, in so far as the matter is not provided for in European Community legislation or the powers of the institutions of the European Union have not been suspended.

The pharmaceutical factory shall have a direct employment manager, who shall be primarily responsible for ensuring that the medicinal products manufactured by the factory meet the requirements imposed on them by or pursuant to this Law and that they are of sound quality and must have a direct employment relationship with a responsible manager, who shall be primarily responsible for ensuring that the medicinal products manufactured by the pharmaceutical factory meet the requirements imposed on them by or pursuant to this Law and that they are of sound quality and that, in the industrial preparation of medicinal products, the provisions of this Law relating to the manufacture and control of the quality of medicinal products and the provisions adopted pursuant thereto are complied with.

The responsible manager of a pharmaceutical plant must be a qualified pharmacist or other relevant master's degree. In addition, the accountable manager is required to have been active in a pharmaceutical plant for a sufficient period of time in the manufacturing or quality assurance of medicinal products. The general manager shall not be at the same time a director of another company authorised to manufacture medicinal products on an industrial basis. In addition, the accountable manager may not be a responsible director in the wholesale distribution of medicinal products by another company, or a pharmacist, a hospital or pharmaceutical centre manager, a military pharmacy manager or a pharmacy or branch pharmacy manager. The qualifications of the accountable

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This Law also lays down rules on limited stocks of medicinal products for shared use held in social care housing units, their use in medical treatment and their supervision.

ARTICLE 9

manager may, if necessary, be laid down in more detail by Government decree.

If, in addition to the qualification requirements referred to in paragraph 2, the accountable manager does not satisfy the eligibility criteria laid down in Article 53 of the Veterinary Medicinal Products Directive or Article 49 of the Medicinal Products Directive, the holder of the authorisation which manufactures some or all of the medicinal products shall have a direct employment relationship with at least one of the persons eligible under those directives. The qualified person is responsible for ensuring that batches of medicinal products have been manufactured in accordance with the marketing authorisation and good manufacturing practice. The Centre for Safety and Development of Medicinal Products may issue further provisions on the tasks of the qualified person.

Derogations from the qualification requirements laid down in subsections 2 and 3 may be provided by Government decree for the responsible head and qualified person of the unit responsible for the quality of medicinal products and of the laboratory.

compliance with the provisions of this Act concerning the manufacture and quality control of medicinal products and the regulations and regulations adopted pursuant thereto when medicinal products are manufactured industrially.

The responsible manager of a pharmaceutical plant must be a qualified pharmacist or other relevant master's degree.

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In addition, the accountable manager is required to have been active in a pharmaceutical plant for a sufficient period of time in the manufacturing or quality assurance of medicinal products. The general manager shall not be at the same time a director of another company authorised to manufacture medicinal products on an industrial basis. In addition, the accountable manager may not be a responsible director in the wholesale distribution of *medicinal products by another company, or a pharmacist, a hospital pharmacy or a pharmaceutical centre, a manager of a military pharmacy, a manager of a pharmacy or a branch pharmacy, or a holder of a retail licence for self-medical medicinal products, a member of his management or a person responsible for the sale of self-medical medicinal products.* The qualifications of the accountable manager may, if necessary, be laid down in more detail by Government decree.

If, in addition to the qualification requirements referred to in paragraph 2, the accountable manager does not satisfy the eligibility criteria laid down in Article 53 of the Veterinary Medicinal Products Directive or Article 49 of the Medicinal Products Directive, the holder of the authorisation which manufactures some or all of the medicinal products shall have a direct employment relationship with at least one of the persons eligible under those directives. The qualified person is responsible for ensuring that batches of medicinal products have been manufactured in accordance with the marketing authorisation and good manufacturing practice. The Centre for Safety and Development of Medicinal Products may issue further provisions on the tasks of the qualified person.

Derogations from the qualification requirements laid down in subsections 2 and 3 may be provided by Government decree for

the responsible head and qualified person of the unit responsible for the quality of medicinal products and of the laboratory.

Article 23b

If a condition attached to a marketing authorisation, according to which a medicinal product for human use may only be supplied on the basis of a prescription (prescription condition), has been removed on the basis of extensive pre-clinical or clinical trials carried out by the marketing authorisation holder, the marketing authorisation holder of another medicinal product containing the same active substance may apply for the waiver of the prescription on the basis of those studies at least one year after the change of the term of the marketing authorisation for the reference medicinal product.

(New article)

Article 23b

When granting a marketing authorisation for a medicinal product, the Centre for Safety and Development of Medicinal Products shall decide, as part of the terms of the marketing authorisation for a medicinal product referred to in Article 21(2), whether the medicinal product may be sold or otherwise released for consumption only on the basis of a prescription.

The Medicinal Products Safety and Development Centre may amend the decision referred to in paragraph 1 on the basis of new

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information received on the medicinal product which affects the classification of the supply.

If a condition attached to a marketing authorisation, according to which a medicinal product for human use may only be supplied on the basis of a prescription (prescription condition), has been removed on the basis of extensive pre-clinical or clinical trials carried out by the marketing authorisation holder, the marketing authorisation holder of another medicinal product containing the same active substance may apply for the waiver of the prescription on the basis of those studies at least one year after the change of the term of the marketing authorisation for the reference medicinal product.

The marketing authorisation holder and the registration holder referred to in Section 22 shall ensure that the authorised medicinal product and the registered traditional herbal medicinal product are available at all times to wholesalers *and* pharmacies of medicinal products, in accordance with the needs of patients and other users.

The marketing authorisation holder may apply to the Finnish Medicines Agency for an extension of the sales channel for his own-care medicinal product to sales outside pharmacies. The extension of the sales channel is granted—

Don’t forget if:

1) a self-treatment medicinal product shall be included in the categories of medicinal products referred to in Article 23d which constitute a limited range of self-medication products;

A limited range of self-medicines consists of a number of categories of medicinal products which are assessed to present low risks and which are assessed as capable of safe treatment without advice.

The limited range of self-treatment medicinal products referred to in subsection 1 shall be further defined by Government decree.

*(New article)*Article 23e

If, in accordance with Paragraph 23b(1) or (2), the Finnish Medicines Agency has attached to the marketing authorisation a condition that the medicinal product may be sold or otherwise released for consumption without prescription (as a self-treatment product),*the*medicinal product may only be sold in a pharmacy.

Article 23d
ARTICLE 26

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2) the risks associated with the self-treatment product are low; and
3) treatment with the medicinal product can be carried out safely without medical advice.

The provisions of paragraphs 1 and 2 shall not apply to the products referred to in sections 22, 22a or 54a. Self-care medicinal products which are supplied to the purchaser of the medicinal product as reimbursed in accordance with the Health Insurance Act (1224/2004) are only sold in a pharmacy.

The Medicinal Products Safety and Development Centre may amend the decision referred to in paragraph 2 on the basis of new information received on the basis of a

Article 30u

Wholesale distribution of medicinal products shall check the safety features of the medicinal product and remove the individual section tun30u referred to in the Falsified Medicinal Products Directive and the EU Regulation on the safety features of medicinal products.

Wholesale trade must check the safety features of a medicinal product and remove the unique identifier referred to in the Falsified Medicinal Products Directive and the EU Regulation on the safety features of medicinal products before it is handed over to a military pharmacy, a veterinarian for veterinary purposes, a university, a university

Sales from a pharmaceutical plant

ARTICLE 31

Only another pharmaceutical factory, wholesale medicine, pharmacy, branch pharmacy, military pharmacy, hospital pharmacy and pharmaceutical centre may sell or otherwise distribute pharmaceutical substances and proprietary medicinal products. In addition, medicinal products

marketing authorisation holder's application or on its own initiative, which affects the sales channel.

ARTICLE 26

The marketing authorisation holder and the holder of the registration referred to in Article 22 shall ensure that the authorised medicinal product and the registered traditional herbal medicinal product are *available on an ongoing basis to wholesale distributors, pharmacies and retail licence holders of self-*medication medicinal products, in accordance with the needs of patients and other users.

or a scientific research institute for research, or a health and welfare institution when it maintains stocks of medicinal products for civil protection or disaster management.

niste käytöstä ennen kuin lääkevalmiste luovutetaan Sotilasapteekille, *itsehoitolääkkeen vähittäismyyntiluvanhaltijalle,* eläinlääkärille eläinlääkintää varten, yliopistolle, korkeakoululle tai tieteelliselle tutkimuslaitokselle tutkimustoimintaa varten taikka Terveyden ja hyvinvoinnin laitokselle silloin, kun se ylläpitää lääkevarastoja väestönsuojelua tai katastrofien hallintaa varten.

which are not prescribed or prescribed for sale only from pharmacies may also be sold and otherwise disposed of to retailers of those products.

Pharmaceuticals and own pharmaceutical products may also be sold or otherwise disposed of by a pharmaceutical plant to a university, a university and a scientific research institute for research purposes. The

pharmaceutical factory shall report this to the Finnish Medicines Agency.

Medicinal products outside Finland may only be supplied from a pharmaceutical factory to an operator who is legally entitled in that country to obtain medicines from a pharmaceutical factory.

Sales from a pharmaceutical plant

ARTICLE 31

Only another pharmaceutical factory, wholesale medicine, pharmacy, branch pharmacy, military pharmacy, hospital pharmacy and pharmaceutical centre may sell or otherwise distribute pharmaceutical substances and proprietary medicinal products. In addition, medicinal products which are not prescribed or prescribed for sale only from pharmacies may also be sold and otherwise disposed of to retailers of those products. *In addition, self-care medicinal products for human use which have been granted the extension of the sales channel referred to in Paragraph 23e(2) may be sold to holders of retail licences for self-treatment medicinal products.*

Pharmaceuticals and own pharmaceutical products may also be sold or otherwise disposed of by a pharmaceutical plant to a university, a university and a scientific research institute for research purposes. The pharmaceutical factory shall report this to the Finnish Medicines Agency.

Medicinal products outside Finland may only be supplied from a pharmaceutical factory to an operator who is legally entitled in that country to obtain medicines from a pharmaceutical factory.

Practising the wholesale trade of medicines

ARTICLE 32

“Wholesale distribution of medicinal products” means any professional *activity and for* consideration.

ARTICLE 32

Wholesale distribution of medicinal products shall mean any activity carried out on a professional basis and for consideration, the purpose of which is to:

(1)receipt of orders for medicinal products and delivery other than those referred to in paragraph 2;

(2)the acquisition and possession of medicinal products for onward delivery to pharmacies, social and health institutions and other entities referred to in Sections 34, 35 and 88 of this Act; or

(3)exporting medicinal products.

However, the wholesale distribution of medicinal products does not constitute the sale to the public of medicinal products and medicinal products in accordance with Paragraph 38, the supply of medicinal products and medicinal products from one pharmacy to another pharmacy or social and healthcare establishment, the supply of medicinal products and medicinal products from a hospital pharmacy or a pharmaceutical centre in accordance with Paragraph 62, or marketing and billing by the holder of the marketing authorisation or his representative, which does not involve the holding, distribution or storage of the products.

The wholesale distribution of medicinal products may be carried out only with the authorisation of the Centre for Safety and Development of Medicinal Products. The authorisation shall be granted on condition that the applicant has at its disposal the appropriate facilities, facilities and facilities to preserve and ensure the operation of the medicinal products and that the applicant has

the necessary staff to do so. Operating conditions may be attached to the permit. The Centre for Safety and Development of Medicinal Products is responsible for entering information related to the authorisation into a database maintained by the European Medicines Agency.

The recognition of a wholesale distribution licence granted in a Member State of the European Economic Area in accordance with the provisions of the European Communities and the period within which an application for a licence must be decided shall be laid down by Government decree.

activities carried out for the purpose of:

(1)receipt of orders for medicinal products and delivery other than those referred to in paragraph 2;

(2)the acquisition and possession of medicinal products for onward delivery to pharmacies, social and health institutions and other entities referred to in Sections 34, 35 and 88 of this Act; or

(3)exporting medicinal products.

However, the wholesale distribution of medicinal products does not constitute the sale to the public of medicinal products and medicinal products in accordance with Paragraph 38a, the supply of medicinal

ARTICLE 33

The wholesale distribution of medicinal products must have a direct employment relationship with responsibility under Section 33

The wholesale distribution of medicinal products shall have a direct employment manager, who shall be responsible for ensuring that medicinal products sold in the wholesale trade of medicinal products meet

products and medicinal products from one pharmacy to another pharmacy or social and healthcare establishment, the supply of medicinal products and medicinal products from *a* hospital pharmacy or a pharmaceutical centre in accordance with Paragraph 62, or marketing and billing by the holder of the marketing authorisation or his representative, which does not involve the holding, distribution or storage of the products.

The wholesale distribution of medicinal products may be carried out only with the authorisation of the Centre for Safety and Development of Medicinal Products. The authorisation shall be granted on condition that the applicant has at its disposal the appropriate facilities, facilities and facilities to preserve and ensure the operation of the medicinal products and that the applicant has the necessary staff to do so. Operating conditions may be attached to the permit. The Centre for Safety and Development of Medicinal Products is responsible for entering information related to the authorisation into a database maintained by the European Medicines Agency.

The recognition of a wholesale distribution licence granted in a Member State of the European Economic Area in accordance with the provisions of the European Communities and the period within which an application for a licence must be decided shall be laid down by Government decree.

the requirements imposed on them by this Law or by the provisions and regulations adopted pursuant to it and that the provisions governing the storage, handling and labelling of medicinal products are complied with in the wholesale distribution of medicinal products. In addition, the responsible manager is responsible for the proper distribution of medicinal products in the wholesale distribution of medicinal products.

The responsible manager of the wholesale trade must be a qualified pharmacist. The

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general manager shall not be at the same time a director in charge of another company authorised to engage in the wholesale distribution of medicinal products. In addition, the accountable manager may not be a responsible director of another company's pharmaceutical plant, nor a pharmacist, a hospital pharmacy or a pharmaceutical centre, a manager of a military pharmacy or a pharmacy or branch pharmacy. The qualification requirements of the accountable manager may be laid down in more detail by Government decree.

The wholesale distribution of medicinal products shall immediately inform the Centre for Safety and Development of Medicinal Products and, where appropriate, the marketing authorisation holder of medicinal products received by or offered to the wholesaler which it finds or suspects to be falsified.

ARTICLE 34

a director who is responsible for ensuring that medicinal products sold in the wholesale trade of medicinal products meet the requirements imposed on them by this Act or by the provisions and regulations adopted pursuant to it and that the provisions governing the storage, handling and labelling of medicinal products are complied with in

The wholesale distribution of medicinal products may be sold or otherwise disposed of to a pharmaceutical factory, another pharmaceutical wholesaler, a pharmacy, a branch pharmacy, a military pharmacy, a hospital pharmacy and a pharmaceutical centre, and a veterinarian for veterinary purposes. In addition, medicinal products which are not prescribed or prescribed for sale only from pharmacies may also be sold and otherwise disposed of to retailers of those

the wholesale distribution of medicinal products. In addition, the responsible manager is responsible for the proper distribution of medicinal products in the wholesale distribution of medicinal products.

The responsible manager of the wholesale trade must be a qualified pharmacist. The general manager shall not be at the same time a director in charge of another company authorised to engage in the wholesale distribution of medicinal products. In addition, the accountable manager shall not be a responsible director of another company's pharmaceutical plant, nor a pharmacist, a hospital pharmacy or a pharmaceutical centre manager, a manager of a military pharmacy, a pharmacy or branch pharmacy, *nor a holder of a retail licence for self-medical medicinal products, a member of his management or a person responsible for the sale of self-medical medicinal products.* The qualification requirements of the accountable manager may be laid down in more detail by Government decree.

The wholesale distribution of medicinal products shall immediately inform the Centre for Safety and Development of Medicinal Products and, where appropriate, the marketing authorisation holder of medicinal products received by or offered to the wholesaler which it finds or suspects to be falsified.

products. When selling or otherwise dispensing medicinal products outside the EU and the EEA, a wholesaler shall ensure that medicinal products are supplied only to an operator who is legally entitled in that country to obtain medication.

The wholesale distribution of medicinal products may be sold or otherwise disposed of to a pharmaceutical factory, another pharmaceutical wholesaler, a pharmacy, a branch pharmacy, a military pharmacy, a

The Act in force *Proposal*

hospital pharmacy and a pharmaceutical centre, and a veterinarian for veterinary purposes. In addition, medicinal products which are not prescribed or prescribed for sale only from pharmacies may also be sold and otherwise disposed of to retailers of those products. *Self-care medicinal products which have been granted the extension of the sales channel referred to in Paragraph 23e(2) may also be sold to holders of retail licences for self-treatment medicinal products.* When a wholesaler of medicines sells or otherwise dispenses medicines outside the EU/EEA, who is involved in the wholesale trade of medicines. When selling or otherwise disposing outside the EU/EEA of medicinal products received by wholesalers from outside the EU/EEA without having been imported into the Union, wholesalers shall ensure that medicinal products are only obtained from persons authorised or entitled to supply medicinal products to the wholesaler in that country.

In addition, the wholesale distribution of medicinal products may be sold or otherwise handed over to another trader for use in the course of manufacturing activities other than as a medicinal product, as well as medicinal products to the universities, universities and scientific research institutes referred to in Article 17(1)(5) for the purpose of carrying out research activities.

Where medicinal products are supplied to the purchasers referred to in subsections 1 and 2, the supply of the medicinal product shall be accompanied by a document containing the information relating to the medicinal product. The Centre for Safety and Development of Medicinal Products may issue further provisions on the particulars to be included in the dossier and on the procedures by which wholesale distributors ensure the legal right of suppliers and recipients of medicinal products to supply and receive medicinal products.

ARTICLE 35

ensure that medicinal products are only supplied to an operator that is legally entitled in that country to purchase medicinal products from the wholesale distribution of medicinal products. When selling or otherwise disposing outside the EU/EEA of medicinal products received by wholesalers from outside the EU/EEA without having been imported into the Union, wholesalers shall ensure that medicinal products are only obtained from persons authorised or entitled to supply medicinal products to the wholesaler in that country.

In addition, the wholesale distribution of medicinal products may be sold or otherwise handed over to another trader for use in the course of manufacturing activities other than as a medicinal product, as well as medicinal products to the universities, universities and scientific research institutes referred to in Article 17(1)(5) for the purpose of carrying out research activities.

Where medicinal products are supplied to the purchasers referred to in subsections 1 and 2, the supply of the medicinal product shall be accompanied by a document containing the information relating to the medicinal product. The Centre for Safety and Development of Medicinal Products may issue further provisions on the particulars to be included in the dossier and on the procedures by which wholesale distributors ensure the legal right of suppliers and recipients of medicinal products to supply and receive medicinal products.

ARTICLE 35

Medicinal products may be supplied free of charge from the pharmaceutical factory and

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wholesale medicine to doctors, dentists, veterinary surgeons and pharmacists, hospital pharmacies and medical centre operators for sample and stand-by purposes. Accordingly, medicinal products which are not *prescribed or* prescribed for sale *only* from*pharmacies may be supplied to* retailers of those products.	medicinal product. An upholstery pack is a special packaging intended to be delivered free of charge to the patient for the immediate start of treatment. Further provisions on the conditions and restrictions on the supply of sample and standby packs may be laid down by Government decree. In addition, the Centre for Safety and Development of Medicinal Products may issue more detailed regulations on the labelling, storage and monitoring of the use of sample and on-call packages.
‘Sample of medicinal products’ means the smallest pack size of a medicinal product supplied from a pharmaceutical factory and from a wholesale trade in medicinal products, which may be *supplied free of charge to doctors, dentists, veterinarians and non-prescription medicinal products* to pharmacists, hospital pharmacists and medical centre operators for sample and standby purposes. *Packages of samples of registered homeopathic products and traditional herbal medicinal products* which are not prescribed exclusively for sale in *pharmacies may be supplied from the pharmaceutical factory and the* wholesaler to retailers of those products. ‘Sample of medicinal products’ means the smallest pack size of a medicinal product, which is supplied free of charge from a pharmaceutical factory or from a wholesale trade for the purpose of accessing the	ARTICLE 37 free of charge from a pharmaceutical factory or from a wholesale medicine shop for access to a medicinal product. An upholstery pack is a special packaging intended to be delivered free of charge to the patient for the immediate start of treatment. Further provisions on the conditions and restrictions on the supply of sample and standby packs may be laid down by Government decree. In addition, the Centre for Safety and Development of Medicinal Products may issue more detailed regulations on the labelling, storage and monitoring of the use of sample and on-call packages.
The wholesale distribution of medicinal products must seek to ensure that it has the necessary quantity of medicinal products to be sold. The wholesaler must immediately inform the pharmacy, hospital pharmacy, centre of medicine or veterinarian who ordered the medicinal product of a break in the distribution of the medicinal product ordered. The wholesale distribution of medicinal products shall include information on the shortage of the medicinal product and an estimate of the duration of the supply disruption.	ARTICLE 37 The wholesale distribution of medicinal products shall immediately inform the Finnish Medicines Agency and all pharmacies, hospital pharmacies, pharmaceutical centres and veterinary surgeons of any disruption or interruption of the supply of medicinal products which has a significant impact on the implementation of the distribution of medicinal products.
	The wholesale distribution of medicinal products must seek to ensure that it has the

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necessary quantity of medicinal products to be sold.

The wholesaler of medicinal products shall immediately inform the pharmacy, hospital pharmacy, pharmaceutical centre, retail licence holder of self -*treatment medicinal products or* veterinary surgeon of the dispensation of the medicinal product ordered. The wholesale distribution of medicinal products shall include information on the shortage of the medicinal product and an estimate of the duration of the supply disruption.

The wholesale distribution of medicinal products shall immediately inform the Finnish Medicines Agency and all pharmacies, hospital pharmacies, pharmaceutical centres, holders of retail licences for self-treatment *medicinal products and veterinarians of* any disruption or interruption in the distribution of medicinal products, which has a significant impact on the implementation of the distribution of medicinal products.

Article 37a

The wholesale price of a medicinal product shall be the same for all pharmacies and branch pharmacies. The wholesale price shall take into account all discounts, rebates and other benefits granted to pharmacies and branch pharmacies. The wholesale price shall be notified to the entities providing information on the prices of medicinal products. Those wholesale restrictions do not apply to the wholesale prices of medicinal products which may also be sold outside pharmacies.

37 section A

The wholesale price of a medicinal product shall be the same for all pharmacies and branch pharmacies. The wholesale price shall take into account all discounts, rebates and other benefits granted to pharmacies and branch pharmacies. The wholesale price shall be notified to the entities providing information on the prices of medicinal products. Those wholesale price restrictions do not apply to the wholesale prices of medicinal products which, by way of derogation from paragraph 1, may also be sold in respect of a medicinal product used for the distribution of medicinal products falling within the list of interchangeable medicinal products referred to in Article 57c and in the reference price category referred to in Chapter 6, Paragraph 18, of the Health Insurance Act (1224/2004). The reduction may be granted if the fixed reference price changes and the medicinal product used when the change takes effect is more expensive than the new reference price. The reduction shall not be granted for more than 30 days after the change in the reference price.

38 section A

below as in pharmacies. Furthermore, the *restrictions do not apply to a limited range of self-medication products, as defined in Article 23d. However, the national wholesale price of self-treatment medicines in the range must be communicated to the entities providing the price information.*

By way of derogation from paragraph 1, a person carrying out a mechanised distribution of medicinal products may be granted a discount on a medicinal product used for dosage distribution which is included in the list of interchangeable medicinal products referred to in section 57c and in the reference price category referred to in Chapter 6, Section 18 of the Health Insurance Act (1224/2004). The reduction may be granted if the fixed reference price changes and the medicinal product used when the change takes effect is more expensive than the new

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reference price. The reduction shall not be granted for more than 30 days after the change in the reference price.	
Medicinal products may be sold to the public only from a pharmacy, a branch pharmacy, a pharmacy service facility and an online pharmacy service within the meaning of this Law. However, the traditional herbal medicinal products *and homeopathic products referred to in Sections 22 and 22a may also be sold elsewhere unless the Finnish Medicines Agency has decided otherwise at the time of registration. In addition, nicotine products may also be sold elsewhere in accordance with the provisions of Article 54a below.*	Medicinal products may be sold to the public only from a pharmacy, a branch pharmacy, a pharmacy service facility and an online pharmacy service within the meaning of this Law. *However, the traditional herbal medicinal products and homeopathic products referred to in Sections 22 and 22a may also be sold outside a pharmacy, unless the Finnish Medicines Agency has decided otherwise at the time of registration. In addition, nicotine products and self-care medicinal products which have been granted the extension of the sales channel referred to in Article 23e(2) may also be sold:*
Article 38a Article 52b	
A pharmacist, a pharmacy at the University of Helsinki and a pharmacy at the University of Eastern Finland can also provide pharmacy services through the pharmacy's online service. The operator of the pharmacy's online service must have a website where medicinal products are offered for sale at a distance. *Those pages*shall contain *a link to the list of legal online pharmacies services kept by the Centre for Safety and Development of Medicinal Products and clearly visible in non-pharmaceutical sites 85, as provided for in Paragraphs 54a to 54i below.*	service. *The holder of a retail licence for self-treatment medicinal products may also offer, through an online service, self-care medicinal products for which the extension of the sales channel referred to in Paragraph 23e(2) has been granted. The common logo used in the European Union for the sale of medicinal products* at a distance in accordance with Article (c).
Article 52b	
A pharmacist, a pharmacy at the University of Helsinki and a pharmacy at the University of Eastern Finland can also provide pharmacy services through the pharmacy's online	The maintenance of the pharmacy's online service shall be subject to prior notification to the Centre for Safety and Development of Medicinal Products. The prior notification shall be accompanied by a plan for the organisation of the medical advice provided for in Article 57(2). Operations may be commenced unless, within 60 days of receipt of the notification, the Centre has requested further clarification on the matters referred to

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in this article or has refused to commence the activity. The Centre shall be notified of the commencement, termination and material changes. The Centre may prohibit the commencement of an activity or order the termination of an online service if the pharmacy's online service does not meet the conditions laid down in this section, in the provisions referred to in paragraph 6, in Sections 55(3), 56, 57 *or* 57, or in the orders issued pursuant to Paragraphs 49(2), 50, 51 or 80b.	
The *pharmacy operating the online service of a pharmacy* must ensure that the marketing of the medicinal product is lawful in the State to which the medicinal product is sold. Prescription-only medicinal products may only be supplied on the basis of an electronic prescription under the ePrescription Act (61/2007) from the pharmacy's online service. The pharmacist is responsible for operating and operating the pharmacy's online service. The online service shall be inspected annually by the pharmacist. *The pharmacist shall provide the pharmacy's network*with appropriate storage and transport conditions for the medicinal products supplied through the service. The operators of the pharmacy's*online* service must have a website where medicinal products are offered for sale at a distance. The website should contain a link to the Catalogue of Legal Distance Selling Services for *Medicinal Products, maintained by the Centre for Safety and Development of Medicinal Products, and* clearly display the common logo in the European Union in accordance with Article 85c of the Medicinal Products Directive. *The distance sales service of medicinal products* shall be subject to prior notification to the Centre for Safety and Development of Medicinal Products. *Pharmacies shall attach*	*to the notification* a plan for the organisation of the medical advice provided for in Article 57(2). Operations may be commenced unless, within 60 days of receipt of the notification, the Centre has requested further clarification on the matters referred to in this article or has refused to commence the activity. The Centre shall be notified of the commencement, termination and material changes. The Centre may prohibit the commencement of an activity or order the termination of the service if the distance sales service for *medicinal products does not* meet the conditions *laid down in this section, the provisions referred to in paragraph 6, the pharmacy's online service does not meet the conditions laid down in Paragraph 55(3), Paragraph 56 or 57 or the orders adopted pursuant to Article 57(3), the holder of a retail licence for self-medical medicinal products does not meet the conditions laid down in Article 54h, or the pharmacist* is subject to measures under Paragraph 49(2), Paragraphs 50, 51 or 80b, *or to the holder of a retail licence for self-pharmaceutical medicinal products under Paragraph 79.* *The operator of* a distance sales service for medicinal products must satisfy itself that the marketing of the medicinal product is lawful in the State to which the medicinal product is sold. Prescription-only medicinal products may only be supplied on the basis of an electronic prescription under the ePrescription Act (61/2007) from the pharmacy's online service. *The operator* is responsible for operating *and managing the distance sales service for medicinal products*. *The latter* shall inspect the *service* annually *and* ensure appropriate storage and transport conditions for the medicinal products supplied through the service. The pharmacy's online service should have an adequate menu, taking into account the different therapeutic groups, and

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the cheapest available medicinal products should be available.	
A *pharmacy's network service entered in the register kept by the Centre for Safety and Development of Medicinal Products may, once a pharmacy licence* has been opened, be maintained by a pharmacist who ceases to operate a pharmacy within the meaning of Article 46 or by a pharmacy operator within the meaning of Article 59 until the pharmacy has been taken over by a new pharmacy licensed. A new pharmacy licensed shall submit a notification to the Centre for Safety and Development of Medicinal Products pursuant to paragraph 1 if he continues to operate the pharmacy's online service.	Article 52d Man should be adequate for the different therapeutic groups and the cheapest available medicines should also be available. A pharmacy's online service may, once a pharmacy licence has been opened, be maintained by a pharmacist who ceases to operate a pharmacy within the meaning of Paragraph 46 or by a pharmacy operator within the meaning of Article 59 until the pharmacy has been taken over by a new pharmacy licensed. A new pharmacy licensed shall submit a notification to the Centre for Safety and Development of Medicinal Products pursuant to paragraph 1 if he continues to operate the pharmacy's online service. *The notification referred to in paragraph 1 shall also be made if the holder of the retail licence for self-treatment medicinal products has changed and the new authorisation holder continues to provide a distance sales service for medicinal products.*
Otherwise, the provisions of Chapter 6 of the Consumer Protection Act (38/1978) on distance selling apply to the pharmacy's online service activities. The provisions on the pharmacy's online service shall also apply to the sale of medicinal products by other means of distance communication. More detailed provisions on the *network*for advice on the use of the service and*on fees charged to* customers in connection with service activities may be issued by government decree. The Centre for Safety and Development of Medicinal Products may issue orders to *pharmacies* concerning the content and submission of prior notification, as well as the provision of advice on medicinal products, the packaging and checking of consignments of medicinal products, transport, outsourcing of activities, returns, handling of product defects, information to be provided by the pharmacy's online service on the medicinal product, storage of medicinal products, delivery of medicinal products via the web service, premises, technical implementation, the range of medicinal products, treatment, and the performance and documentation of the inspection of online service activities.	Otherwise, the provisions of Chapter 6 of the Consumer Protection Act (38/1978) on distance selling apply to distance sales of medicinal products. The provisions on distance sales of medicinal products also apply to the sale of medicinal products through other information society services. More detailed provisions on advice provided in connection with the use of the service and on fees charged to customers may be laid down by government decree. The Centre for Safety and Development of Medicinal Products may issue orders concerning the content and submission of prior notification, as well as the provision of advice on medicinal *products, the packaging and checking of consignments of medicinal products, transport, outsourcing of activities, returns, handling of product defects, information to be provided in the distance sales service for medicinal* products, the storage of medicinal products, the supply of

medicinal products via an online service, premises, technical implementation, the range of medicinal products on the *pharmacy's online* service, the treatment of medicinal products and the conduct and documentation of the inspection.

The Centre for Safety and Development of Medicinal Products shall maintain and make publicly available on the internet an up-to-date list of legal pharmacies' online services.

Article 52d

The Centre for Safety and Development of Medicinal Products shall maintain and make publicly available on the internet an up-to-date list of legal distance sales *services for medicinal products.* of medicinal products supplied illegally to the public by means of information society services.

The website of the Centre for Safety and Development of Medicinal Products shall provide information on the national legislation applicable to the provision of medicinal products at a distance via the internet, including information that there may be differences in the classification of medicinal products and in the conditions of supply of medicinal products between the Member States of the European Union. In addition, the website should include information on the purpose of the common logo and background information on the risks

Article 54a

The website of the Centre for Safety and Development of Medicinal Products shall provide information on the national legislation applicable to the provision of medicinal products at a distance via the internet, including information that there may be differences in the classification of medicinal products and in the conditions of supply of medicinal products between the Member States of the European Union. In addition, the website should include information on the purpose of the common logo and background information on the risks of medicinal products supplied illegally to the public by means of information society services.

By way of derogation from Article 38a, nicotine products may also be sold in retail stores, kiosks and service stations and catering establishments selling tobacco on the basis of a retail licence issued by the municipality where the point of sale is located. Nicotine products may only be sold to those aged 18 or over. The seller must be able to monitor the purchase situation. Sales from automatic sales equipment are prohibited.

Article 54a

The municipality shall, upon written request, grant an authorisation for the sale of nicotine products if the applicant is in a position to preserve and sell nicotine products in accordance with this Act. The application shall contain the following information:

(1)the name of the applicant or the business name and contact details of the entity, the business and company identification number and the addresses of the sales points of the nicotine products;

(2)a description of the storage of nicotine products and the arrangements for controlling sales of nicotine products;

(3)the name and contact details of the person responsible for the sale; and

(4)the number of sales outlets at the point of sale of nicotine products and an indication of their location.

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The person authorised for retail sale of the preparation of nicotine shall notify the municipality of any change in the information provided in the application for authorisation and of the cessation of the sale. The municipality must inform the Finnish Medicines Agency about the granting of the authorisation and the closure of the sale.	
By way of derogation from Article 38a*(1)*, nicotine products may also be sold in retail stores, kiosks and service stations and catering establishments selling tobacco on the basis of a retail licence issued by the municipality where the point of sale is located. Nicotine products may only be sold to those aged 18 or over. The seller must be able to monitor the purchase situation. Sales from automatic sales equipment are prohibited. The municipality shall, upon written request, grant an authorisation for the sale of nicotine products if the applicant is in a position to preserve and sell nicotine products in accordance with this Act. The application shall contain the following information: (1)the name of the applicant or the business name and contact details of the entity, the business and company identification number and the addresses of the sales points of the nicotine products; (2)a description of the storage of nicotine products and the arrangements for controlling sales of nicotine products; 3) the name and contact details of the person responsible for the sale; and 4) the number of sales outlets at the point of sale of nicotine products and an indication of their location. The person authorised for retail sale of the preparation of nicotine shall notify the municipality of any change in the information provided in the application for authorisation and of the cessation of the sale. The municipality must inform the Finnish Medicines Agency about the granting of the authorisation and the closure of the sale.	
(New article)	Article 54f
	The sale outside a pharmacy of self-medication medicinal products which have been granted an extension of the sales channel referred to in Paragraph 23e(2) shall be subject to the issue of a retail licence for self-treatment medicinal products issued by the Finnish Medicines Agency for Safety and Development. The authorisation authorises the retail sale of self-medical medicinal products at the premises specified in the authorisation. The authorisation referred to in paragraph 1 shall be granted if: 1) the applicant is a sole trader or a legal person registered in the commercial register; (564/2023) pursuant to section 3; 2) the applicant is not an operator within the meaning of Sections 8, 32 or 34a; 3) the applicant appoints a responsible person who is familiar with the legislation and procedures for self-care medicinal products; and

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	4) the sales and storage facilities and the induction given to staff meet the conditions laid down in this Act and the regulations issued on the basis thereof.
(New article)	Article 54 g
	A retail licence for a self-treatment medicinal product shall be applied for in writing or electronically to the Finnish Medicines Agency. The application or the accompanying documents shall contain the following information: 1) the name or business name of the applicant, the business identification number and contact details of the applicant and, where applicable, the name and contact details of the applicant's contact person; 2) the address and contact details of the branch; 3) the name and contact details of the responsible person and a declaration that that person has knowledge of self-medication products within the meaning of Paragraph 54f(2)(3); and 4) a description of the applicant's sales and storage facilities and the planned induction for staff. The authorisation holder shall notify the Medicinal Products Safety and Development Centre of any material change in the operation. The Centre may require the authorisation to be re-applied if, as a result of a change in activity, the conditions for authorisation under section 54 septies need to be re-assessed. The retail licence for the self-treatment product is valid indefinitely. The authorisation may be withdrawn by notification by the holder of the authorisation or by a decision of the Finnish Medicines Safety Agency pursuant to Article 79(2).
(New article)	Article 54h
	The holder of a retail licence for self-treatment medicinal products shall: 1) sell only medicinal products of sound quality which have obtained a marketing authorisation in force in Finland and which have been granted the extension of the sales channel referred to in Section 23e(2); 2) properly handle and store self-care medicinal products;

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	3) sell self-care medicines in complete sales packages, comply with product-specific restrictions and ensure that sales are always carried out under staff supervision; 4) sell and store self-care medicinal products in a business premises of the authorised establishment that meets the storage condition requirements for the medicinal products; 5) provide staff with training and guidance on self-medicines commensurate with their duties; 6) comply with the provisions of this Act, the regulations adopted on the basis thereof and the Consumer Protection Act in relation to the sale, pricing and marketing of self-treatment medicinal products, and 7) when ordering self-care medicinal products from a pharmaceutical factory or from a medication tobacco, it can be reliably demonstrated that, as the holder of a retail licence for self-medical medicinal products, he is entitled to receive self-medicines. The retail licence holder and the person working at the outlet shall not provide medical advice or provide unauthorised disclosure of any private or family secret of which they have become aware in the course of their duties; Further provisions on the premises of the licensee, on the induction and guidance of staff, on control arrangements, on storage, treatment of self-treatment medicinal products and on the resulting pharmaceutical waste may be laid down by Government decree.
(New article)	Article 54i
	The responsible person appointed by the retail authorisation holder for self-treatment medicinal products shall be responsible for: 1) regularly monitor the storage conditions and sales of self-medicines; 2) Act as the contact person for the licence holder vis-à-vis the authorities; and 3) check the office on an annual basis. Further provisions on the tasks of the responsible person may be laid down by Government decree.
(New article)	Article 57f

A pharmacist or pharmacist working at a pharmacy, a branch pharmacy or an online pharmacy on the basis of a prescription for a medicinal product may deviate from the prescription as regards the pack size, the pharmaceutical form, the strength, the dosage instructions and the trade name of the prescribed medicinal product. Derogation from the prescription may be made if the following conditions are met:

(1)the medicinal product prescribed and the medicinal product that can be exchanged with it are not available in a pharmacy due to a national shortage or withdrawal of the medicinal product from the market;

2) it is not possible to order a prescribed medicinal product and an interchangeable medicinal product from a wholesale trade and it is not possible to refer the user of the medicinal product to another pharmacy;

3) the deviation does not alter the intended effects of the medicinal treatment;

4) there shall be no derogation from the particulars prescribed by the prescriber and shall not constitute a prescription issued or retained by telephone, or a prescription for a medicinal product which is compassionate, a medicinal product containing a narcotic substance, a medicinal product primarily active on the central nervous system or a medicinal product containing alcohol;

5) the total amount of the prescription shall not be exceeded, except where the quantity of medicinal product not supplied is less than the lowest available package or the most economically advantageous package, if it is cheaper than the smallest available package per dose, the dosage form of the medicinal product makes it impossible to distribute the package, or

The situation referred to in paragraph 3, and

(6) any deviation from the prescription does not compromise the safety of medication and is necessary on the basis of pharmaceutical judgement.

The prescription may also be waived for a specific reason, as provided for in paragraph 1, in a specific exceptional case where, for other reasons, a prescribed medicinal product or a medicinal product that can be exchanged with it is not available in the pharmacy's warehouse and the customer necessarily needs the medicinal product immediately, because delay in treatment would be detrimental to the treatment of the patient's illness or its symptoms. In such cases, a derogation may be made if the conditions laid down

in subparagraph 1, points 2 to 6, are met and if, despite the attempt, the prescriber of the medicinal product is not reached.

If the prescription of a medicinal product used regularly by the customer has expired or has been exhausted less than three months previously, a pharmacist or pharmacist working in a pharmacy, branch pharmacy or online pharmacy service may, in a specific exceptional case, deviate from the period of validity of the prescription or from the total quantity of the medicinal product and, on the basis of a prescription, provide the customer with up to three months' dose of the prescribed medicinal product or of the medicinal product that can be exchanged with it. An abnormal supply is subject to compliance with the conditions laid down in subparagraph 1, points 3 to 6, and to the condition that the dissimilar supply of the medicinal product is necessary in order to ensure the continuity of the medical treatment of the customer.

(New article) Article 57 g

The derogation from the prescription referred to in Article 57f shall be made in agreement with the purchaser of the medicinal product and in accordance with Article 57. In case of derogation from the prescription:

ARTICLE 58

The retail sale of a medicinal product shall be carried out at a price in accordance with the pharmaceutical tariff laid down by Government decree. The price of the medicinal product shall consist of the retail selling price of the medicinal product and, in the cases referred to in subparagraphs 2 and 3, an item-by-item delivery fee to be added to the retail price, and VAT. The retail price of a medicinal product shall be based on the wholesale price notified by the holder of the marketing authorisation for the medicinal product in accordance with Paragraph 37a and on the margin calculated on the basis of the wholesale price. The margin calculated *on the basis of the pharmaceutical tax may be proportionally lower than the pharmacy tax levied on that medicinal product under Section 6 of the Act on the taxation of pharmacies (770/2016). The difference shall not exceed EUR 6 for an individual medicinal product.*

The retail price of a medicinal product to be supplied on the basis of a prescription is increased by an item-by-item delivery fee, which is part of the pharmacy's margin. In addition, VAT is added.

By way of derogation from subparagraphs 1 and 2, the retail selling price of a medicinal product prepared in a pharmacy on the basis of a prescription shall be based on the purchase price of the ingredients used, the manufacturing fee, the manufacturing quantity supplement and the packaging used, subject to the marketing authorisation restrictions. The purchaser of the medicinal product shall be provided with a dosage guide for the medicinal product and shall be invited to contact the prescriber if necessary.

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Where a pharmacist or pharmacist working in a pharmacy, branch pharmacy and pharmacy's online service, in accordance with Paragraph 57f, derogates from a prescription order, records records with the prescription centre of the supply of the medicinal product, the reason for it and any contact with the prescriber. Information about the deviation and the reason for it is recorded in the data on purchases of medicinal products submitted to the Social Insurance Institution.

ARTICLE 58

The retail sale of a medicinal product shall be carried out at a price in accordance with the pharmaceutical tariff laid down by Government decree. The price of the medicinal product shall consist of the retail selling price of the medicinal product and, in the cases referred to in subparagraphs 2 and 3, an item-by-item delivery fee to be added to the retail price, and VAT. The retail price of a medicinal product shall be based on the wholesale price notified by the holder of the marketing authorisation for the medicinal product in accordance with Paragraph 37a and on the margin calculated on the basis of the wholesale price.

The retail price of a medicinal product to be supplied on the basis of a prescription is increased by an item-by-item delivery fee, which is part of the pharmacy's margin. In addition, VAT is added.

By way of derogation from paragraphs 1 and 2, the retail selling price of a medicinal product prepared in a pharmacy on the basis of a prescription shall be based on the purchase price of the ingredients used, the manufacturing fee, the manufacturing quantity supplement and the selling price of

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the packaging materials and equipment used. The retail price is increased by the delivery fee and VAT per consignment.

The price of a medicinal product which may be supplied from a pharmacy without prescription shall consist of the retail selling price and value added tax (VAT) of the medicinal product. If the medicinal product referred to in this paragraph is supplied on the basis of a prescription, the retail price shall be increased by the delivery fee and VAT per consignment. The retail selling price of a medicinal product *supplied from a pharmacy without prescription* shall be no more than the retail price at the retail price of the medicinal product and shall not be less than the wholesale price of the medicinal product available at national level in accordance with Paragraph 37a. The price must be the same for all pharmacies and online services. *However, by way of derogation from the above, the retail selling price of self-prescription medicinal products requiring additional advice shall be the retail price of the medicinal product in accordance with the tariff and the retail price of a medicinal product supplied from a pharmacy without prescription shall be the retail price of the medicinal product, provided* that the nationally uniform price is justified in the light of the medical advice required for the use of the medicinal product, any adverse effects of the medicinal product or public health.

Further provisions on the price of medicinal products, exemptions from the maximum price and discounts to be granted are laid down by government decree.

If necessary, a government decree shall revise the pharmaceutical tariff in accordance

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with the provisions adopted pursuant to this section.

The provisions of subsections 1 to 6 shall not apply to medicinal products which may also be sold at the selling price of materials and equipment. The retail price is increased by the delivery fee and VAT per consignment.

The price of a medicinal product for self-treatment is made up of the retail price of the medicinal product and VAT. If the medicinal product referred to in this paragraph is supplied on the basis of a prescription, the retail price shall be increased by the delivery fee and VAT per consignment. The *retail* price of a self-treatment medicinal product shall be no more than the retail price of the medicinal product and shall not be less than the wholesale price of the medicinal product available at national level in accordance with Paragraph 37a. The price must be the same for all pharmacies and online services. *However,* the *retail price* of a self-treatment medicinal product shall be the*retail price of a medicinal product in accordance with the tariff if it is a self-medication medicinal product requiring additional advice or* if the nationally uniform price is justified by the need to provide medical advice, any adverse effects of the medicinal product or public health. *By way of derogation from paragraph 1 and this paragraph, the maximum retail selling price of a self-medication medicinal product within the limited range of self-medication medicinal products referred to in Article 23d shall be the sum of the nationally available wholesale price notified by the marketing authorisation holder in accordance with Paragraph 37a and the margin calculated on that basis, and the maximum price in accordance with the pharmaceutical tariff shall be the maximum retail price plus VAT. VAT must always be added to the retail price of a medicinal product in a limited range. If a product in the range is supplied on prescription, a delivery fee per batch is also added to the price.*

More detailed provisions on the *price of the medicine*, the exemptions from the price and the discounts to be granted are laid down by Government decree.

If necessary, a government decree shall revise the pharmaceutical tariff in accordance with the provisions adopted pursuant to this section.

The provisions of subsections 1 to 6 shall not apply to *registered homeopathic products*, except in pharmacies, branch pharmacies, pharmacies and pharmacy online services.

On an annual basis, the Centre for Safety and Development of Pharmaceuticals shall provide the Ministry of Social Affairs and Health with information on the margin of pharmacies and other factors affecting the pharmaceutical tax.

ARTICLE 77

registered traditional herbal medicinal products and nicotine products, which can also be sold outside pharmacies, branch pharmacies, pharmacy outlets and online pharmacy services.

On an annual basis, the Centre for Safety and Development of Pharmaceuticals shall provide the Ministry of Social Affairs and Health with information on the margin of pharmacies and other factors affecting the pharmaceutical tax.

The Centre for Safety and Development of Medicinal Products shall ensure that manufacturers of medicinal products and pharmaceuticals and importing advanced

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therapy medicinal products by individual patient units, contract manufacturers and analysers, laboratories carrying out pre-clinical safety studies of medicinal products, wholesale distributors of medicinal products, brokers, pharmacies, branch pharmacies, hospital pharmacies and pharmaceutical centres, as well as military pharmacies, are inspected as often as is necessary for proper pharmacovigilance. In addition, the Centre may check the pharmacovigilance activities and premises of the holder of the pharmacy service, the pharmacy web service, the marketing authorisation for the medicinal product and the registration of the traditional herbal medicinal product, as well as manufacturers of excipients used in the manufacture of medicinal products. The Centre for Safety and Development of Medicinal Products may carry out inspections in cooperation with the European Medicines Agency as agreed.

If necessary, the inspection may be carried out without prior notice. The inspector shall be allowed access to all premises of the place of work which are not used for permanent housing. The audit shall include any documents requested by the auditor which are necessary to carry out the audit. In addition, the inspector shall be provided free of charge with the inspector’s request for Article 77:

The Centre for Safety and Development of Medicinal Products shall ensure that manufacturers of medicinal products and pharmaceuticals and importing advanced therapy medicinal products, units manufacturing advanced therapy medicinal products for individual patients, contract manufacturers and analysers, laboratories carrying out pre-clinical safety studies of medicinal products, the system for *recording and maintaining the safety features of medicinal products*, wholesale medicine distributors, brokers, pharmacies, branch pharmacies, hospital pharmacies and pharmaceutical centres, and the military pharmacy are inspected as often as is necessary for the proper supervision of medicinal products. In addition, the Centre may check the pharmacovigilance activities and premises of the pharmacy counter, the pharmacy web service, the holder of a retail licence for self *-medication medicinal products*, the holder of the marketing authorisation for the medicinal product and the registration of the traditional herbal medicinal product, as well as manufacturers of excipients used in the manufacture of medicinal products. The Centre for Safety and Development of Medicinal Products may carry out inspections in cooperation with the European Medicines Agency as agreed.

If necessary, the inspection may be carried out without prior notice. The inspector shall be allowed access to all premises of the place of work which are not used for permanent housing. The audit shall include any documents requested by the auditor which are necessary to carry out the audit. In addition, the inspector shall be provided free of charge with copies of the documentation necessary to carry out the inspection, as well as samples of substances and preparations at the site for further examination, free of charge. The auditor is also entitled to take image recordings during the inspection.

A record of the inspection shall be kept. Prior to the adoption of the minutes, the Centre for Safety and Development of Medicinal Products shall give the auditee the opportunity to express an opinion on the audit findings. The matters to be taken into account in particular during the inspection and the more detailed content of the inspection procedure, as well as the Protocol and its retention and retention period, shall be laid down by Government decree. Upon request,

the Centre for Safety and Development of Medicinal Products shall issue a certificate of good manufacturing practice or good distribution practice to the pharmaceutical factory and wholesale medicinal product concerned if the inspection shows that the factory or wholesale distributor complies with the principles and guidelines of good manufacturing practice or good distribution practice as laid down in European Union legislation. The Centre for Safety and Development of Medicinal Products shall be responsible for entering the certificates of good manufacturing practice or good distribution practice in a database maintained by the European Medicines Agency.

(New article)

extensions of the documentation necessary to carry out the inspection and samples of substances and preparations at the site for further examination. The auditor is also entitled to take image recordings during the inspection.

A record of the inspection shall be kept. Prior to the adoption of the minutes, the Centre for Safety and Development of Medicinal Products shall give the auditee the opportunity to express an opinion on the audit findings. The matters to be taken into account in particular during the inspection and the more detailed content of the inspection procedure, as well as the Protocol and its retention and retention period, shall be laid down by Government decree. Upon request, the Centre for Safety and Development of Medicinal Products shall issue a certificate of good manufacturing practice or good distribution practice to the pharmaceutical factory and wholesale medicinal product concerned if the inspection shows that the factory or wholesale distributor complies with the principles and guidelines of good manufacturing practice or good distribution practice as laid down in European Union legislation. The Centre for Safety and Development of Medicinal Products shall be responsible for entering the certificates of good manufacturing practice or good distribution practice in a database maintained by the European Medicines Agency.

ARTICLE 79

The Centre for Safety and Development of Medicinal Products may issue an oral or written warning to the holder of a retail licence for self-treatment medicinal products if the authorisation holder is acting in breach of this Act or the provisions adopted pursuant thereto, and the act is not of such a nature that the holder of the authorisation should be prosecuted in court.

The Medicinal Products Safety and Development Centre shall revoke the retail licence for self-treatment medicinal products if:

1) the entire business of the authorisation holder shall be terminated;

2) the entire business of the licensee is sold to another trader or the control of the licensee's undertaking referred to in Chapter 1, Section 5 of the Accounting Act (1336/1997), Section 84b.

Pharmacies, including the pharmacy of the University of Helsinki and the pharmacy of the University of Eastern Finland, wholesalers and manufacturers of medicines carry out an inspection relating to the monitoring of trade in medicinal products and pharmaceuticals to the Finnish Medicines Agency, two thousands of the difference between the price of the sale and purchase of medicinal products, exclusive of VAT (quality control fee). The pharmacy tax or the pharmacy fee is deducted from the corresponding margin for pharmacies before

the charge is imposed. Manufacturers of medicinal products pay a fee for the supply of goods directly to a pharmacy or any other person entitled to purchase, without brokering medicinal products. is transferred to another undertaking and the authorisation has not been appealed;

3) the holder of a retail licence for self-treatment medicinal products is declared bankrupt and, within one year of the start of bankruptcy, does not regain control of his assets;

4) the holder of a retail licence for self-treatment medicinal products shall receive a written warning as referred to in paragraph 1 or an order from an inspector within the meaning of Article 78 and shall not correct his procedure within the prescribed time limit or, failing that, within a reasonable period;

5) the holder of a retail licence for self-medical medicinal products substantially abuses the rights conferred by the retail licence for self-medical medicinal products or fails to comply with this Act or the provisions adopted pursuant thereto in a manner that seriously endangers patient safety.

The Centre for Safety and Development of Medicinal Products may also provisionally order the cessation of the sale of self-treatment medicinal products where the conditions laid down in paragraph 2 are met. The order may be issued for a maximum period of one year or until a decision has been taken on the withdrawal of the authorisation. If the suspicion of abuse proves to be unfounded, the Medicinal Products Safety and Development Centre shall revoke the order without delay.

Article 84b

Pharmacies, the pharmacy of the University of Helsinki and the pharmacy of the University of Eastern Finland, holders of retail licences for self-pharmaceuticals, including wholesalers and manufacturers of medicinal products, carry out an inspection relating to the monitoring of trade in medicinal products and pharmaceuticals to the Centre for Safety and Development of Medicinal Products two thousands of the difference between the VAT-exempt selling and purchase price of medicinal products (quality control fee). The pharmacy tax or the pharmacy fee is deducted from the corresponding margin for pharmacies before the charge is imposed. Manufacturers of medicinal products pay a fee for the supply of goods directly to a pharmacy or any other person entitled to purchase, without brokering medicinal products.

ARTICLE 89

A pharmaceutical plant, a licensee manufacturing or importing medicinal products for clinical trials, a laboratory carrying out pre-clinical safety studies of medicinal products, a contract analysis or contract preparation unit and a laboratory, a holder of wholesale, marketing authorisation or registration of medicinal products, a pharmacist, a pharmacy at the University of Helsinki, a pharmacy, a pharmacy, a hospital pharmacy and a pharmaceutical centre at the University of Eastern Finland; without prejudice to confidentiality provisions, the entity manufacturing advanced therapy medicinal products for an individual patient and the Military pharmacy shall provide the Centre for Safety and Development of Medicinal Products free of charge, without prejudice to confidentiality provisions, with such information and reports relating to the importation, manufacture, inspection, distribution, sale or other release for consumption of medicinal products which are necessary for the performance of the tasks

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laid down in this Act, in another law or in an act of the European Union. The Centre shall also have the right to obtain from the above-mentioned entities the information necessary for the protection of patients and other persons, as well as for the performance of its supervisory tasks, including medical records.

The pharmacy, the pharmacy of the University of Helsinki and the pharmacy of the University of Eastern Finland shall provide the Centre for Safety and Development of Medicinal Products with the information necessary for its development, planning and supervision tasks, for the determination of the quality control fee and for compiling statistics, for the purposes of the identification, income and expenditure and, otherwise, of the financial standing of the pharmacy, and the pharmacy shall establish the fee referred to in subsection 1 on an annual basis and shall be entitled to receive the information necessary for the calculation of the fee free of charge. The Centre for Safety and Development of Medicinal Products shall lay down more detailed rules on the levying of the fee.

ARTICLE 89

A pharmaceutical plant, a licensee manufacturing or importing medicinal products for clinical trials, a laboratory carrying out pre-clinical safety studies of medicinal products, a contract analysis or contract preparation unit and a laboratory, a holder of wholesale, marketing authorisation or registration of medicinal products, a pharmacist, a pharmacy at the University of Helsinki, a pharmacy, a pharmacy, a hospital pharmacy and a pharmaceutical centre at the University of Eastern Finland; the entity which manufactures advanced therapy medicinal products for an individual patient, the holder of a retail licence for self-treatment

medicinal products and the Military pharmacy shall, *upon* request, provide the Centre for Safety and Development of Medicinal Products free of charge, without prejudice to confidentiality provisions, with such information and reports relating to the importation, manufacture, inspection, distribution, sale or other release for consumption of medicinal products which are necessary for the performance of the tasks laid down in this Act, in another law or in a European Union act. The Centre shall also have the right to obtain from the above-mentioned entities the information necessary for the protection of patients and other persons, as well as for the performance of its supervisory tasks, including medical records.

The pharmacist, the pharmacy of the University of Helsinki and the pharmacy of the University of Eastern Finland shall provide the Centre for Safety and Development of Medicinal Products with the information necessary for the purposes of its development, planning and supervision tasks, the determination of the quality control fee and the compilation of statistics, of the identification, income and expenditure and otherwise of the financial status of the pharmacy and of other business activities carried out in the same premises as the pharmacy. Further provisions on the information to be provided may be laid down by Government decree. The Centre for Safety and Development of Medicinal Products may issue further provisions on the procedure to be followed for the provision of information.

other business activities carried out in miniaturised mode. *The holder of a retail licence for self-treatment medicinal products shall provide the Centre for Safety and Development of Medicinal Products with the information necessary for its development, planning and supervision tasks and the*

The Act in force	*Proposal*
imposition of a quality control fee on sales of self-care medicinal products. More detailed	provisions on the road to be surrendered may be laid down by Government decree—
Article 91b	
Medicinal products referred to in Paragraph 91a(1) may also be marketed to persons qualified to prescribe *or supply* a medicinal product. Such marketing shall take place only in presentations and publications for persons qualified to prescribe or supply a medicinal product, as well as in electronic media. Electronic marketing must be carried out in such a way that it cannot target bystanders.	Article 91b Medicinal products referred to in Paragraph 91a(1) may also *be marketed to persons qualified to prescribe a medicinal product and to pharmacies, hospital pharmacies and pharmaceutical centres authorised to supply* a medicinal product. Such marketing shall take place only in presentations and publications for persons qualified to prescribe or supply a medicinal product, as well as in electronic media. Electronic marketing must be carried out in such a way that it cannot target bystanders.
Advertising of medicinal products to persons qualified to prescribe or supply a medicinal product shall contain relevant information on the medicinal product and its use. The exception is, however, the reminder marketing of the medicinal product. Only the name of the medicinal product, its international non-proprietary name or trade mark and, in addition, the holder of the marketing authorisation or registration may be mentioned in the reminder.	Advertising of medicinal products to persons qualified to prescribe or supply a medicinal product shall contain relevant information on the medicinal product and its use. The exception is, however, the reminder marketing of the medicinal product. Only the name of the medicinal product, its international non-proprietary name or trade mark and, in addition, the holder of the marketing authorisation or registration may be mentioned in the reminder.
ARTICLE 97	ARTICLE 97
dot. The Centre for Safety and Development of Medicinal Products may issue further provisions on the procedure to be followed for the provision of information.	
The penalty for breaching the confidentiality obligation laid down in Sections 30e(3) and 90 shall be sentenced in accordance with Chapter 38, Sections 1 or 2 of the Criminal Code, unless the offence is punishable under Chapter 40, Section 5 of the Criminal Code or a more severe penalty is provided for elsewhere in the Act.	The penalty for breaching the obligation of professional secrecy laid down in Sections 30e(3), 54h *(2) and* 90 shall be sentenced in accordance with Chapter 38, Sections 1 or 2 of the Criminal Code, unless the offence is punishable under Chapter 40, Section 5 of the Criminal Code or a more severe penalty is provided for elsewhere in the Act.
	ARTICLE 102

The Act in force	*Proposal*
Rectification of an inspector's order referred to in section 78 may be requested from the Finnish Medicines Agency. The decision of the Centre for Safety and Development of Medicinal Products in the cases referred to in Sections 2, 6, 8, 12a, 15a, 15c, 17a, 30e, 30 l, 30n, 32, 48, 51, 52a, 52b, 53, 57c, 61, 62, 67, 76a, 84b, 87 and 87a may also be challenged. The objection is governed by the Administrative Procedure Act (434/2003). An administrative court decision in a case referred to in sections 29(2), 49, 50, 66, 80, 80a, 80b, 87c, 88a, 93, 101 and 101a may be appealed to the Supreme Administrative Court without leave to appeal.	notwithstanding an appeal, unless otherwise ordered by the appeal authority. To the extent that this section does not provide otherwise, the provisions of the Administrative Procedure Act (808/2019) shall apply to appeals to the administrative court.
	ARTICLE 102
The decisions referred to in Sections 2(4), 6, 23c, 30 l, 30n, 59, 66, 80, 80a, 80b, 87, 87c, 88a, 93 and 101 of the Centre for Safety and Development of Medicinal Products, the decisions referred to in Sections 68 and 71 of the Regional State Administrative Agencies and the National Supervisory Authority for Welfare and Health, as well as the inspector's orders, shall be complied with notwithstanding the lodging of an appeal, unless the appeal authority orders otherwise. Decisions of the Centre for Safety and Development of Medicinal Products pursuant to Sections 21, 21a and 21c of the marketing authorisation for a medicinal product may be enforced before they have become final, unless otherwise ordered by the appeal authority. The decisions of the Centre for Safety and Development of Medicinal Products pursuant to Articles 40, 41, 52, 53 *and* 54 may not be enforced until they have become final.	Rectification of an inspector's order referred to in section 78 may be requested from the Finnish Medicines Agency. The decision of the Centre for Safety and Development of Medicinal Products in the cases referred to in Sections 2, 6, 8, 12a, 15a, 15c, 17a, 30e, 30 l, 30n, 32, 48, 51, 52a, 52b, 53, 54f, 57c, 61, 62, 67, 76a, 84b, 87 and 87a may also be challenged. The objection is governed by the Administrative Procedure Act (434/2003). An administrative court decision in a case referred to in Sections 29(2), 49, 50, 66, *79(2) to (3),* 80, 80a, 80b, 87c, 88a, 93, 101 and 101a may be appealed to the Supreme Administrative Court without leave to appeal. The decisions referred to in Sections 2(4), 6, 23c, 23e(3), 30 l, 30n, 59, 66, *79(3), 80,* 80a, 80b, 87, 87c, 88a, 93 and 101 of the Centre for Safety and Development of Medicinal Products, the decisions referred to in Sections 68 and 71 of the Regional State Administrative Agencies and the National Supervisory Authority for Welfare and Health and the orders of the inspector shall be complied with notwithstanding the lodging of an appeal, unless otherwise ordered by the appeal authority. Decisions of the Centre for Safety and Development of Medicinal Products pursuant to Sections 21, 21a and 21c of the marketing authorisation for a medicinal product may be enforced before they have become final, unless otherwise ordered by the appeal authority. The *decisions of the Centre for Safety and Development of Medicinal*
A decision issued under Section 19a of the Ministry of Social Affairs and Health and the Centre for Safety and Development of Medicinal Products may be enforced	

The Act in force	*Proposal*
Products pursuant to Sections 40, 41, 52, 53, 54 and 54f shall not be enforced until they have become final. A decision issued under Section 19a of the Ministry of Social Affairs and Health and the Centre for Safety and Development of Medicinal Products may be enforced notwithstanding an appeal, unless otherwise ordered by the appeal authority. To the extent that this section does not provide otherwise, the provisions of the Administrative Procedure Act (808/2019) shall apply to appeals to the administrative court.	
This Act shall enter into force on 1 January 2026.	*The provisions of Sections 23d, 35(1), 37a(1), 57f, 57 g and 58 of this Act and, with regard to the operator of a system for recording and storing the safety features of medicinal products, Article 77(1) shall apply from 1 January 2026.* *The provisions of Section 2(1), Sections 23b and 23e and Section 102(3) of this Act concerning decisions pursuant to Section 23e shall apply from 1 October 2026.* *The provisions of Articles 9(2), 26, 30u, 31, 32(2), 33(2), 34(1), 37(2) and (3), 38a, 52b(1), 52d(1), 54a(1), 54f to 54i, in the case of holders of retail licences for self-treatment medicinal products, in Articles 77(1), 79; 84b(1), 89, 91b, 97, 102(1) and (2), and (3) relating to Articles 54f and 79(3) shall apply from 1 January 2027.*

2.

Law

amending the Act on the taxation of pharmacies

In accordance with the Parliamentary resolution,
sections 1 and 5-7 of the Act on the taxation of pharmacies *(* 770/2016) are amended in the version of Section 5 of the Act.

1235/2022 is replaced by the following:

The Act in force	*Propo sal*
PARAGRAPH 1	PARAGRAPH 1
Scope	*Scope*
A taxable person is required to pay pharmacy tax to the State in respect of a pharmacy which he operates.	The taxable person is required to pay pharmacy tax on thes*ale* of *medicinal products* by a pharmacy to the State.
ARTICLE 5 *Taxable amount*	ARTICLE 5 *Taxable amount*
In calculating the amount of the pharmacy tax for the tax year, VAT is deducted on the turnover of a pharmacy, a branch pharmacy, a pharmacy's service point, a pharmacy's online service and a medical cabinet.	The taxable amount *for pharmacy tax for the tax year shall be the combined profit margin of the pharmacies of the taxable person on the sales of medicinal products, net of VAT. The profit margin for the sale of medicinal products is the difference between the consideration received by the pharmacies of the taxable person for the sale of medicinal products free of VAT and the purchase prices, exclusive of VAT, of the medicinal products sold immediately, plus the delivery fee per consignment of the medicinal product referred to in Article 58 of the Medicines Act (395/1987). In the case of a medicinal product prepared on prescription in a*
In addition, the following VAT-exempt proportions shall be deducted from turnover exempt from VAT:	

The Act in force *Proposal*

pharmacy, the purchase prices of the substances, packaging materials and devices used to administer the medicinal product shall be deducted from the consideration received for the sale of the medicinal product before the abovementioned delivery fee is added.

The taxable person shall not be taken into account in determining the taxable amount:

(1) contract *manufacturing within the meaning of Section 12(2) of the Medicines Act (395/1987);*

(1) the value of sales of the contract manufacturing referred to in Section 12(2)of the Medicines *Act (395/1987) and the sale of medicinal products to social and healthcare establishments;*

(2) the *value* of sales of nicotine-replacement medicinal products which, under the Medicines Act, may also be sold outside a pharmacy;

(3) sales of products other than medicinal products, up to a maximum of 20 % of turnover subject to deductions pursuant to paragraphs 1 and 2;

(4) the proportion of sales of medicinal products with a wholesale price above EUR 1500, to the extent that the retail price, exclusive of VAT, of each such medicinal product exceeds EUR 1683,92.

Tax scale

The pharmacy tax is calculated by turnover group as follows:

Turnover, EUR	TaxoproApharmacy tax – leveraging ALARA in the case of senior leagues, eu-leading lira — ROA spring dosta, %
871 393 — 1 016 139	0 6,10

ARTICLE 6

(2) sales of medicinal products to social and healthcare institutions;

3) the *sale of medicinal products for nicotine replacement treatment which,* under the Medicines Act, may also be sold outside a pharmacy; *nor*

4) the sale of self-treatment medicinal products within the limited range of self-treatment medicinal products referred to in Article 23d of the Law on medicinal products.

ARTICLE 6

1 016 139— 1 306 607	8 830	7,15
1 306 607— 1 596 749	29 598	8,15
1 596 749— 2 033 572	53 245	9,20
2 033 572— 2 613 2	93 432	9,70

12 2 613 2 12— 3 194 4 64	149 657	10,20
3 194 4 64— 3 775 3 94	208 945	10,45
3 775 3 94— 4 792 5 03	269 652	10,70

The pharmacy tax scale is calculated by profit *margin group for pharmaceutical sales as follows*

Sales of *medicinal products* *margin,* EUR	Pharmacy tax at *the* lower margin on pharmaceutical sales, EUR	Gross salary *margin on sales of medicinal products above the* lower threshold
0-250 000	*0*	*0*
250000-500 000	*0*	*22*
500000-750 000	*55 000*	*37*
750000-1 000 000	*147 500*	*39*
1 000 000 — 1 500 000	*245 000*	*41*
1500000 —	*450 000*	*43*

4 792 503 — 6 243 857	378 483	10, 95
6 243 857 —	537 40 6 7	11, 20

Calculation of the amount of tax

The pharmacy tax is calculated for each taxable person separately.

If the pharmacy does not have a branch pharmacy, the pharmacy tax shall be calculated on the basis of the combined taxable amount of the pharmacy, the pharmacy's service *centre, the pharmacy's online service and* the medical cabinet, on the basis of the tax scale provided for in Paragraph 6.

Where a pharmacy has one or more branch pharmacies and the combined taxable amount of the pharmacy and its branch pharmacies, service outlets, online services and medical cabinets is less than EUR 2600000, the pharmacy tax shall be calculated on the basis of the combined taxable amount of the pharmacy and its service points, network services and medical cabinets and separately on the taxable amount of each branch pharmacy on the basis of the scale laid down in Paragraph 6.

Where a pharmacy has one or more branch pharmacies and the combined taxable amount of the pharmacy and its branch pharmacies, service outlets, online services and medical cabinets pursuant to Paragraph 5 exceeds EUR 3500000, the pharmacy tax shall be calculated from that common taxable amount on the basis of the scale laid down in Paragraph 6. In that case, one third of the taxable amount calculated in accordance with Paragraph 5 of the branch pharmacy shall be

deducted, but not less than EUR 50500, and, if the taxable amount of the branch pharmacy is less than EUR 50500, the total taxable amount before the branch pharmacy's taxable amount is added to the common taxable amount. However, no deduction shall be made if at least five years have elapsed since the establishment of the branch pharmacy at the end of the tax year and the turnover of the branch pharmacy during the tax year corresponds to at least half of the average turnover of the private pharmacies for the year preceding the tax year, excluding the turnover of the branch pharmacies. The average turnover of private pharmacies is established annually by the tax authorities.

ARTICLE 7

Calculation of the amount of tax

The pharmacy tax is calculated for each taxable person separately.

The pharmacy tax shall be calculated on the basis of the combined taxable amount of the pharmacy, *branch* pharmacy, pharmacy service centre and pharmacy's online service on the basis of the tax scale provided for in Section 6.

If the combined taxable amount of a pharmacy and its branches, service outlets, online services and medical cabinets pursuant to Paragraph 5 is EUR 2600000 or more, but not more than EUR 3500000, the pharmacy tax shall be calculated as a weighted average as provided for in paragraphs 6 and 7.

For the purpose of calculating the weighted average, the notional pharmacy tax shall be determined, as provided for in paragraph 3, on the basis of the scale laid down in Article 6. In addition, the notional pharmacy tax shall be determined separately, as provided for in paragraph 4, on the basis of the scale of Article 6.

Following the determination of the notional pharmacists, the amount of the pharmacy tax is calculated as their weighted average, using weighting factors determined by reference to the total taxable amount of pharmacy activities, as follows:

Turn-over; EUR calculated	*Coefficient 3 with counting on Ve Rolle*	*including to be tax*
—2 699 999	*0,90*	*0,10*
2 7992 700 999 000 —		*0,80*
	0,20 2	
8992 800 999 000 —		*0,70*
	0,30 2	
9992 900 999 000 —		*0,60*

The Act in force			*Proposal*
	0,40 3		
0993 000 999 000 —	*0,50*		
	0,50 3		
1993 100 999 000 —	*0,40*		
	0,60 3		
2993 200 999 000 —	*0,30*		
	0,70 3		
3993 300 999 000 —	*0,20*		
	0,80		
3 5003 400 000 000 — —	*0,10*	*0,90*	*This Act shall enter into force on 1 January XX XX 2026.* *The provisions of this Act shall apply for the first time to the collection of a pharmacy in 2026.*

3.

Law

amending Sections 10 and 13 of the ePrescription Act

In accordance with the Parliamentary resolution,
sections 10 and 13(3) of the ePrescription Act (61/2007) are *amended*
Paragraph 4 in the version of Section 10 in Acts 251/2014, 786/2021, 706/2023 and 13(3)

subsection 4 of Act 706/2023 is replaced by the following:

The Act in force	*Propo sal*
ARTICLE 10	
Correction, annulment and renewal of prescriptions and end-of-use labelling	
If the prescription in the centre of prescription is incorrect, the prescriber treating the prescription may make the necessary corrections to the prescription. In addition, pharmacists and pharmacists supplying the medicinal product from a pharmacy may make the necessary technical corrections at the time of delivery. If the content of the prescription is unclear or incomplete, the oral consent of the prescriber shall be obtained.	
A non-delivered or partially delivered prescription in the medical prescription centre may be invalidated without the patient's consent by the prescriber and the pharmacist who made the recording of the prescription referred to in Article 12(4) if the prescription was drawn up on the basis of false information provided intentionally by the patient or by coercion. In addition, all prescriptions are invalidated by the patient's death.	
The ePrescription will be renewed by issuing a new prescription on the basis of a	prescription in the centre of prescription, which will terminate the validity of the previous prescription. Patient or patient section 10
	Correction, annulment and renewal of prescriptions and end-of-use labelling
	If the prescription in the centre of prescription is incorrect, the prescriber treating the prescription may make the necessary corrections to the prescription. In addition, pharmacists and pharmacists supplying the medicinal product from a pharmacy may make the necessary technical corrections at the time of delivery. If the content of the prescription is unclear or incomplete, the oral consent of the prescriber shall be obtained.
	A non-delivered or partially delivered prescription in the medical prescription centre may be invalidated without the patient's consent by the prescriber and the pharmacist who made the recording of the prescription referred to in Article 12(4) if the prescription was drawn up on the basis of false information provided intentionally by the patient or by coercion. In addition, all

prescriptions are invalidated by the patient's death.

The ePrescription will be renewed by issuing a new prescription on the basis of a prescription in the centre of prescription, which will terminate the validity of the previous prescription. The patient or, at the patient's request, a pharmacy may submit a request for renewal of the prescription to the prescriber and the healthcare provider. However, the person entitled to prescribe a medicinal product may prevent a request for the renewal of a prescription stored in the prescription centre on medical grounds and where the prescription is drawn up on the basis of false information provided intentionally by the patient or by coercion.

If the prescriber decides to stop using the patient's medicine, the prescriber should record the discontinuation in the prescription centre. The filtration mark terminates the validity of the prescription recorded for the medicinal product. If a prescription was issued before 1 October 2027 and the prescription is manifestly unnecessary, the discontinuation label may also be issued, in agreement with the patient, by a nurse, pharmacist or pharmacist designated by the service provider or by a pharmacy entitled to supply the medicinal product.

upon request, the pharmacy may submit a request for the renewal of a prescription to the prescriber and the healthcare provider. However, the person entitled to prescribe a medicinal product may prevent a request for the renewal of a prescription stored in the prescription centre on medical grounds and where the prescription is drawn up on the basis of false information provided intentionally by the patient or by coercion.

If the prescriber decides to stop using the patient's medicine, the prescriber should record the discontinuation in the prescription centre. The filtration mark terminates the validity of the prescription recorded for the medicinal product. If a prescription was issued before 1 October 2027 and the prescription is manifestly unnecessary, the discontinuation label may also be issued, in agreement with the patient, by a nurse, pharmacist or pharmacist designated by the service provider or by a pharmacy entitled to supply the medicinal product.

A pharmacist and pharmacist supplying an *industrially manufactured medicinal product from a pharmacy may correct an obvious error in the prescription addressed to the user of the medicinal product which is not supplied, as regards the trade name, pack size, pharmaceutical form, strength or dosage instructions of the prescribed medicinal product. The correction must be necessary on the basis of pharmaceutical judgement. The repair shall not compromise the safety of medication, indicate that the total quantity of the medicinal product is exceeded or deviate from the particulars prescribed by the prescriber. In the case of a prescription or prescription issued or stored by telephone for a medicinal product which is compassionate, a medicinal product containing a narcotic substance, a medicinal product primarily active on the central nervous system or a medicinal product containing alcohol, the repair shall be subject to the consent of the prescriber. The repair must be made in agreement with the purchaser of the medicinal product and in accordance with Article 57 of the Medicines Act. The purchaser of the medicinal product shall be invited to communicate with the prescriber, if necessary.*

The Act in force	*Proposal*
Information on the rectification of the prescription, on the person who issued it, on the reason, and on the rectification, cancellation, non-renewal or discontinuation of a medicinal product in use referred to in paragraphs 1 to 4 shall be justified.	*any contact with the prescriber is recorded at the prescription centre.*
	The repair, cancellation, non-renewal or discontinuation of a medicinal product in use referred to in paragraphs 1 to*5* shall be justified.
More detailed provisions on the rectification, annulment, renewal and non-renewal of an electronic prescription and on the indication of cessation of use of the medicinal product may be laid down by decree of the Ministry of Social Affairs and Health.	More detailed provisions on the rectification, annulment, renewal and non-renewal of an electronic prescription and on the indication of cessation of use of the medicinal product may be laid down by decree of the Ministry of Social Affairs and Health.
ARTICLE 13	ARTICLE 13
Patient's right to order the disclosure of information	Notwithstanding paragraph 1, the following may be surrendered:
	Patient's right to order the disclosure of information
Without prejudice to confidentiality regulations, the information in the National Medical List at the Centre on medicinal products prescribed for the patient and related labelling may be disclosed to healthcare and social care providers and to the prescriber for the organisation and implementation of the patient's health and medical care. However, the patient may refuse the disclosure of the information relating to the medicinal product prescribed to the persons and pharmacies referred to above. The issuing and revocation of the prohibition is governed by Section 58 of the Customer Information Act.	Without prejudice to confidentiality regulations, the information in the National Medical List at the Centre on medicinal products prescribed for the patient and related labelling may be disclosed to healthcare and social care providers and to the prescriber for the organisation and implementation of the patient's health and medical care. However, the patient may refuse the disclosure of the information relating to the medicinal product prescribed to the persons and pharmacies referred to above. The issuing and revocation of the prohibition is governed by Section 58 of the Customer Information Act.
If a minor patient is capable, within the meaning of Paragraph *7* (1) of the Law on the Status and Rights of Patients (785/1992) ('the Patients' Act'), on the basis of his or her age and maturity, to decide on the adoption and withdrawal of the prohibition referred to in paragraph 1 of this article. The guardian or legal representative of the minor shall not be entitled to prohibit his or her surrender. In addition, a minor within the meaning of Section 51(1) of the CID has the right to prohibit the disclosure of information relating to a particular medicinal product to his or her guardian or other legal representative.	If a minor patient is capable, within the meaning of Paragraph *7* (1) of the Law on the Status and Rights of Patients (785/1992) ('the Patients' Act'), on the basis of his or her age and maturity, to decide on the adoption and withdrawal of the prohibition referred to in paragraph 1 of this article. The guardian or legal representative of the minor shall not be entitled to prohibit his or her surrender. In addition, a minor within the meaning of Section 51(1) of the CID has the right to

prohibit the disclosure of information relating to a particular medicinal product to his or her guardian or other legal representative.

Notwithstanding paragraph 1, the following may be surrendered:

1) The information referred to in paragraph 1, where the provision of information or the right to be informed is expressly provided for by law;

2) to the prescribing SME and narcotic medicinal product, information on all prescribed SME and narcotic medicinal products and related labelling;

3) details of the prescription requested by the patient for the renewal of the prescription to the healthcare or social care provider responsible for the renewal of the prescription or to the prescriber;

4) to the prescriber, in the event of a continuing relationship of treatment, of the prescriptions and indications relating to the prescriptions which he has placed at the prescription centre and, irrespective of the medical relationship, irrespective of the prescriptions placed by the pharmacy at the prescription centre pursuant to Paragraph 12(3) and, in accordance with Paragraph 5a, by the nurse, pharmacist or pharmacist to the prescription centre, of any changes to the dosing instructions in which he is indicated as the prescriber of the medicinal product and the indications relating to those prescriptions;

5) for the healthcare or social care provider who drew up the document stored in the prescription centre, in the event of a continuing relationship with the prescription centre, information on the documents stored by the provider in the recipe centre and the related markings;

6) to a healthcare or social care provider or to a health professional, information on prescriptions and related markings stored in the prescription centre in the event of urgent treatment as referred to in Section 8 of the Patients' Act; where the disclosure of information is prohibited in accordance with paragraph 1, the data may be disclosed only if the patient has expressly indicated that it may nevertheless be disclosed in the circumstances referred to above;

7) the information referred to in subsection 1 is provided by the healthcare provider, the Social Insurance Institution or the information system if the provision of the information or the right to information is expressly provided for by law;

2) to the prescribing SME and narcotic medicinal product, information on all prescribed SME and narcotic medicinal products and related labelling;

3) details of the prescription requested by the patient for the renewal of the prescription to the healthcare or social care provider responsible for the renewal of the prescription or to the prescriber;

4) to the prescriber, in the event of a continuing relationship of treatment, of the prescriptions he has placed in the prescription centre and of the related labelling, and of the medical relationship, irrespective of the prescriptions placed by the pharmacy at the prescription centre pursuant to Article 12(3) of the Law on medicinal *products, the storage by a nurse, pharmacist or pharmacist, under Section 5a, of changes to the dosing instructions by a nurse, pharmacist or pharmacist under Paragraph 5a, the rectification of prescriptions made by pharmacists and pharmacists pursuant to Paragraph 10, as well as the exceptions to prescriptions made pursuant to Article 57f of the Law on medicinal products,* in which he is listed as a prescriber and the indications relating to those prescriptions;

5) for the healthcare or social care provider who drew up the document stored in the prescription centre, in the event of a continuing relationship with the prescription centre, information on the

The Act in force	*Proposal*
documents stored by the provider in the recipe centre and the related markings; 6) to a healthcare or social care provider or to a health professional, information on prescriptions and related markings stored in the prescription centre in the event of urgent treatment as referred to in Section 8 of the Patients' Act; where the disclosure of information is prohibited in accordance with paragraph 1, the data may be disclosed only if the patient has expressly indicated that it may nevertheless be disclosed in the circumstances referred to above; 7) information to the technical staff employed by the healthcare provider, the Social Insurance Institution or the IT system provider, to the extent necessary for the investigation of incidents and errors; 8) to the prescriber of the medicinal product and to the healthcare institution acting as the employer or sponsor of the prescriber of the medicinal product, information on prescriptions for biological medicinal products stored in the prescription centre and on the supply of biological medicinal products which are necessary to carry out self-monitoring in accordance with section 24a or to provide information and explanations for the purposes of regulatory supervision as referred to in section 24b; and	9) to the healthcare or social care provider who drew up the document stored in the prescribing centre for checks related to the matter, information on the documents and related markings stored by the provider in the recipe centre. information to the technical staff employed by the contractor, to the extent necessary for the investigation of incidents and errors; 8) to the prescriber of the medicinal product and to the healthcare institution acting as the employer or sponsor of the prescriber of the medicinal product, information on prescriptions for biological medicinal products stored in the prescription centre and on the supply of biological medicinal products which are necessary to carry out self-monitoring in accordance with section 24a or to provide information and explanations for the purposes of regulatory supervision as referred to in section 24b; and 9) to the healthcare or social care provider who drew up the document stored in the prescribing centre for checks related to the matter, information on the documents and related markings stored by the provider in the recipe centre.
This Act shall enter into force on 1 January 2026. *Article 10 shall apply from 1 October—* *as of XX 2027.*	

4.

Law

amending Chapter 5, Section 1 and Chapter 18, Section 10 of the Health Insurance Act

Parliament's decision

Chapter 5, Section 1(1) and Chapter 18, Section 10 of the Health Insurance Act (1224/2004) are *amended* as Chapter 5, Section 1, subsection 1, Act 1221/2019 and Chapter 18, Section 10, Act 693/2024;

read:

The Act in force	*Proposal*
Chapter 5	Chapter 5
Pharmaceutical subsidies	**Pharmaceutical subsidies**
PARAGRAPH 1	
Medicinal product to be reimbursed	
The insured person is entitled to reimbursement of the costs of a medicinal product prescribed by a doctor and a dentist and by a nurse entitled to prescribe a limited or fixed term. The medicinal product shall be reimbursed on condition that it is a medicinal product subject to medical prescription in accordance with the Medicines Act (395/1987) and intended to cure or facilitate the disease or its symptoms, whether used internally or externally. The insured person shall also be entitled to reimbursement of an interchangeable medicinal product listed by the Centre for Safety and Development of Medicinal Products for which the medicinal product prescribed for the patient has been exchanged in a pharmacy in accordance with Section 57b of the Medicines Act. It is also required that the reimbursement of a medicinal product approved by the Medicinal Products Pricing Board is valid and that the price charged to the insured for the medicinal product does not exceed the reasonable wholesale price fixed or the maximum wholesale price referred to in Chapter 6, Paragraph 22, plus a margin and VAT up to the price of the supply of a pharmacy in accordance with the pharmaceutical tariff referred to in Article 58 of the Law on medicinal products.	
	PARAGRAPH 1
	Medicinal product to be reimbursed
	The insured person is entitled to reimbursement of the costs of a medicinal product prescribed by a doctor and a dentist and by a nurse entitled to prescribe a limited or fixed term. The medicinal product shall be reimbursed on condition that it is a medicinal product subject to medical prescription in accordance with the Medicines Act (395/1987) and intended to cure or facilitate the disease or its symptoms, whether used internally or externally. The insured person shall also be entitled to reimbursement in respect of an interchangeable medicinal product listed by the Centre for Safety and Development of Medicinal Products for which the medicinal product prescribed for the patient has been exchanged in *a pharmacy in accordance with Section 57b of the Medicines Act and for a medicinal product supplied to the patient under Section 57f of the Medicinal Products Act or in a pharmacy on the basis of a corrected prescription under*

Section 10 of the Act on electronic prescription (61/2007). It is also required that the reimbursement of a medicinal product approved by the Medicinal Products Price Board is valid and that the price charged to the insured for the medicinal product does not exceed the reasonable wholesale price fixed or the maximum wholesale price referred to in Chapter 6, Section 22, plus no more than 58 of the Medicines Act.

The Act in force

Chapter 5

Pharmaceutical subsidies

Proposal

Chapter 5

Pharmaceutical subsidies

Reimbursable medicinal products within the meaning of paragraph 1 shall also include medicinal products prescribed on medical prescription which may be sold without prescription (self-treatment *medicinal* product) and which are eligible for reimbursement. In the case of such medicinal products, the insured person shall be entitled to compensation in accordance with Article 4 or, in the event of serious and long-term illness, in accordance with Article 5.

As regards the reimbursement of special authorisation products referred to in Section 21 s of the Medicines Act, medicinal products produced in a pharmacy and basic creams, as well as medical oxygen and blood, the provisions on reimbursement of medicinal products shall apply mutatis mutandis.

the margin and value added tax, including the fee for the supply of a pharmacy, in accordance with the pharmaceutical tax referred to in Paragraph 2.

Reimbursable medicinal products within the meaning of paragraph 1 shall also include medicinal products prescribed on medical prescription which may be sold without prescription (self-treatment medicinal product) and which are reimbursable. In the case of such medicinal products, the insured person shall be entitled to compensation in accordance with Article 4 or, in the event of serious and long-term illness, in accordance with Article 5.

As regards the reimbursement of special authorisation products referred to in Section 21 s of the Medicinal Products Act, medicinal products produced in a pharmacy and basic creams, as well as medical oxygen and blood, the provisions on reimbursement of medicinal products shall apply mutatis mutandis.

Chapter 18

Health insurance fund and insurance premiums

Chapter 18

Health insurance fund and insurance premiums

ARTICLE 10

State contribution

ARTICLE 10

State contribution

51.4 % of the total health insurance costs referred to in Article 8(1), points 1 to 4, and Article 8(2) and (3) shall be financed from State resources. In addition, the costs of medical treatment referred to in Section 8(1)(5) are financed from State resources

51.4 % of the total health insurance costs referred to in Article 8(1), points 1 to 4, and Article 8(2) and (3) shall be financed from State resources. In addition, the costs of medical treatment referred to in Section 8(1)(5) are financed from State resources

in so far as they are not covered by reimbursements of expenses received from abroad on the basis of medical care benefits provided in Finland.	in so far as they are not covered by reimbursements of expenses received from abroad on the basis of medical care benefits provided in Finland. *The refund payment referred to in Chapter 6, Section 6a, paragraph 2, fully reduces the State contribution.*
	This Act shall enter into force on 1 January 2026.

The draft Regulation

Government Decree

amending the Government Decree on the pharmaceutical tariff

By Government decision,

a new Section 4a is *added* to the Government Decree on the Tariff for Medicinal Products (713/2013) and Sections 2, 3(1) and 6-7 are *amended* as set out in Section 2 of Decree 342/2015, Section 3(1) in Decree 1090/2022 and Section 7 in Decree 193/2022, as follows:

2 § *Definitions*

For purposes of this Regulation, the following definitions apply:

1) prescription-only medicinal product means a medicinal product which may be supplied from a pharmacy only on prescription;

2) self-treatment medicinal product means a medicinal product which may be supplied from a pharmacy without prescription;

3) a batch of packs of medicinal products to be delivered on a single prescription for the same delivery;

4) ‘differentiated medicinal product’ means a medicinal product which is regularly used by the patient and distributed mechanically or manually by a pharmacy and delivered to the patient in the form of packed batches of medicinal products per dose;

5) a self-medication medicinal product within a limited range of self-medication medicinal products, a self-treatment medicinal product falling within the categories of medicinal products referred to in Article 23d of the Law on medicinal products.

ARTICLE 3

Price of prescription-only medicine

For the sale of prescription-only medicinal products from a pharmacy, the retail price shall be that determined in accordance with the following formula:

Purchase price, EUR	Retail price
0-7,49	1,40 x purchase price
7,50 – 39,99	1,33 x Purchasing price + EUR
0.52 40.00-119,99	1,20 x purchase price + EUR 5,72
120,00 TO 499,99	1.13 x Purchasing price +
EUR 14.12 500,00-1 499,99	1,08 x
Purchasing price + EUR 39,12 1500 ≤	
	1 x purchase price + EUR 159,12.

—.....

Article 4a

Price of self-medicine within the limited range of self-medication

By way of derogation from Paragraph 4, the pharmacy and the holder of a retail licence for a self-care medicinal product may freely determine the retail price of the self-medication medicinal product within a limited range of self-care medicinal products. However, the retail price may not exceed the retail price determined in accordance with the formula laid down in Article 4(1).

The holder of a retail licence for a pharmacy and a self-medication medicinal product shall, if necessary, update the retail price in the event of a change in the wholesale price of a self-treatment medicinal product within the limited self-care range pursuant to Paragraph 37a.

If a self-medication medicinal product from a limited range of self-medication products is supplied on prescription, the retail price of the medicinal product shall be increased by EUR 2.17 per batch. However, the retail price of a prescribing self-treatment medicinal product shall be increased to EUR 0.18 per delivery item per delivery week.

The sale of two or more packets of medicinal products or packs of medicinal products and of free-trade products at an inclusive price shall be prohibited. In addition, the offer and sale of a medicinal product or packaging at a reduced price shall not be combined with the purchase of another medicinal product, packet or other good. Where a pharmacy grants a reduction in the retail price of a self-treatment medicinal product, a corresponding reduction shall also be granted when the self-treatment medicinal product is supplied on prescription.

ARTICLE 6

Value added tax (VAT)

The price of the medicinal product determined in accordance with Sections 3 to 4, 4a and 5 above shall be subject to VAT in accordance with the VAT Act (1501/1993).

ARTICLE 7

Discounts other than those provided for in Sections 4 and 4a

Persons holding a breast magazine symbol, a breast service symbol, a breast symbol, a veteran mark or a certificate referred to in Section 2 of the Act on the Rehabilitation of Certain Tasks in connection with the Finnish War (1039/1997) to participate in the demining activities referred to in Section 1(1)(3) of the Act shall be granted a reduction of 10 % of the price

determined in accordance with Sections 3 to 4, 4a, 5 and 6. However, where a pharmacy has granted the discount referred to in Paragraph 4 for a self-treatment medicinal product, the retail price of the self-treatment medicinal product shall not be less than the wholesale price of the self-treatment medicinal product in accordance with Paragraph 37a of the Law on medicinal products, following the reduction provided for in this paragraph.

However, the 10 % reduction provided for in paragraph 1 shall not be granted for medicinal products eligible for special reimbursement within the meaning of Chapter 5, Section 5, of the Health Insurance Act (1224/2004), for medicinal products which are subject to limited reimbursement within the meaning of Section 6, or for purchases of medicinal products in excess of the annual excess in accordance with Section 8.

In the case of sales to social and health care establishments, the pharmacy may grant a discount on the price determined by the pharmacy in accordance with Sections 3, 4, 4a, 5 and 6. No rebates or benefits may be given on the basis of purchases of medicinal products.

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This Regulation shall enter into force on 1 January 2026.

tDraft Regulation

Government Decree

amending the Medicinal Products Regulation

By Government decision,

section 9 of the Medicinal Products Decree (693/1987), as *amended* by Decree 803/2009, is *hereby repealed*, as amended by Decree 192/2022; and

a new Section 11, a new Section 11 before Section 11, a new Section 12, a new Section 12 and Section 12a and a new subtitle before Section 13 are *inserted* in the Decree in place of Section 11, repealed by Decree-Law 192/2022, as follows:

Self-care medicines that can also be sold outside a pharmacy

ARTICLE 11

Itsehoitolääkkeet, jotka kuuluvat seuraaviin anatomis-terapeuttis-kemiallisen luokituksen (*ATC-luokitus*) mukaisiin ATC-ryhmiin, muodostavat lääkelain 23 d §:ssä tarkoitetun rajatun itsehoitolääkevalikoiman:

1) A02AD01 conventional aluminium/calcium/magnesium compounds;
2) A02BA03 famotidine;
3) A02BA53 famotidine, combination products;
4) A02BX02 sucralphate;
5) A06AC01 ispaghula (psyllium seeds);
6) A06AC51 ispaghula, combination products;
7) A06AD11 lactulose;

8) A06AD15 macrogole;
9) A06AD65 macrogole, combination products;
10) A11DB combinations of vitamin B1 with vitamin B6 and/or vitamin B12;
11) A11HA02 pyridoxin (vitamin B6);
12) B03BA01 cyanocobalamin;
13) A12AX combinations of calcium with vitamin D and/or other medicinal substances;
14) A12AA04 calcium carbonate;
15) A11CC01 ergocalciferol;
16) A11CC05 cholecalciferol;
17) B03AA01 ferroglycine sulphate;
18) B03AB05 Iron oxide polymaltose complexes;
19) B03AA07 ferrous sulphate;
20) D03AX03 dexpantenol;
21) G04BX01 magnesium hydroxide;
22) A12CC04 magnesium citrate;
23) A12CC30 magnesium (combinations of different salts) and
24) S01XA20 artificial pencils and other preparations n.e.c.

ARTICLE 12

The holder of a retail licence for self-treatment medicinal products must comply with the requirements laid down in Section 54h of the Medicinal Products Act, in addition to:

1) sell and store the medicinal products for self-care at the site referred to in the authorisation. A storage facility located in the immediate vicinity of the site and managed by the holder of the authorisation may also be used as a warehouse;
2) provide additional induction to staff, if necessary, and document the induction provided;
3) provide staff with and keep up-to-date policy instructions for self-care medicinal products;
4) store the self-care medicinal products at the temperature and under the conditions set out in their summaries of product characteristics;
5) dispose of back-to-site and unsold self-treatment products as pharmaceutical waste that is kept separate from the sales stock; and
6) prevent unauthorised persons from entering sales and storage premises and pharmaceutical waste.

Article 12a

In addition to the provisions laid down in Section 54i of the Medicines Act, the responsible person appointed by the retail authorisation holder for self-treatment medicinal products shall have the following tasks:

1) regularly monitor and document, through reliable tools and equipment, that self-care medicines are stored under the conditions required by the manufacturer. If anomalies are detected in the monitoring, take immediate action to assess, document and correct the deviations. In the event of an incident, the responsible person shall consult, where appropriate, a pharmaceutical professional with sufficient knowledge and experience;

2) Act as the contact point for the authorisation holder vis-à-vis authorities, marketing authorisation holders and other pharmaceutical operators in the event of product defects and falsifications of self-treatment medicinal products, and ensure that self-medication measures are taken;
3) monitor the sale of self-treatment medicinal products in order to prevent the misuse and misuse of medicinal products;
4) draw up and keep up-to-date a list of marketed self-care medicinal products, indicating the conditions of storage of the medicinal products and any marketing restrictions, and ensuring compliance with that list when storing and selling self-care medicinal products;
5) inspect the office annually and ensure that the sale of self-medical products is carried out in accordance with this Act, the regulations adopted pursuant to it and the Consumer Protection Act. A record of the inspection shall be kept. The Protocol shall be kept for five years.

Pharmacy, branch pharmacy, pharmacy service and pharmacy web service

ARTICLE 13

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Article 21b

When supplying medicinal products ordered through the distance sales service of medicinal products referred to in Section 52b of the Medicines Act, the operator of the service may recover from the customer up to the actual additional costs of appropriate packaging and transport.

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This Regulation shall enter into force on 1 January 2026.

The provisions of Article 11 of this Decree shall apply from 1 January 2026 and the provisions of Articles 12, 12a and 21b shall apply from 1 January 2027.

However, Article 9, which is repealed by the Decree, applies until 30 September 26 to the classification of medicinal products for supply.

Sosiaali- ja terveysministeriö

Briefing note

30.6.2025
VN_14214/2025 STM044:00/2025

Government Decree amending the Medicinal Products Decree

Main content

It is proposed to amend the Government Decree on Medicinal Products. Together with the Government bill to Parliament for legislation on

pharmaceutical reform and the implementation of pharmaceutical savings [HE xxx/2025 vp) and the Government Decree amending the Government Decree on the pharmaceutical tax rate, the proposal forms part of the overall reform of the pharmacy economy.

The proposed amendments to the Medicinal Products Regulation relate to Prime Minister Petteri Orpo's Governmental Program, according to which, on the basis of the report of the pharmacy safety authority, the release of some of the most commonly used self-care medicinal products also for sale outside pharmacies is prudent, ensuring the safety of medicines and medication. A new regulation is proposed in the Medicinal Products Regulation, which would define a limited range of self-medication products. In addition, it is proposed to lay down more precisely the requirements for the activity of the holder of a retail licence for self-treatment medicinal products, the tasks of the responsible person appointed by the holder of the authorisation and the costs to be added to the price of medicinal products ordered through the distance sales service. It is proposed to repeal the section on the classification of medicinal products from the Regulation and to add it to the Medicines Act. In addition, it would be proposed to add a new title over the pharmacy provisions.

The decree is linked to the draft state budget for 2026 and is intended to be dealt with in the context of the draft state budget for 2026.

The Regulation is intended to enter into force on 1 January 2026.

1. Background to the dispute and powers to adopt regulations

The proposed amendments to the Decree on Medicinal Products (693/1987) relate to the government programme of Prime Minister Petteri Orpo, according to which, on the basis of the report of the pharmacy safety authority, the release of medicinal products and medication safety is prudent, some of the most commonly used self-care medicinal products also to be sold outside pharmacies.

The proposed Government Decree amending the Medicinal Products Decree is part of a package of measures, which includes a government proposal to Parliament in preparation for legislation on pharmaceutical reform and the implementation of pharmaceutical savings (HE xxx/2025 vp) and the Government Decree amending the Government Decree on the pharmaceutical tariff. Government bill HE xxx/2025 proposes to provide for extensions of the sales channel for self-medication products, allowing products to be sold outside pharmacies;

authorisations, operating conditions, controls and penalties for retail licence holders. In addition, the Government bill proposes to define a limited range of self-medication products in the Medicinal Products Act and more specifically in the Medicinal Products Decree, which would be subject to exceptional price regulation and exempt from pharmacy taxation, irrespective of whether they would be sold in or outside a pharmacy.

It is proposed to introduce new provisions in the Medicinal Products Regulation to define a more specific range of self-medication products and the performance requirements of holders of retail licences for self-medication medicinal products and the tasks of the responsible person appointed by him. It is proposed to amend the provision in the Medicinal Products Regulation on the costs to be added to the price of medicinal products sold via the pharmacy's online service to include distance sales by holders of retail licences for self-treatment medicinal products. It is proposed to repeal the article of the Medicinal Products Ordinance on the classification of the supply of a medicinal product from the Decree so that it can be added to the Medicines Act in Government proposal HE xxx/2025 vp. In addition, a new title would be proposed before the regulation on pharmacies.

The basic provisions of the proposed new Article 11 of the Medicinal Products Regulation on a limited range of medicinal products and the power to issue decrees would be in the new Article 23d of the Medicines Act proposed in Government proposal HE xxx/2025 vp.

The proposed new Article 12 of the Medicinal Products Regulation would concern the operating obligations of the holder of a retail licence for self-treatment medicinal products, which he would have to comply with in addition to the requirements laid down in Article 54h of the proposed Medicines Act. The basic provision of the new Article 12 of the Medicinal Products Decree and the power to issue regulations would be the new Article 54h of the Medicinal Products Act proposed in Government bill HE xxx/2025 vp.

The proposed new Section 12a of the Medicinal Products Regulation would cover the tasks of the responsible person appointed by the holder of a retail licence for self-medical medicinal products, which he would have to perform in addition to those provided for in Article 54i of the proposed Medicines Act. The basic provision of the new Article 12a of the Medicinal Products Decree and the power to issue regulations would be the new Article 54i of the Medicinal Products Act proposed in Government bill HE xxx/2025.

Under Paragraph 21b of the Medicinal Products Decree, when dispensing medicinal products ordered through the online service of a pharmacy, the pharmacy may recover from the customer up to the actual additional costs of appropriate packaging and transport. It is proposed to amend this section in order to also cover distance sales of self-treatment medicinal products by holders of retail licences for self-treatment medicinal products. The basic provision of this section is contained in the current Section 52b of the Medicines Act, which governs the online service of a pharmacy. The power to issue a decree is contained in Section 52b(6) of the Medicinal Products Act, according to which more detailed provisions on advice on the use of an online service and on fees charged to customers in connection with online service activities may be issued by government decree. The Medicinal Products Act (52b) is proposed in Government bill HE xxx/2025 vp to extend to distance sales of medicinal products by holders of retail licences for self-treatment medicinal products. The power to adopt regulations would also extend to them.

It is also proposed to repeal Article 9 of the Medicinal Products Regulation, according to which the Finnish Medicines Agency is required, when granting a marketing authorisation for a medicinal product, to decide whether a medicinal product may be sold or otherwise released for consumption only on the basis of a prescription. The Medicinal Products Safety and Development Centre may amend the decision referred to in paragraph 1 on the basis of new information received on the medicinal product which affects the classification of the supply. It is proposed to add this section to the Medicines Act.

2. Preparatory work

The amendment to the Medicinal Products Regulation has been prepared together with the Government proposal (HE xxx/2025 vp). The proposed amendments to the Medicinal Products Regulation relate to the preparation of a package of laws allowing the sale outside pharmacies of certain self-medication medicinal products. Its preparation began in July 2023, when the STM commissioned the Centre for Safety and Development of Medicinal Products (' *Fimea*') to draw up a report from the Agency on the sale of self-treatment medicinal products outside pharmacies, provided for in the government programme. The Fimea study was finalised on 31 August 2023. It can be opened at the following web address: https://stm.fi/documents/1271139/148062577/Fimean+selvitys+it treatmentl %C3%A4 %C3 %C3 %A4kke+sales%C3 %A4+outside pharmacies+.pdf. This report has been used to prepare the Government bill xxx/2025 vp and this proposal for a Regulation.

The preparatory work was continued in the context of the working group set up by the Ministry of *Social*Affairs and Health ('the Ministry of Social Affairs and Health') to assess the extension of the sales channel for self-treatment medicinal products ('the Self-medicine Task Force'),whose term of office was from 24 January 2024 to 30 June 2024. The group on self-care medicinal products consisted of representatives of the STM, the Ministry of Finance, the Ministry of Employment and the Economy, Fimea, the Finnish Competition and Consumer Agency ('KKV'), the Association of Finnish Pharmacists ('SAL'), the University of Helsinki pharmacy, the pharmacy of the University of Eastern Finland, the Social and Health ry, the Consumers' Association, the Finnish Medicines Agency, the Rinnakkaislaitos ry and the Päivittaistaistan Trade Association. In addition, the working group had to consult as experts Kela, the Finnish Institute for Health and Welfare, the National Supervisory Authority for Welfare and Health, the Finnish Farmasia Union ry, the Finnish Association of pharmacists, the Finnish Medical Association, the Association of Finnish Local and Regional Authorities (no statement) and Orion Oyj. The working group met 11 times during its term of office. An expert consultation took place on 3 April 2024.

The task of the group on self-care medicinal products was to propose self-medication products which could also be sold outside pharmacies and the conditions under which the sales channel could be extended. In addition, the task was to explore ways of promoting price competition for self-medicines.

The proposal had to assess the need for legislative changes and the impact on users, pharmacies and society. The preparatory work drew on the study completed by Fimea in autumn 2023. The Working Group's note on the assessment of the extension of the sales channel for self-medication medicines, reports from the Ministry of Social Affairs and Health and memos 2024:25 were published on 3 October 2024. The Federation of Commerce, the KKV and the SAL and the pharmacy of the University of Eastern Finland submitted supplementary statements in the note (Annex 3a-3c to the Memorandum). (Link to the Working Party's note and annexes: http://urn.fi/URN:ISBN:978-952-00-8446-2 ; ' *STM 2024:25'*).

The draft regulation has been prepared as an official work at the Ministry of Social Affairs and Health, in cooperation with Fimea. The draft decree was in consultation from 30 June 2025 to 18 August 2025, together with the Government bill xxx/2025 vp and the proposal for a regulation amending the Government Decree on the pharmaceutical tariff. The consultation period was seven weeks. The opinion time was extended during the week from the recommended six weeks during the summer holiday period. This longer consultation period was not considered justified as the main stakeholders have been involved from the outset in the preparation of the proposals. The seven-week consultation period will also ensure that opinions can be taken into account in the further preparation of the government's proposal within the timetable for the budget laws.

The preparatory documents for the Decree can be found on the pages of the government bill on the pharmaceutical economy (STM044:00/2025) on the public project window service:
(https://stm.fi/hanke?tunnus=STM044:00/2025).

3 State of play and assessment of the status quo

3.1. Current status

The sale of a medicinal product to the general public or any other release for consumption is subject to the condition that the medicinal product has been granted a marketing authorisation valid in Finland upon application by a pharmaceutical company. Chapter 4 of the Medicines Act governs the marketing authorisation of a medicinal product and its modification. Under Paragraph 21(2) of the Law on medicinal products, the Finnish Medicines Agency may attach conditions to the marketing authorisation of a medicinal product if they are necessary to ensure the correct and safe use of the medicinal product. The classification of a medicinal product as a prescription or self-treatment product is one of the conditions of the marketing authorisation. In a marketing authorisation procedure, an applicant for marketing authorisation may apply for a medicinal product to be classified as a self-treatment medicinal product. An application may also be made after the authorisation has been granted as an application for variation of the marketing authorisation. Similarly, if, for example, safety concerns are detected in a self-medication medicine, at the initiative of the marketing authorisation holder or Fimea, it may be

converted into a prescription-only medicine. The classification of supplies is regulated at national level by Section 23b of the Medicinal Products Act, Article 9 of the Medicinal Products Ordinance and the Fimea Order on the application for and maintenance of the marketing authorisation and registration of a medicinal product (4/2019). The rules are based on Articles 70 to 72 of Directive 2001/83/EC of the European Parliament and of the Council on the Community code relating to medicinal products for human use ('the Medicinal Products Directive'). The classification of veterinary medicinal products is regulated by the Directive.
Article 34 of Regulation (EU) 2019/6 of the European Parliament and of the Council repealing 2001/82/EC ('the Veterinary Medicinal Products Regulation').

As a general rule, self-care medicines, like all medicines, are sold in Finland only from pharmacies (Section 38a of the Medicines Act). The Medicines Act imposes various obligations on pharmacies, for example as regards persons and premises. The exception to medicinal products sold in a pharmacy is the traditional herbal medicinal products and homeopathic preparations referred to in Paragraphs 22 and 22a of the Law on medicinal products, which may also be sold elsewhere, unless otherwise decided by the Finnish Medicines Agency at the time of registration. In addition, nicotine products classified as medicinal products may be sold outside the pharmacy, with the exception of nicotine products classified as prescription-only medicinal products. The sale of nicotine products classified as a medicinal product sold outside pharmacies is governed by Sections 54a to 54e of the Medicines Act. In addition, both in pharmacies and outside pharmacies, products which are not classified as medicinal products but which are similar in form, mode of use or strength to self-care medicinal products sold in pharmacies are sold as food supplements, medical devices or cosmetics.

A pharmacy may, in principle, supply a customer with a self-treatment medicinal product without prescription only one, the largest package of medicinal products authorised for self-treatment in a single purchase. The strength, quantity and pack size of a self-treatment medicinal product to be purchased at one time is based on the decision to classify the medicinal product as a self-treatment medicinal product. The restrictions are not of general application as they are decided on a product-by-product basis.

The online services of pharmacies are governed by Section 52b of the Medicines Act. According to the section, the pharmacist, the pharmacy of the University of Helsinki and the pharmacy of the University of Eastern Finland may also provide pharmacy services through the pharmacy's online service. The operator of the pharmacy's online service must have a website where medicinal products are offered for sale at a distance. These websites shall contain a link to the list of legal online pharmacies services kept by the Centre for Safety and Development of Medicinal Products and clearly display the common logo in the European Union in accordance with Article 85c of the Medicinal Products Directive. This section lays down rules on prior notification, start-up of operations, notification of changes and bans on the

operation and termination of the online service, obligations of the network operator. Otherwise, according to subsection 6 of the section, the provisions of Chapter 6 of the Consumer Protection Act (38/1978) on distance selling apply to the online service activities of a pharmacy. The provisions on the pharmacy's online service shall also apply to the sale of medicinal products by other means of distance communication. More detailed provisions on advice provided in connection with the use of an online service and on fees charged to customers in connection with online service activities may be issued by government decree. The Centre for Safety and Development of Medicinal Products may issue orders to pharmacies concerning the content and submission of prior notification, as well as the provision of advice on medicinal products, the packaging and checking of consignments of medicinal products, transport, outsourcing of activities, returns, handling of product defects, information to be provided by the pharmacy's online service on the medicinal product, storage of medicinal products, delivery of medicinal products via the web service, premises, technical implementation, the range of medicinal products, treatment, and the performance and documentation of the inspection of online service activities.

Under Paragraph 21b of the Medicinal Products Decree, when dispensing medicinal products ordered through the online service of a pharmacy, the pharmacy may recover from the customer up to the actual additional costs of appropriate packaging and transport.

3.2. Assessment of the current situation

The Medicines Act regulates the supply of self-treatment medicines to consumers as part of pharmacy activities and the retail sale of nicotine products. The regulation does not apply to the sale of self-treatment medicinal products outside pharmacies. The implementation of the government programme entry for self-care medicinal products requires new regulation in the Medicines Act, the Medicines Decree and the Medicines Tax Regulation. This assessment of the current state of play summarises the assessment of the current state contained in the Government proposal (HE xxx/2025 vp) in so far as it relates to proposals for amendments to the Medicinal Products Regulation. The full assessment can be found in Government bill HE xxx/2025 vp (paragraph 2.4).

Range of self-medication products sold outside the pharmacy

In a self-care medicine study, Fimea identified the 30 most commonly used self-care medicines in Finland between 2019 and 2022. The most accurate anatomical Therapeutic Chemical Classification (ATC) of medicinal products was used. The World Health Organisation (WHO) maintains the ATC classification of medicines. In the ATC classification, medicinal products are divided into groups of five levels depending on the organ or organ system they affect and on the basis of their chemical, pharmacological and therapeutic properties. The classification consists of 14 main groups (level 1), therapeutic and pharmacological sub-categories (levels 2 and 3), pharmacological,

chemical or therapeutic groups (level 4) and individual chemical substances or combinations of substances in the combination formulation (level 5). The Fimea study takes into account the safety of medicines and medication, the 2023 national classification of risk medicines and the recommendation on self-medication.

In the Fimea study, the most commonly used self-care medicines were divided into four groups. The study concluded that the initial release of medicinal products and medication safety risks can be reduced, mainly in the case of medicinal products for which experience has already been gained in selling active substances outside pharmacies. In addition, products with a known safety profile that are not subject to specific contraindications or precautions and which are in line with current treatment recommendations could be considered. If this wider range of medicinal products is sought, the provision of pharmaceutical advice to the user of the medicinal product should be ensured.

Preparations continued in the framework of the self-medication working group set up by the STM. Based on the Fimea report, the Working Group's note looked at the 30 ATC groups of the most commonly used self-treatment medicines in Finland. Nicotin products were excluded from the assessment as they can currently be sold outside pharmacies (STM 2024:25).

The Working Party on Self-therapy Medicinal Products divided the self-care medicines into three portfolios based on their level of risk. Selection 1 consists of 12 self-medicines with a low level of risk whose sale without medical advice was not assessed as posing a risk from a public health perspective. Selection 1 corresponds to group 2 of the Fimea study, with the exception of the removal of melatonine and saccharomyces boulardii (STM 2024:25 pp. 37-39). Batch 2 consisted of self-medicines requiring the availability of 11 advices, assessed as medium-risk, and Option 3 containing medicinal substances in the national risk category. According to the assessment of the Working Party on Self-medicines, if the reform were to be implemented as a stand-alone project, it should be limited to the range allowed by minor changes in existing legislation. In practice, this would mean a selection 1 (STM 2024:25 pp. 8-9).

In accordance with its mandate, the Working Party on Self-medicines assesses the most commonly used self-care medicines in Finland. However, the note of the Working Group emphasises the importance of an indication-based assessment based on rational drug therapy and accessibility. According to the note, it would be appropriate for each point of purchase of a self-medication product to have priority self-care options in line with the recommended treatment. The Working Party considered that in some cases less used alternatives should also be assessed instead of or in addition to the most commonly used product. However, the main grouping should be done on a risk-based basis through the selections 1 to 3 (STM 2024:25 p. 37).

The government proposal proposes that the range of self-medicines, which could also be sold outside a pharmacy, should be based on a range 1 defined by the self-medication working group. It would correspond to category 2 of the

Fimea study, with the difference that melatonine and saccharomyces boulardii would have been removed from the selection (STM 2024:25 pp. 32 and 36).

However, in line with the position of the Working Party on Self-therapy Medicinal Products, Option 1 would be considered on a therapeutic basis and complemented by priority self-treatment options for the same indication, which were not included in the list of the 30 most commonly used medicines, but whose level of risk is assessed as being similar to the level of risk of the medicinal substances in List 1 and for which ATC groups currently contain authorised self-treatment medicinal products. The evaluation has sought to maintain a limited range of self-pharmaceuticals in line with the government plan, which would focus on the indications of products in range 1.

The solution would be justified from the point of view of the user of the medicinal product, so that the range sold outside pharmacies could also form an appropriate package of different treatment options. The solution would be justified from the point of view of pharmaceutical companies, since the market conditions for competing self-pharmaceuticals with the same therapeutic indication and with a similar safety profile would remain as equal as possible and companies would have the same opportunity to apply for an extension of the sales channel for their own-care medicinal product outside pharmacies. In practice, however, the formation of a range of self-medication products outside the pharmacy would depend on whether the pharmaceutical companies would apply for an extension of the sales channel for their product and whether holders of retail licences for self-treatment medicinal products would select all rational options.

Starvation

In the case of self-medicines used to treat starvation, only conventional aluminium/calcium/magnesium compounds belonging to ATC group A02AD01 are included in group 1 of the self-medication group and group 2 of the Fimea report. For self-medication, the preferred option for self-treatment would be different protonum inhibitors (PPIs) as the preferred option for self-treatment. A secondary option would be H2 blockers (STM 2024:25 p. 31). Based on the solution taken in the follow-up assessment, protonum inhibitors would not be proposed in List 1 due to the safety concerns raised for these products. In Sweden and Denmark, PPIs are also restricted to pharmacy sales. Instead, it would be possible to supplement the selection with H2 blockers such as famotidine, famotidine in combinations and products containing sucralphatate. As with ATC group A02AD01, the sale to the consumer of the above products is assessed as low-risk and suitable for the range.

Constipation

Self-medicines used to treat constipation would include ispaghula (psyllium seeds, ATC group A06AC01), lactulose (ATC group A06AD11) and macrogol (ATC group A06AD15) as defined by the Self-medicine Task Force and group 2 of the Fimea study. They would provide a rational range of medicines to treat

constipation. It is true that, according to the Working Party, the likelihood of an expansion of the sales channel would be reduced by the fact that ispaghula self-medicines are sold almost without exception with a prescription, whereas in the case of lactulosis, the proportion of prescription-only packaging is around half. Macrogol should not be replaced, but a significant proportion of it is also sold on prescription.

It is proposed to complement Option 1 with combinations of ispaghula and macrogole, which are assessed as low-risk. The ATC group of Macrogol combinations (A06AD65) includes combinations of macrogole with electrolytes. Their indications correspond in part to those of macrogol, but some products are intended to purify the casing prior to clinical procedures or bowel moths, which should be taken into account when assessing the inclusion of individual products in the range of self-medicines sold outside pharmacies. Constipation can also be treated with sodium picosulfate preparations (ATC group A06AB08). However, they are not proposed to be added to the range sold outside pharmacies, as they are only a last resort treatment option for constipation, in line with the therapeutic advice, and their safe use would require access to medical advice.

Substitution treatment of pancreas enzymes

Of the products used for substitution treatment of pancreas enzymes, the list 1 defined by the self-medication working group and group 2 of the Fimea study included products containing several enzymes (lipase, protease, etc.) in ATC group A09AA02. However, in this category, medical diagnosis and prescription are generally required for starting treatment. A significant proportion of self-medication is de facto therapeutic experiments with gastrointestinal symptoms due to other causes. In the follow-up evaluation of the presentation, it has been concluded that, as a result, the inclusion of a category of medicinal products in the reprogramm would not have a marginal benefit in relation to the potential disadvantages of inappropriate use, and it is proposed that the group be removed from the range.

Vitamin and mineral substitution therapy

Of the products used for vitamin and mineral substitution treatment, the list 1 and category 2 of the Fimea study included combinations of vitamins B1 and B6 and/or B12 (ATC group A11DB), other combinations of vitamin B (ATC group A11EX), calcium combinations with vitamin D and/or other medicinal substances (ATC group A12AX), ferroglycine sulphate (ATC group B03AA01) and magnesium hydroxide (ATC group G04BX01).

However, on the basis of a further assessment carried out in the preparation of the proposal, it is proposed to remove ATC Group A11EX, the other combinations of vitamin B, from the list, since no authorised medicinal product is currently included in the group.

For vitamin combination products in List 1, the follow-up assessment concluded that there is no medication safety barrier to the exclusion of groups of medicinal products containing one vitamin in combination products in List 1 as the only active ingredient, provided that the ATC group in question were self-medicated products on the market. Following this review, it is proposed to add vitamin B6 pyridoxine (ATC group A11HA02), vitamin B12 cyanocobalamin (ATC group B03BA01), calcium carbonate (ATC group A12AA04), cholecalciferol and ergocalciferol (ATC groups A11CC05 and A11CC01) vitamins, iron oxide polymaltose complexes (ATC-group B03AB05) and ferrous sulphate (B03AA07) and magnesium citrate (ATC-group A12CC04) and magnesium (mixed salts, ATC group A12CC30) of iron products. For vitamin B1 and other vitamin B12, calcium, iron and magnesium, there are currently no authorised self-medication medicines. In addition, vitamin D self-treatment preparations belonging to other ATC groups are currently not available for sale. For these reasons, it is not necessary to include other ATC groups at this stage.

Treatment of small skin lesions

In the case of self-medicines used to treat small skin lesions, only dexpantenol products should be included in the list 1 and category 2 of the Fimea study, as set out in the note on self-medication. Hydrocortisone, which is used to treat mild skin inflammation and rash, was also evaluated during the preparation of the presentation. However, it is not proposed to add it to the range, as the products cannot be considered as alternative treatments with dexpantenol products and the appropriate use of hydrocortisone was considered to require access to medical advice.

Artificial cupboards

In addition, artificial pens and other unclassified products belonging to the same ATC group (S01XA20) would be included in the group 1 defined by the Working Party on Self-therapy Medicinal Products and Fimea in Group 2. For these, no extension needs were identified in the follow-up evaluation.

Definition of the selection

The implementation of government programme recording requires that the choice of self-medication products sold outside pharmacies should also be defined by law in a predictable manner. During the preparation of the government proposal (xxx/2025 vp), it was decided to define a limited range of self-medicines for general conditions in the Medicines Act and more specifically at ATC group level in the Medicinal Products Regulation. The general conditions would be based on the characteristics that have been identified as combining products in the SMP 1, such as the low level of risk and the possibility to sell the product without any medical advice.

However, as the same ATC group may include different medicinal products, it would also be necessary to assess the suitability of an individual medicinal

product for off-pharmacy sales on a product-by-product basis. The starting point should be that the categories of medicinal products included in the list of medicinal substances provided for in the Regulation meet these conditions. However, Fimea should assess the fulfilment of the conditions on a product-by-product basis.

Obligations to be imposed on the holder of a retail licence for self-treatment medicinal products and on the responsible person

According to the Working Party on Self-Pure Medicinal Products, the conditions for authorisation for the retail sale of self-treatment medicinal products should correspond to the pharmacy's obligations. However, during the preparation of the Government proposal (HE xxx/2025 vp), it was agreed that holders of retail licences for self-medication medicinal products would be subject to the minimum requirements and authorisation conditions necessary to reliably identify the holder of the retail licence and to ensure the safety of medicinal products and medication when selling self-medicines from a limited range that would have been granted an extension of the sales channel.

The holder of a retail licence for self-treatment medicinal products could not be made subject to pharmacy staff requirements comparable to those laid down in Article 56 of the Law on medicinal products. However, it would be justified, from the point of view of the safety of medicinal products and medication, to ensure that the personnel of the authorisation holder are adequately trained in the handling, storage and sale of self-treatment medicinal products. Furthermore, it would be justified to require the authorisation holder to indicate a responsible person who could act as a point of contact with the authorities and be subject to various practical obligations. Induction training should be repeated in the event of staff changes and, where appropriate, changes in legislation or other requirements. In addition, the retail licence holder should be required to ensure that up-to-date operational instructions are available to staff.

The space allowances provided for in Article 56(2) of the Law on medicinal products and Article 15 of the Decree on Medicinal Products relate specifically to pharmacy business and would not, as such, be suitable for holders of retail licences for self-treatment medicinal products, whose main activity would not, in most cases, be the sale of medicinal products. However, space requirements should ensure that the retail authorisation for self-treatment medicinal products is site-specific and that appropriate conditions for the storage of medicinal products are safeguarded. The authorisation holder's staff would not be able to provide medical advice to customers, so similar confidentiality facilities would not be required. However, the premises should be suitable for business purposes, as public authorities should be able to check the premises. This would not allow the holding to be part of the operator's home. In addition, Order 1/2011 on service points at Fimea's pharmacy states that medicinal products must be stored at the service point in appropriate lockable cabinets/space reserved for external purposes, separately from other products. A similar requirement for lockable cabinets in the sales premises should not be required for the retail sale of self-treatment medicinal products, as the limited range

available on sale would not require such measures in terms of risk. However, the authorisation holder should ensure that unauthorised persons have no access to the premises. For example, the locking of storage facilities for medicinal products should be ensured.

In the course of the preparation of the Government proposal, it was considered that it would be justified to impose on licence holders an obligation similar to that of pharmacies to ensure the correct quality of the self-care medicinal products they sell and to require the retailer of self-care medicinal products to sell the self-care medicinal products in complete sales packages. The requirements would be comparable to the obligations laid down in Article 55(3) of the Law on medicinal products for pharmacies and to the Ordinance on service points at the pharmacy of Fimea (Fimea Order 1/2011). The responsible person could also have operational obligations in this regard.

The Working Party on Self-therapy Medicinal Products required that holders of retail licences for self-treatment medicinal products should be subject to an obligation of internal audit and self-monitoring. A pharmacist is subject to an obligation to monitor and inspect a branch pharmacy, an online pharmacy service and a service point (Sections 52a to 52c of the Medicines Act and Article 20 of the Medicinal Products Ordinance). The responsible person of the authorisation holder could carry out an annual inspection of the sales of the medicinal product. Because of the limited choice, self-monitoring would be more limited in practice than in a pharmacy. However, in order to allow for regulatory control, it would be necessary to require that a protocol be kept.

When a medicinal product is classified as a self-treatment medicinal product, it may be subject to sales restrictions in terms of strength or pack size, which, in principle, allow a medicinal product to be sold to a customer in a single purchase, for example, one of the largest packages of self-treatment medicinal products on sale. These sales restrictions should also be introduced for sales outside pharmacies.

It should also be required that the holder of a retail licence for self-treatment medicinal products is properly handled and stored. The treatment requirements for medicinal products should also cover the treatment of pharmaceutical waste.

Retail sale of self-treatment medicinal products at a distance

The Government proposal (HE xxx/2025) considers it justified to allow holders of retail licences for self-treatment medicinal products to sell at a distance the self-medication medicines in the limited range proposed in the proposal. The assessment of the government proposal concludes that the Working Party on Self-medicines considered it justified, in terms of a level playing field for operators, to allow online sales, provided that a level playing field comparable to that of pharmacies would be respected. The proposal would also be justified from the perspective of the customer, who could order a self-treatment medicine, for example in the case of other food orders (STM 2024:25 p. 57).

The Government proposal proposes that retail licence holders of self-medication medicinal products be subject to operating requirements equivalent to pharmacies' online services in legislation. The national legislation is based on Article 85c of the Medicinal Products Directive. The Medicinal Products Directive allows holders of retail licences for self-treatment medicinal products to be included among the entities legally obliged to operate a distance sales service for medicinal products.

Pursuant to Section 52b(6) of the Medicinal Products Act, more detailed provisions on advice provided in connection with the use of an online service and on fees charged to customers in connection with online service activities may be issued by government decree. Under Paragraph 21b of the Medicinal Products Decree, when dispensing medicinal products ordered through the online service of a pharmacy, the pharmacy may recover from the customer up to the actual additional costs of appropriate packaging and transport. It would be necessary to amend the section in order to cover also holders of retail licences for self-treatment medicinal products. This could be done by referring to the distance sales service of medicinal products in the section, rather than an online pharmacy service. This term is proposed in the Medicines Act to cover the online services of a pharmacy and the distance sales service of the holder of a retail licence for self-medical medicinal products. Article 21c of the Medicinal Products Decree concerns the provision of advice on medicinal products in the context of distance selling. The section would not be proposed to be amended as the holder of a retail licence for self-treatment medicinal products would not be allowed to provide advice on medicinal products.

4 Objectives and key proposals for the amendment of the Regulation

The proposal for a regulation has a common objective with the Government proposal HE xxx/2025 vp. By making it possible to sell certain self-medication medicinal products outside pharmacies, with separate authorisation and conditions, a government programme record is carried out, according to which, on the basis of a report from the pharmacy safety authority, the release of medicinal products and medication safety is prudent, while ensuring some of the most commonly used self-medication medicinal products also for sale outside pharmacies. The aim of the amendment is to improve the accessibility of self-medication medicines and to create price competition between self-medicines in a limited range.

Article 9 of the Medicinal Products Decree concerns the decision of the public authority on the classification of a medicinal product for the supply of a medicinal product. The Centre for Safety and Development of Medicinal Products decides whether a medicinal product may be sold or otherwise released for consumption only on prescription or on a non-prescription basis, i.e. as a self-treatment product. It is proposed to repeal this section from the Medicinal Products Regulation and to add the Government proposal HE xxx/2025 vp to Article 23b of the Medicines Act.

The Medicinal Products Decree proposes to define the limited range of self-treatment medicinal products referred to in Section 23d of the Medicinal Products Act as proposed in the Government proposal. The proposed new Article 11 of the Regulation would define the range of self-pharmaceuticals defined by a total of 24 categories of medicinal products based on the ATC classification.

The Decree would propose to provide for the provisions of Sections 54h and 54i of the Medicines Act proposed in Government bill HE xxx/2025 vp, complementing the operating requirements of holders of retail licences for self-health medicinal products and the role of the responsible person. In addition, it is proposed to amend the provision in the Medicinal Products Regulation on the cost of medicinal products supplied online by pharmacies to cover also holders of retail licences for self-treatment medicinal products. It is also proposed to change the title of the Regulation.

5 ***Main effects***

We refer to the Government proposal HE xxx/2025 vp for the impact assessment of the proposal for a regulation. Apart from the effects set out in the Government bill, the proposed amendments to the decree did not identify any autonomous effects.

6 Other options for implementation

The comparison of the ranges 1 to 3 assessed by the Working Party on Self-therapy Medicinal Products is included in the Government proposal HE xxx/2025 vp.

8 Opinion feedback

[To be completed after consultation]

9 Detailed explanatory memorandum

9.1. Government Decree amending the Medicinal Products Decree

9 §. Paragraph 1 of the current article provides that the Centre for Safety and Development of Medicinal Products is to decide, when granting a marketing authorisation for a medicinal product, whether a medicinal product may be sold or otherwise released for consumption only on the basis of a prescription. Paragraph 2 provides that the Medicinal Products Safety and Development Centre may amend the decision referred to in paragraph 1 on the basis of new information received on a medicinal product which has an impact on the classification of supplies.

This section is proposed to be repealed from the Medicinal Products Regulation and transferred to Section 23b of the Medicinal Products Act in the context of other regulations on the classification of medicinal products and the proposed extension of the sales channel for self-medicine medicinal products. The procedural rules on classification for supply should be consistent at the

regulatory level with those governing the extension of the sales channel for certain self-medication medicinal products.

ARTICLE 11. It is proposed to add a new heading before the section entitled ‘Societal medicinal products which may also be sold outside pharmacies’, which would refer to the proposed regulation in the new Sections 11, 12 and 12a.

The proposed Article 11 would be new. This section would be based on the new Article 23d of the Medicines Act proposed in the Government bill (HE xxx/2025 vp), which provides that a limited range of self-medication products would be made up of certain categories of medicinal products which are assessed to present low risks and which are assessed as capable of safe treatment without medical advice. The limited range of self-treatment medicinal products referred to in subsection 1 shall be further defined by Government decree. The proposed Article 11 would provide that self-treatment medicinal products belonging to the ATC categories listed in the following section would constitute a limited range of self-medication products within the meaning of Section 23d of the Medicines Act. This section would include a total of 24 ATC groups, including self-treatment medicines, which would constitute a limited range of medicinal products.

According to paragraph 1 of the proposed article, a limited range of self-medication products would include conventional aluminium/calcium/magnesium compounds of ATC group A02AD01, which are used to treat starvation. These products were included in the Pool 1 of the Self-medicine Task Force. In addition, following further preparation, paragraphs 2 to 4 would suggest that ATC groups A02BA03 famotidine, A02BA53 famotidine, combination products and A02BX02 sucralphatate preparations, which, as H2 blockers, would complement the range of self-medicines used to treat starvation, should be included. As with ATC group A02AD01, the sale of these products to the consumer is assessed as low-risk and suitable for the range.

According to paragraphs 5 to 9 of the proposed Article, the limited range of self-medication products would include ATC groups A06AC01 ispaghula (psyllium seeds), A06AD11 lactulose and A06AD15 macrogol macrogol on substances used to treat constipation. They would provide a rational range of medicines to treat constipation. On the basis of further preparation, it is proposed to supplement the range of self-treatment medicines used to treat constipation with ATC groups A06AC51 ispaghula, combinations and A06AD65 macrogol, which are assessed as medication safe and low-risk.

According to paragraphs 10 to 19 and 21 to 23 of the proposed article, a limited range of self-medication products would include several groups of self-medicines used for vitamin and mineral substitution treatments. A limited range of ATC groups A11DB combinations of vitamin B1 with vitamin B6 and/or B12, A12AX calcium combinations with vitamin D and/or other pharmaceuticals, B03AA01 ferroglycine sulphate and G04BX01 magnesium hydroxide, as defined by the Working Party on Self-therapy Medicinal

Products. In the course of further preparatory work, it was decided to add the following ATC groups: A11HA02 pyridoxin (vitamin B6), B03BA01 cyanocobalamin, A12AA04 calcium carbonate; A11CC01 ergocalciferol, A11CC05 cholecalciferol, B03AB05 iron oxide polymaltose complexes, B03AA07 ferrous sulphate, A12CC04 magnesium citrate and A12CC30 magnesium combinations.

According to point 20 of the proposed article, the limited range would include D03AX03 dexpantenol in List 1 defined by the Self-Medicinal Products Working Group. In addition, according to paragraph 24 of the proposed section, the limited range would include the ATC group S01XA20 in List 1 defined by the Self-House Working Group and other unclassified products.

ARTICLE 12. The proposed section would be new. This article would be based on the new Article 54h of the Medicines Act proposed in Government bill xxx/2025 vp, which provides in subsections 1 and 3 that the holder of a retail licence for self-treatment medicinal products must: (1) sell only medicinal products of sound quality which have obtained a marketing authorisation in force in Finland and which have been granted the extension of the sales channel referred to in Paragraph 23e(2); (2) appropriate handling and storage of self-care medicinal products; (3) sell self-care medicines in complete sales packages, comply with product-specific restrictions and ensure that sales are always carried out under staff supervision; (4) sell and store self-care medicinal products in a business premises of the authorised establishment that meets the storage condition requirements for the medicinal products; (5) provide staff with training and guidance on self-medication commensurate with their duties; (6) comply with the provisions of this Act, the regulations adopted pursuant to it and the Consumer Protection Act in relation to the sale, pricing and marketing of self-care medicinal products, and (7) when ordering self-care medicinal products from a pharmaceutical factory or from a magazine, it is reliable to prove that he, as the holder of a retail licence for self-medical medicinal products, is entitled to receive self-care medicinal products. Further provisions on the premises of the licensee, on the induction and guidance of staff, on control arrangements, on storage, treatment of self-treatment medicinal products and on the resulting pharmaceutical waste may be laid down by Government decree.

According to point 1 of the proposed section, the holder of a retail licence for self-treatment medicinal products should comply with the requirements laid down in section 54h and, in addition, sell and store the self-care medicinal products at the premises referred to in the authorisation. A storage facility located in the immediate vicinity of the site and managed by the holder of the authorisation could also be used as a warehouse. This provision would complement the space allowances in Section 54h(4) of the proposed Medicines Act.

According to paragraphs 2 and 3 of the proposed section, the holder of a retail licence for self-medication medicinal products should provide staff with

additional induction where necessary and document the training provided and provide and keep up-to-date instructions to staff on self-medicines. The provisions would complement the operational requirements for staff in Section 54h(5) of the proposed Medicines Act.

According to paragraphs 4 to 6 of the proposed Article, the holder of a retail licence for self-treatment medicinal products should store the self-care medicinal products at the temperature and under the conditions set out in their summaries of product characteristics, dispose of returned and unsold self-care medicinal products as waste of medicinal products, which is kept separate from the sales stock and prevents unauthorised persons from entering sales and storage premises and pharmaceutical waste. The provisions would complement the obligation under Section 54h(2) of the proposed Medicines Act.

12 **section A.** The proposed section would be new. This section would be based on the new Article 54i of the Medicines Act proposed in Government proposal xxx/2025 vp, according to which the task of the responsible person appointed by the retail authorisation holder for self-treatment medicinal products would be (1) to regularly monitor the storage conditions and sales of self-medicines, (2) to act as a contact person for the holder of the authorisation vis-à-vis the authorities, and (3) to inspect the site annually. Further provisions on the tasks of the responsible person may be laid down by Government decree.

According to paragraphs 1, 3 and 4 of the proposed section, (1) the responsible person appointed by the retail authorisation holder for self-medical medicinal products would, in addition to the provisions of Section 54i of the Medicinal Products Act, have the following tasks: (1) regularly monitor and document, through reliable tools and equipment, that self-care medicines are stored under the conditions required by the manufacturer. If anomalies are detected in the monitoring, take immediate action to assess, document and correct the deviations. In the event of an incident, the responsible person should, where appropriate, consult a pharmaceutical professional with sufficient knowledge and experience to assess the incident and the necessary measures. According to the proposed paragraph 3, the responsible person should also monitor the sale of self-treatment medicinal products in order to prevent the misuse and misuse of medicinal products. According to the proposed paragraph 4, the latter should also draw up a list of self-treatment products sold, indicating the conditions of storage of the medicinal products and any restrictions on their sale, keeping it up-to-date and ensuring compliance with the list when storing and selling self-care medicinal products. Paragraphs 1, 3 and 4 of the proposed section would relate to Section 54i(1) of the proposed Medicines Act, which provides that the responsible person should regularly monitor the storage conditions and sales of self-medicines.

According to paragraph 2 of the proposed section, the responsible person should act as the contact point for the authorisation holder vis-à-vis the

authorities, marketing authorisation holders and other pharmaceutical operators in the event of product defects and falsifications of self-treatment medicinal products, and should take measures in relation to self-medication products. This paragraph would be related to Section 54i(2) of the proposed Medicines Act, according to which the responsible person should act as the contact person for the authorisation holder vis-à-vis the authorities.

According to paragraph 5 of the proposed section, the responsible person should carry out an annual inspection of the branch and ensure that the sale of self-treatment medicinal products complies with this Act, the regulations adopted pursuant to it and the Consumer Protection Act. A record of the inspection should be kept. The Protocol shall be kept for five years. This paragraph would be based on Section 54i(3) of the proposed Medicines Act, according to which the responsible person should carry out an annual audit of the site.

13 §§. It is not proposed to amend the section. However, it is proposed that the sub-title 'Pharmacy, branch pharmacy, pharmacy service point and pharmacy online service', which was previously mentioned in Section 11, be transferred before it. The transfer would take place because Articles 11, 12 and 12a of the Decree would provide for self-medication products which could also be sold outside pharmacies.

Article 21b. Under the current section, when dispensing medicinal products ordered via the pharmacy's online service, the pharmacy may charge the customer up to the actual additional costs of appropriate packaging and transport. It is proposed to amend this section to replace the online service of a pharmacy with the use of the term 'distance sales of medicinal products' and to oblige the operator of the service instead of a pharmacy. In the future, in addition to online pharmacy services, the scope of this section would be extended to holders of retail licences for self-treatment medicinal products sold outside the pharmacy at a distance under Section 52b of the Medicinal Products Act proposed to amend the Medicines Act.

10 Entry into force

It is proposed to enter into force on 1 January 2026. The Regulation is intended to enter into force at the same time as the provisions of the Medicines Act and the Act on the taxation of pharmacies proposed in the Government bill (HE xxxx/2025 vp).

It is proposed that the articles of the Decree be applied in a graduated manner, so that the provisions of the proposed new Article 11 would apply from the entry into force of the Act on 1 January 2026. The Government's proposal proposes that Section 23d of the Medicines Act on a limited range of self-medication products, the price regulation and the pharmacy tax law could become applicable to pharmacies as early as 1 January 2026, i.e. one year before the start of off-pharmaceutical sales.

The proposed new Sections 12 and 12a and the amended Section 21b are proposed to apply from 1 January 2027. The application would start at the same time as the regulation of the Medicines Act on holders of retail licences for self-treatment medicinal products (HE xxx/2025 vp). According to the Centre for Safety and Development of Medicines, the receipt of applications for retail licences for self-medication medicinal products could start from the beginning of 2027. In practice, in order to facilitate the permit-granting process, e.g. electronic access and the establishment of an electronic register would be necessary.

It is proposed to repeal Article 9 of the Regulation on classification for supply of medicinal products. However, it is proposed that this article applies until 30 September 26 to the classification of medicinal products for supply, as Government bill HE xxx/2025 proposes that the new Article 23b of the Medicines Act on the classification of medicinal products for the supply of medicinal products should not apply until 1 October 2026. The date of application of the Medicinal Products Act would be due to the fact that, according to Fimea’s assessment, when the proposed Law amending the Medicinal Products Act entered into force from the beginning of 2026, marketing authorisation holders’ applications for extensions of the sales channel could start to be received from 1 October 2026 due to changes to the register of authorised preparations and to the pharmaceutical search service.