VN/14215/2025

Government proposal to Parliament for legislation on the development of pharmacy activities

MAIN CONTENT OF THE PROPOSAL

The proposal proposes to amend the Medicines Act, the ePrescription Act and the Act on the Processing of Customer Data in Social Welfare and Healthcare.

According to the proposal, the content of pharmacy services would be clarified in terms of what activities should be carried out in the pharmacy and how the skills of pharmacy staff can be further used as part of successful medical treatment and to support both self-care by clients and self-care co-designed with a healthcare professional. To support the success of pharmaceutical treatment, changes are proposed to the pharmacy contract regulation in the Medicines Act.

Qualitative and operational requirements for pharmacy operations would also be added to the Medicines Act by introducing into the Medicines Act obligations to support the maintenance of patient safety, such as the preparation of the pharmacy's own policy and incident reporting and handling. The proposed amendments also safeguard the equal position of customers by introducing into the Law on Medicinal Products the basis for price regulation for the issuance of the Schengen Certificate. The aim of the proposals is to ensure high-quality and equal pharmacy services in Finland by clarifying the operational requirements.

The proposal also proposes changes to the pharmacy licensing system that would contribute to the well-functioning of the national pharmacy network and ensure its social sustainability. The aim is to reform the regulation of branch pharmacies to better reflect actual regional needs and to involve the social and health care service providers in the management of the network of pharmacies in the region. It is proposed to exempt pharmacy pick-up clubs from location regulation.

The proposal proposes to enable an online service for holders of retail licences for non-prescription medicinal products. In addition, remote pharmacy services will be streamlined by improving the regulation of the pharmacy's online service and the conditions for its provision. The amendments allow for more flexible cooperation between pharmacies for the supply of the medicinal product. The conditions for competition on the price of medicinal products would be strengthened by allowing a different pricing from that of a brick-and-mortar pharmacy in an online pharmacy. In addition, amendments are proposed to the Medicines Act aimed at identifying the mechanical dispensing activity as a separate activity from the pharmacy activity, which would clarify the position of both the dispensing operators and the customer base as part of the medical treatment and regulatory supervision.

The proposal is based on the records of the government programme of Prime Minister Petteri Orpo for the safe and effective provision of medicines and the pharmacy system.

The amendments to the Medicines Act are intended to enter into force on 1 January 2027. However, the repeal of Paragraph 55b of the Law on medicinal products is to take effect from 1 October 2028. The amendments to the ePrescription Act are intended to enter into force on 1 October 2028. The amendments to the Act on the Processing of Customer Data in Social Welfare and Healthcare are intended to enter into force on 1 October 2028.

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RATIONALE

1 Background and preparation

1.1 Background

According to the government programme of Prime Minister Petteri Orpo, the regulation of pharmacies will be reformed in a responsible and gradual manner, ensuring quality and safe pharmacy services throughout Finland. The role of pharmacies as part of the healthcare system and their important role in the success of patient medication is recognised and taken into account in regulatory development. The reforms aim to enable the development and more cost-effective organisation of pharmaceutical services at a distance and to strengthen the conditions for price competition for medicinal products. The reform will be implemented in such a way as to ensure regional access to medicines and pharmaceutical services, as well as the safety of medicines and medication. The proposal is also based on the provisions of the Government Programme concerning the overall reform of the pharmacy economy as regards the possibility of cooperation between pharmacies. The presentation also explores how to make more use of the skills of pharmacy staff as part of social and health care.

The presentation is also based on records of safe and effective medicine provision. According to the government programme of Prime Minister Orpo, pharmaceutical reform will continue on the basis of the Pharmaceutical Roadmap (STM 5/2019) and ensure rational pharmaceutical treatment. The proposal supports the development of dosage distribution of medicines, which, according to the government's programme, aims to increase medication safety and the efficient use of human resources.

The proposal is in line with the statements adopted by Parliament in connection with the consideration of Government Bill 111/2025 vp. Parliament required the Government to monitor the effects of the reform of the pharmacy economy on the economic viability of pharmacies, the availability of medicines, including in sparsely populated areas, the security of supply and the development and implementation of medication safety, including the longer-term effects of changes related to self-medication on the pharmacy economy and medication safety. Parliament also required the Government to take measures, if necessary, to safeguard the nationwide network of pharmacies and to make any necessary changes to the regulations in the context of the government proposal to be presented in spring 2026. Parliament required the Government to assess the extension of the range of services provided by pharmacies as part of the social and health services system and to take the necessary measures to enable it. Parliament required the Government to monitor the smooth functioning and reasons for waiving pharmacy licences for pharmacists and, if necessary, to take action if waiving pharmacy licences would lead to disproportionate consequences. The Finnish Parliament required the Government to examine the need for regulation to prevent vertical integration in relation to the retail sale of non-prescription medicines and to make any necessary changes to the regulation in the context of the government proposal to be presented in spring 2026.

The proposal to regulate the price of a Schengen certificate issued by a pharmacy is based on a decision of the Deputy Parliamentary Ombudsman in a complaint case (16.6.2021, EOAK/1081/2020).

1.2 Preparation

The government bill has been prepared as an official work by the Ministry of Social Affairs and Health as part of the Pharmaceuticals and Pharmacy Economy project (STM076:00/2024, VN/15865/2024). The preparatory work has been supported by a multi-actor observatory and a

study group of public authorities from 13 May 2024 to 31 December 2026 (VN/7472/2024). Two public stakeholder consultations were held on 27 October 2025 and 3 November 2025 to support the preparation of the presentation. In addition, two consultations were held on the development of the mechanical dispensing of medicinal products on 26 October 2025 and 13 February 2026, to which existing dispensing operators were invited, and on 13 February 2026, on the development of information management in the field of medicinal products, to which proposals for amendments to the pharmaceutical contract were submitted.

The government bill is part of a long-term reform of the pharmaceutical sector based on the pharmaceutical roadmap of the Ministry of Social Affairs and Health (STM 5/2019). In addition, a study on the current state of pharmacy operations has been used in the preparation (development of the pharmacy system: Assessment of the current situation and proposals for further action, STM 6/2023). In addition, the Ministry of Social Affairs and Health launched two studies to support the preparation, of which Fimea produced a study on the development needs of the mechanical dispensing system (Development needs for the mechanical dispensing of medicinal products: study, STM 30/2025) and a consortium coordinated by the University of Eastern Finland produced a study on the development needs of pharmaceutical advice (Study on the content and documentation of pharmaceutical advice by pharmacies, STM 9/2025).

A consultation on the draft government bill took place between 21 April and 1 June 2026. A total of 77 key authorities and actors were consulted. Not only those mentioned in the distribution were given the opportunity to submit an opinion. The draft amendments to the pharmaceutical agreement were also the subject of a public consultation on 19 June. — 14.8.2025 (VN/19773/2024) and an online service outside the pharmacy for a limited range of self-care medicines, 30 June. Period from 18.8.2025 (VN/14214/2025).

The preparatory documents for the Government proposal are available on the public service https://stm.fi/hanke?tunnus=STM079:00/2024 under the case number STM079:00/2024.

The proposal has been submitted on xx/xx/xxxx for assessment by the Legislative Review Board.

In accordance with Article 5 of Directive (EU) 2015/1535 laying down a procedure for the provision of information in the field of technical regulations and of rules on Information Society services, a draft of the Government proposal submitted for consultation has been transmitted to the Commission on xx/xx/xxxx. The identifier of the notice in the draft order database is X. It is subject to a standstill period of at least three months under the Directive, ending on xx.xx.2026. The proposed legislative amendments should not be adopted before the expiry of the time limits provided for in the Directive to the extent that they fall within the scope of the Directive.

In addition, a draft law containing permit conditions for access to or exercise of a service activity must be submitted to the European Commission, at the latest after its adoption, under the notification procedure provided for in Article 15 of Directive (EU) 2006/123 of the European Parliament and of the Council on services in the internal market.

2 Current situation and its assessment

2.1 Pharmacy functions and activities

Current status

Tasks of pharmacies

The pharmacy and its tasks are governed mainly by the Medicines Act (395/1987), the Medicines Ordinance (693/1987) and the Electronic Prescription Act (61/2007) ('the prescription act'). A pharmacy is defined in the Medicines Act as a pharmaceutical activity unit whose object is the retailing, distribution and manufacture of medicinal products and the provision of advice and services relating to medicinal products. The pharmacy's statutory tasks include supplying medicinal products (Article 12 of the Law on prescriptions), providing advice and guidance, exchanging medicinal products, storing medicinal products and ensuring the availability of medicinal products, and drawing up the certificate provided for in Article 75 of the Schengen Convention (Articles 55 to 55a, 57 and 57b of the Law on medicinal products).

In addition to the statutory tasks of pharmacies, the statutory tasks of university pharmacies are, pursuant to Paragraph 42 of the Law on medicinal products, to carry out training in pharmacy teaching and to carry out research relating to the supply of medicinal products. The University of Helsinki's pharmacy also has a special service role in the manufacture of certain rare medicinal products (HE 87/1986 vp, p. 23).

Supply of medicinal products, advice and guidance

With some minor exceptions, the retail sale and supply to the public of medicinal products used in outpatient treatment is the exclusive right of pharmacies (Article 38a of the Medicines Act). The dispensation of a medicinal product from a pharmacy is also referred to as the dispensation of a medicinal product, which includes various stages. The stages of supply differ depending on whether it is a prescription medicine or a non-prescription medicine. The dispensation of a medicinal product subject to medical prescription shall consist of: (1) ensuring the right to purchase the medicinal product and selecting the prescriptions to be supplied, (2) ensuring the correctness and expediency of the prescriptions, (3) price advice and selection of the product to be supplied, (4) making delivery notes and providing advice and guidance on the use of the medicinal product, (5) ensuring the authenticity of the packaging of the medicinal product, and (6) labelling the packaging of the medicinal product, providing written explanations and handing over the medicinal product to the purchaser. The supply of a medicinal product for self-care shall consist of: (1) treatment needs assessment supported by a pharmacy professional, (2) price advice and selection of the product to be supplied (if the product is necessary), (3) advice on the use of the medicinal product and (4) supply of the medicinal product to the purchaser.

The rules governing the dispensation from a pharmacy of a prescription-only medicinal product are divided into a number of different pieces of legislation. A key aspect of the regulation of the supply of medicinal products is the exchange of information in the field of social and healthcare and the supply of medicinal products is closely linked, inter alia, to health insurance and the level of regulation at EU level in the area of pharmacovigilance.

Under Paragraph 12 of the Law on prescription, the customer or anyone acting on his or her behalf must provide reliable evidence that he or she is entitled to receive the medicinal product when it is supplied on the basis of a prescription. The prescription for the dispensation of Fimea (Order 2/2016 of Fimea) requires the pharmacy to ensure the accuracy of the

prescription and the dosage. In addition, the pharmacy must verify that the content of the prescription corresponds to what is required by the Decree of the Ministry of Social Affairs and Health on prescribing the medicinal product (Sections 13, 15-18 and 20-23) and assess the possibility of dispensing the medicinal product. In addition, according to Fimea's prescription, which governs the dispensing of the medicinal product, the prescription and dispensing of the medicinal product must constitute a safe and appropriate whole from the point of view of the user of the medicinal product, the prescriber, the pharmacy and other healthcare.

The supply of a medicinal product on the basis of a medical prescription essentially involves advising on and advising on the use of the medicinal product, since, in accordance with Paragraph 57 of the Law on medicinal products, the pharmaceutical personnel supplying the medicinal product must seek to ensure 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 the treatment. In addition, the supply of the medicinal product should inform the customer about the cheapest option actually available and offer it to the customer. Under Paragraph 57b of the Law on medicinal products, a pharmacy is required to exchange a medicinal product prescribed by the prescriber for a publicly available interchangeable medicinal product in accordance with the list referred to in Paragraph 57c which is the cheapest or the difference in price between the cheapest and the cheapest does not exceed EUR 0.50. A prerequisite for a change of medicinal product is that the prescriber has not, on medical or therapeutic grounds, imposed a ban on the change of prescription and that the purchaser does not prohibit the change.

In addition, the pharmacy ensures compliance with the conditions for direct reimbursement under the Health Insurance Act (1224/2004) for any medicinal product supplied on the basis of a medical prescription and determines the price of the medicinal product on the basis of the customer's reimbursement criteria, in accordance with the instructions drawn up by Kela for the pharmacy. The direct compensation function is based on an agreement between the pharmacies and Kela.

Before dispensing a medicinal product, the pharmacist shall verify the authenticity and identification of the medicinal product by means of the safety features on the packaging. The safety features are laid down in Article 25 of 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.

Under Paragraph 12 of the Law on prescriptions, in the event of dispensation of a medicinal product, the purchaser of the medicinal product must be provided with a written statement of the medicinal product supplied, together with an indication of the part of the medicinal product not supplied, unless the purchaser states that he does not wish to receive such a statement. The prescription for the dispensation of Fimea's medicinal products requires the pharmacist to affix instructions to the packaging of the medicinal product before handing it over to the customer. Under Paragraph 12 of the Law on prescriptions, the purchaser of a medicinal product may be provided with a compilation in which, with the consent of the patient, information on the patient's national medication list or equivalent information on prescriptions may be provided. If the medicinal product is collected by someone other than the patient or his or her legal representative, a full prescription information package may only be issued if authorised by the patient or his or her legal representative. The delivery details of the prescription will be attached to the prescription at the prescription centre.

Medicinal products supplied on prescription shall be prepared for supply by a qualified pharmacist. Fimea's prescription requires a pharmacist to check and certify in a documented manner that the medicinal product to be supplied corresponds to the order before packaging and sending out the order. The supply of the packaged medicinal product from the point of

contact or the packaging and dispatch of the medicinal product in connection with the pharmacy's online service may also be carried out by an employee other than a pharmacist.

There are no detailed rules on the supply of non-prescription medicinal products comparable to those on the supply of prescription medicinal products. The obligations laid down in Paragraph 57 of the Law on medicinal products to ensure that pharmacists seek to ensure, by means of advice and guidance, that the medicinal product is used correctly and safely also apply to the supply of non-prescription medicinal products. A customer can purchase almost all self-care medicines from a pharmacy, even without advice, if he or she indicates that he or she does not need advice if it is offered and does not himself or herself seek to interact with a pharmacy professional. If the client's symptoms require medical examination and diagnosis, the pharmacist should refer the client to a doctor.

A small proportion of the out-of-home medicinal products sold in a pharmacy are classified by the pharmacy authority as out-of-home medicinal products requiring further advice. Those medicinal products are, for example, those which are intended only for a specific class of customers (post-conventional medicinal product), a lower dose of the corresponding prescribed medicinal product (inflammatory anti-inflammatory medicinal product) or a small package of an acute need for a prescribed medicinal product (migracene medicinal product). Pharmacists must always provide the customer with advice in accordance with written material approved by the authority before dispensing the medicinal product in the case of a self-care medicinal product requiring additional advice.

Advice and advice in the pharmacy is an essential part of the supply of the medicine. In addition to the provisions of the Medicines Act, Fimea's dispensing order imposes requirements for advice and guidance. The prescription requires that, in order to ensure the correct and safe use of the medicinal product, the pharmacy must take into account the overall care, illness and age of the user of the medicinal product. Particular attention shall be paid to the provision of advice to customers taking high-risk medicinal products and starting new treatments. When advising on medicinal products, pharmacists should take into account the other medicinal products used by the customer in order to avoid combinatorial effects and guide them in choosing the appropriate medicinal product and pack size. When dispensing medicinal products, care should also be taken to ensure that customers of home care, nursing homes or similar services are advised on medicinal products. If necessary, the prescriber and the pharmacy should cooperate to ensure that the user receives consistent and comprehensive information on the medicinal product.

The prescription for the supply of Fimea's medicinal product also requires that, in the case of the supply of interchangeable medicinal products, the pharmacist must ensure that the customer is aware that the medicinal product supplied will replace a previously used medicinal product. Under Section 57 of the Medicines Act, the pharmacists of a pharmacy must provide equipment advice when the pharmacy changes an inhaled medicinal product, a biological medicinal product or a biosimilar used for the treatment of asthma or chronic obstructive pulmonary disease.

According to Fimea's dispensing regulation (2/2016), pharmaceutical advice must be interactive, allowing the customer and the pharmacist or pharmacist who serves him to discuss the medicine. Advice on medicinal products should take into account confidentiality provisions. If the customer so wishes, he or she should be able to obtain advice on medicinal products by telephone from the pharmacy or branch pharmacy in which he or she has been established. The pharmacy must have the necessary sources of information to support the advice of medicinal products and be able to use them. The pharmacy should have a protocol for advice on medicinal products, including advice on the correct and safe use of non-prescription medicinal products and non-prescription medicinal products requiring further advice. Staff

should be made aware of the terms of reference. The pharmacy's technical staff should be made aware of the restrictions on the sale of non-prescription medicines.

According to the Fimea Pharmacy Online Service Regulation (Fimea Regulation 2/2011), the purchaser of a non-prescription medicinal product on the pharmacy's online service must have access to advice and advice from pharmacists on the correct and safe use of medicinal products, information on the prices of medicinal products and other factors affecting the choice of medicinal products. In accordance with the regulation on the online service provided by pharmacies, in the case of non-prescription medicinal products, the customer may choose, when placing his order, whether or not he wishes the pharmacy to contact him in order to obtain advice on medicinal products. Under Article 21c of the Decree on Medicinal Products, it must be possible to obtain advice before paying for an order or otherwise confirming it. When dispensing prescription-only medicinal products and self-care medicinal products requiring additional advice, advice should always be provided via the pharmacy's online service. In the case of online and remote pharmacy services, advice can be provided, for example, in a chat or by telephone. According to the Fimea Regulation on the Supply of Medicinal Products (2/2016), pharmaceutical advice must be interactive, allowing the customer and the pharmacist or pharmacist who serves him/her to have an opportunity for discussion. A similar requirement applies to both face-to-face and online advice.

Schengen Certificate

Under Paragraph 55a of the Law on medicinal products, a pharmacy may act as the competent authority within the meaning of Article 75 of the CISA and issue the certificate referred to in that article for the carriage of medicinal products containing narcotic drugs or psychotropic substances when travelling from one Contracting State to another.

During the parliamentary proceedings on the amendment to the Medicinal Products Act (700/2002), it was not assessed what fee pharmacies could charge for carrying out this public administrative task. The circular of 14 January 2003 from the Ministry of Social Affairs and Health to pharmacies states that pharmacies may charge a reasonable fee for the issue of the certificate. The amount of the fee is therefore freely determined by the pharmacies. The opinion of the Constitutional Law Committee (PeVL 19/2002 vp, p. 4) assessed the relationship between regulation and mainly Article 124 of the Constitution and the transfer of public authority to the private sphere. The Constitutional Law Committee has taken the view that, by its very nature, the Schengen Certificate is issued without any particular consideration to any applicant who satisfies the conditions for obtaining it. According to the Constitutional Law Committee, given the nature of the certificate, pharmacies have sufficient specific expertise to issue it. In addition, the Constitutional Law Committee stated in its opinion that the law should indicate the technical conditions for obtaining the certificate.

Services provided in pharmacies

Pharmacies have access not only to the supply of medicines but also to other business activities related to the provision of services or other sales of products. Under Paragraph 58a of the Law on medicinal products, other service activities relating to the promotion of health and well-being and the prevention of illness may also be carried out in a pharmacy and in its establishments. The activity must not be aimed at unnecessarily increasing the use of medicinal products and neither the activity nor the sale of non-medicinal products should be detrimental to the supply of medicinal products and the provision of advice on medicinal products.

The services offered in different pharmacies vary.	The services are mainly provided by:
professionals trained as carers; and	pharmacy trained

professionals, but also, for example, cosmetics, in which case it is not a health service. According to a domestic pro gradu study, the most common service provided by pharmacies and the largest number of customers was mechanical dispensing when looking at service provision between 2010 and 2020 (Valve, Kiia). Development of pharmaceutical services in Finnish pharmacies. Pro gradu – thesis; Helsinki University 2021. Available at: https://helda.helsinki.fi/server/api/core/bitstreams/9fdb80eb-423a-4025-9eed-b23628e7240d/content).

According to the annual financial statement analysis published by Fimea, pharmaceutical services are widely available in pharmacies, but so far they are not well established (Fimea). Financial analysis of pharmacies for 2020-2023. Fimea 1/2025. Available at: https://urn.fi/URN:ISBN:978-952-7299-77-7).

Typical paid clinical pharmacy services include assessments at different levels of medication, asthma and diabetes service, and review of inhalation therapy. In a 2024 economic survey of pharmacies by Fimea, 110 private pharmacies reported turnover in clinical pharmacy services, with a total turnover of EUR 566270 (data collected by Fimea from pharmacies). The average turnover for those services was EUR 5148 (EUR 1265 in 2023 and EUR 746 in 2022) and the median was EUR 143 (EUR 105 in 2023 and EUR 170 in 2022). Overall, the provision of health services as part of pharmacy activities is still modest.

Assessment of the status quo

Tasks of pharmacies

The legislation in force on the licensing of pharmacies was enacted with the involvement of the Constitutional Law Committee (see, inter alia, PeVL 69/2014 vp, p. 2, and PeVL 36/2021 vp, p. 2-3). By way of exception, in the opinion practice of the Constitutional Law Committee, the requirement for a licence to conduct a business has been assessed as possible (PeVL 69/2014 vp, p. 2, and PeVL 58/2014 vp, p. 5). Authorisation to operate a pharmacy is based on public health considerations, the guarantee of safety of medicines and the availability of medicines throughout the country. According to the opinion practice of the Constitutional Law Committee, restrictions on the freedom to conduct a business laid down by law must be precise and precise, and the extent and conditions of the restriction must be apparent from the law. According to the Constitutional Law Committee, the specificities of pharmacy activities also involve public administrative tasks assigned to pharmacies, which increase the regulatory competence of the public authorities compared to the regulation of clean business (e.g. PeVL 31/2018 vp, p. 3).

Only a pharmacy is specifically defined in the Medicines Act as having different tasks. The pharmacy's primary task is to supply medicinal products and to provide advice and guidance in this regard. In addition, there are other activities in pharmacies that have actually been necessary for the provision of quality pharmacy services. A pharmacy may also engage in other health and well-being promotion and disease prevention service activities and sell non-medicinal products. The possibility for a pharmacy to carry out other activities is partly restricted by the Medicines Act.

Further regulation of the pharmacy's tasks would be necessary not only to define and ensure high-quality pharmacy services, but also to monitor the need to finance long-term pharmacy services and reform the financing of the pharmacy system. From the point of view of assessing the need for adequate financing of pharmaceutical services, it would also be necessary to establish a more precise qualitative framework for pharmaceutical services.

The operation of pharmacies is financed mainly through the regulation of the price of medicinal products and the taxation of the pharmacy's margin on sales of medicinal products. The pharmaceutical economy, the pharmaceutical tax and the pharmacy tax have been subject to fiscal austerity measures, most recently amendments to the Pharmacy Tax Act 2025 (1427/2025) and amendments to the Government Decree on the pharmaceutical tax (1438/2025). Monitoring the development of the pharmacy economy and assessing the need for sufficient funding also applies to the consideration of other health and well-being business activities carried out in the context of a pharmacy. Some pharmacies sell non-pharmaceutical products or services through a company separate from the pharmacy premises, and the customer may not know whether he is buying the product or service from the pharmacy or from a related limited company. According to Fimea's data, 38 % of private pharmacies invest in the sale of non-pharmaceutical products and services in connection with a pharmacy (Fimea1/2025, p. 37). The pharmacy and the company often have joint staff, so it can be assumed that there is a common business strategy and that the company benefits from the pharmacy's customer flows. The activities and finances of the pharmacy and the associated company should be assessed as a whole. The overall assessment shall identify and, where appropriate, take into account the fact that activities related to the operation of a pharmacy may also be associated with a public limited company.

An amendment to the status quo would implement the programme record, which provides for greater financial transparency in pharmacies and clarification of the status and taxation of limited liability companies operating in connection with pharmacies. Taxation as a whole would not be proposed, but should be part of a wider further development of the financing of pharmaceutical services. Further development will be possible once the changes to the functions of pharmacies and the content of the statutory services, as estimated in this proposal, are confirmed.

Supply of medicinal products

The supply of medicinal products from a pharmacy to customers is, as a general rule, carried out well. According to a survey carried out in 2020 on the basis of the Government's mandate for studies and research, the majority of pharmacy customers are satisfied with the activities of pharmacies, such as the provision of pharmaceutical and price advice, the implementation of the exchange of medicinal products and the direct reimbursement of medicinal products (Saastamoinen, Leena et al. Activation of price competition for pharmaceuticals and public expectations for pharmacy operations. Government Reports and Research series 2021:32, p. 88). According to the customer, the medicinal product he or she needs will almost always be directly reimbursed and authenticated and properly verified through the medication verification system. According to the survey, customers feel sufficiently informed about how to take the medicine, how long to use it and how to store it when visiting a pharmacy. According to the study, there is no need to change the regulation of the supply of medicinal products. As the regulation is divided into several laws, decrees and Fimea regulations, the study suggests that it would be necessary to consolidate the key steps in a single law on medicinal products, clarify the requirements for the provision of services and clarify in legislation where the potential of digitalisation could be exploited in the supply of a medicinal product.

As things stand at present, the rules on the supply of medicinal products are in part aimed at the pharmacy, in part at the holder of a pharmacy licence and in part at a pharmacist. The regulation specifically targeted at the professional has been interpreted as preventing, for example, the use of technologies at the dispensing stages of a pharmacy. Workflows where technology could be used, for example, to advise on the price of a medicine, which, as things stand at present, is closely linked to the provision of advice on medicines. The modernisation of the criteria for dispensing a medicinal product in the Medicines Act should allow for a

flexible way of organising and practically implementing the different stages of dispensing a medicinal product on a pharmacy-by-pharmacy basis. Nationally defined data management approaches should be followed, regardless of how the activities are organised. Clarifying the regulation of the supply of a medicinal product could also allow for cooperation in the supply process of a medicinal product, making it possible to obtain a service based on an authorisation from another authorisation holder on a contractual basis. Such amendments would, in accordance with the government programme, enable cooperation between pharmacies.

Defining the process for dispensing a medicinal product and amending the Medicines Act to support it would also be important to clarify the core role of pharmacies vis-à-vis other organisations in the pharmaceutical treatment process. The therapeutic process is a chain of activities that includes the assessment of the need for treatment, prescribing, dispensing, carrying out medication, monitoring and evaluation of medication and termination of medication. The determination of the service involved in the supply of a medicinal product is a prerequisite for the development and provision of other services based on the competence of the pharmacy's pharmacists as a separate entity for the supply of the medicinal product. The amendment would implement the governmental programme recording that the pharmacy regulation will be reformed in a responsible and gradual manner, ensuring high-quality and safe pharmacy services throughout Finland. It would also make it possible to recognise the role of pharmacies as part of the healthcare system and the important role they play in the successful treatment of patients.

Advice and guidance

Under the current legislation, when dispensing medicinal products, the advice and guidance of the pharmacist's staff must 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 the treatment (Section 57 of the Medicines Act). According to studies, the current definition of the legal advice of pharmacies is too general and does not define, among other things, the roles and responsibilities of pharmacies in monitoring medication and identifying and resolving medication problems (STM 6/2023 and Dimitrow et al. cited therein). 2021 and Hämeen-Anttila and Others 2022, STM 6/2023). According to the STM's report, the current regulations leave unclear the pharmacy's responsibilities and responsibility for the supervision of medicinal treatment as part of the pharmaceutical treatment process (STM 6/2023). In addition, the distinction between regulatory advice and guidance and possible paid pharmaceutical services has been perceived as unclear. In addition, the Medicines Act does not explicitly recognise advice and guidance on self-medication and the related support of a pharmacy professional in assessing the need for care.

The need to develop advice and guidance for pharmacies has also been identified in mystery shopping surveys carried out by Fimea in 2018, 2021 and 2023 (Fimea develops, evaluates and informs series 14/2018, 13/2021, 8/2024). According to the findings of the 2018 mystery shopping survey, the provision of advice to pharmacies is quite good when a customer requests a self-care medicine or nasal spray requiring further advice. In particular, when a customer requests an analgesic under a trade name, there is a need to develop drug advice and to assess the need for, and suitability of, medication. In addition, cheaper analgesics are rarely recommended and almost always two packages of 30 tablets (400 mg) of analgesics are sold without any explanation as to why two packages are needed. Based on the 2021 mystery shopping survey, the customer applying for the symptom is well advised about the medicine. On the other hand, there is scope for improvement, in particular where the customer requests an analgesic under the trade name. In the pharmacy's online services, the provision of advice on medicinal products varies. Low-priced products and non-medicated treatments were rarely recommended by pharmacies. A study carried out in 2023 described the handling of

pharmacies as smooth and good service. The majority of clients received a service from a pharmacist in less than five minutes. The customer service was described as friendly and expert. The pharmacy as an environment was described as a pleasant place of business. The mystery shopping survey shows that the need for and suitability of a self-care medicine is well established in pharmacies. Instead, the quality and extent of drug advice needs to be improved when a medicine is requested for a specific symptom, such as fever in a young child or an adult's sight. A significant proportion of customers would have needed more advice.

There is a comparatively high number of literature and studies available on guidance and advice from pharmacies on the supply of medicinal products. The purpose of the advice provided at the time of dispensing is to enable the successful and optimal effectiveness of medicinal treatments, on the one hand, and to prevent and prevent the occurrence of risks and harms, on the other hand (STM 9/2025 and Mononen 2020, Kallio 2021, STM 24/2022, STM 6/2023). In population surveys, apart from doctors and package leaflets, pharmacies have been the main sources of information on medicines for users. However, in several domestic studies, advice has been found to be product-oriented and insufficiently responsive to customers' individual medical needs (STM 6/2023). In particular, users of medicines would like to be informed about the therapeutic effects, potential harms and synergistic effects of medicines (STM 9/2025 and Dimitrow et al. cited therein). 2021). There are variations in the delivery and quality of advice, both between different patient groups, pharmacies and pharmacy professionals, and between prescription and self-care advice (STM 9/2025 and Regina 2017, Alastalo et al. cited therein). 2018, Mononen and Others 2018, Dimitrow and Others 2021, Alastalo and Others 2023, STM 24/2022, STM 6/2023). In order to ensure uniform access to advice from all pharmacies, the need to define the content of pharmaceutical advice from pharmacies and their roles and responsibilities in providing advice as part of the pharmaceutical treatment process has been identified to ensure the delivery and quality of advice (STM 6/2023).

The Ministry of Social Affairs and Health instructed the University of Eastern Finland to define the content of the advice to be given when supplying the medicinal product. The study by the University of Eastern Finland (STM 9/2025) focused on defining what is included in the advice aimed at ensuring the correct and safe use of the medicinal product and the success of medical treatment when supplying the medicinal product, as required by Section 57 of the Medicines Act.

According to the literature, advice given in pharmacies at the time of dispensing a medicinal product, that is to say, pharmaceutical advice given by pharmacies, should be understood as consultation between the client and the pharmacist, taking into account the client's personal needs and situation and supporting the client's survival with his or her medical treatment (STM 9/2025, with reference to Hakkarainen and Airaksinen 2001, Puumalainen et al.). 2005, FIP and IPSF 2012). According to the proposals of the study (STM 9/2025), advice in a pharmacy should increasingly be based on ensuring medication safety and health promotion. Medication safety is the set of principles and practices that ensure that a customer's medication is safe, correct and fit for purpose.

According to the study (STM 9/2025), in the case of advice on medicinal products, account should be taken of the overall pharmacological treatment of the client, the illnesses and age, as well as the categories of clients requiring special attention, i.e. persons initiating pharmacological treatment, persons using high-risk medicinal products, multi-medicated clients and clients with problems with pharmacological treatment. Particular attention should be paid to the provision of advice to these groups of clients in pharmacies, as they are at greater risk of medication problems and can therefore achieve greater benefits if problems are prevented or risks reduced. Regardless of individual customer needs, the study has identified a

variety of content that it would be appropriate for pharmaceutical advice to consist of supporting the success of medication. Advice on prescription-only medication should be quite different when it comes to the initial phase of treatment or to long-term medication.

At the start of treatment with a medicinal product, emphasis should be placed on the control of the use of the medicinal product, which should be advised, as appropriate, on the purpose of the medicinal product, mode of action, the benefits of the medicinal product, the objectives of the treatment, the use of the medicinal product, such as dosage, eating and regularity of use, the duration of use of the medicinal product, the adverse reactions of the medicinal product, the interaction of the medicinal product with food, alcohol and food supplements, the suitability of the medicinal product for other medicinal treatments, contraindications, action in the event of problems, the storage of the medicinal product, the characteristics of the medicinal product, such as halving, advice on the exchange of medicinal products, the cost-effectiveness of the treatment for the customer and the verification of the equivalence of the dose with authorised treatment practices.

Other provisions of Section 57 of the Medicines Act, price advice, injection advice and guidance on the use of the administration device have also been mentioned in the study as part of the guidance on the use of the medicinal product. The content of the prescription-only advice is compiled in accordance with STM Report 9/2025, Table 1.

On the other hand, the advice of a long-term user should focus on monitoring the implementation and success of medication and supporting adherence to treatment and self-care, as well as the resolution of potential problems. The tasks related to the identification and resolution of medication problems are summarised in Table 2 STM 9/2025, as explained in the report. The pharmacy's monitoring of medicinal treatment would consist of ensuring the prescribed use of the medicinal product, reviewing the method of taking the medicinal product, monitoring the regular use of the medicinal product and ensuring its effects, discussing problems experienced in the treatment of medicinal products, supporting self-care and self-monitoring, encouraging adherence to the treatment of medicinal products and participation in self-care, discussing non-medicinal treatments, investigating the need for the prescription to be renewed, reviewing the timeliness of the medication list and, where appropriate, referring the customer to healthcare, Table 1.

Table 1. Content of prescription-only medical advice (STM 9/2025).

Control of the use of the medicinal product	**Monitoring of medication**
Intended use of the medicinal product	Ensuring that the medicinal product is used as intended
Mode of action of the medicinal product	Revision of the prescribing technique
Objectives of the medication	Monitoring of the regular use of the medicinal product
Use of the medicinal product (dosage, food, regularity of use)	Verification of the effects of the medicinal product
Duration of use of the medicinal product	Asking about problems experienced with medication

Control of the administration device	Exchange of views on personal care
Pistol advisory services	Self-monitoring exchange of views
Adverse drug reactions	Supporting adherence to pharmacotherapy
Drug interactions (food, alcohol, food supplements)	Incentivising self-care
Suitability of the medicinal product for other medicinal treatments	Discussion on non-medicated therapies
Contraindications for the use of the medicinal product	The need to renew a prescription;

	settlement
Action in case of problems	Check the timeliness of the medication list
Storage of the medicinal product	Referral to healthcare if necessary
Characteristics of the medicinal product (e.g. halving)	–
Price advice	–
Advice relating to the exchange of medicinal products	–
Cost-effectiveness of medication for the customer	–
Verification of dose equivalency for approved treatment practices	–

Table 2. Tasks related to the identification and resolution of problems with medication in pharmacies to ensure the correct and safe use of the medicine and the success of medication treatment (STM 9/2025).

Identification of problems with medication	**Solving problems with medication**
Unclear guidance on the medicine	How to solve a problem with advice
Unclear indication of the medicinal product	Customer referral to healthcare, unless solved in a pharmacy
Problems related to the take-up of medicines	Straight contact pharmacy healthcare, unless the case can be resolved in a pharmacy;
Organisation	Therapeutically more justified recommending a medicinal product for self-care
Therapeutically significant risks of adverse reactions	Non-sale of a self-medication product for therapeutic reasons
Adverse combination effects	–
Risk medicine related risk availability	–

Duplicate medication	–
Over-execution	–
Under-utilisation and non-utilisation	–
Abuse	–
Reluctance to treat medicinal products	–
Multiple medication and the problems it poses	–
Need for a health surveillance mission	–

In pharmacies, guidance on the use of the medicinal product, monitoring the implementation of the treatment, identifying problems and supporting adherence to treatment can mainly be done on the basis of already available information and discussion with the client. A key knowledge gap is that the pharmacy may not be aware of the intended use of the medicine, which is essential information to support the success of the treatment or to ensure that the medicine is prescribed at the correct dose. Monitoring of the effects of medication is also possible in some respects, but some of the monitoring requires patient data that are currently not available to pharmacies (STM 9/2025, p. 18, mentioning, inter alia, Kallio 2021, Laakso 2023).

A study (STM 9/2025) has found that problems with pharmacy treatment are identified and, to some extent, can be resolved (Kallio 2021). The main ways to solve problems with prescription-only medicine are advice, a call to a doctor and direct contact of a pharmacy with a doctor (Kallio, 2021). A smoother resolution of problems would require new communication solutions between pharmacies and other social and healthcare services, as well as stronger cooperation structures and approaches (STM 6/2023).

According to a study (STM 9/2025), advice on self-care in pharmacies differs from advice on prescription-only medicine in that the customer’s visit to a pharmacy is often not preceded or followed by a visit to a doctor or nurse. Thus, the role of pharmacies in providing advice on self-care is essential, as customers purchasing self-care medicinal products do not necessarily meet other healthcare professionals when choosing and carrying out medical treatment. It is the responsibility of the pharmacy to ensure that the user of the medicinal product chooses the non-medicinal and/or medication treatment appropriate to his situation, can use his self-medication appropriately and safely. In certain situations, where the best treatment associated with the situation would be something other than the use of the product to be purchased in the pharmacy, the pharmacy should refer the customer to it, e.g. to rest, without unnecessary selling of the product.

While the assessment of the need for prescription-only medical treatment is carried out by a doctor, the assessment of the need for self-treatment is carried out by a pharmacist in a pharmacy together with the client. According to the report (STM 9/2025), advice on self-care does not only concern the medicinal product to be supplied and the advice on it, but also includes the assessment of the need for care, the choice of the appropriate treatment option, consideration of the overall pharmacological treatment and,

if necessary, referral to other healthcare (see Annex 1 to the report (STM 9/2025): Chapter 1.2.2.2). The content of the self-care advice collected in the report is presented in Table 3.
Table 3. In line with the content of self-care advice (STM 9/2025).

Assessment of the need for care supported by a pharmacy professional	**Control of the use of the medicinal product**
Need for medication	Intended use of the medicinal product
Suitability of medical treatment	Use of the medicinal product (e.g. dosage, food)
Treatment options appropriate to the client's situation and overall care	Duration of use of the medicinal product
Co-selection of the medicinal product with the customer	Action in situations where symptoms persist despite the use of a self-care medicine
Objectives of the medication	Control of the administration device
Immediate referral to healthcare (without self-care)	Adverse drug reactions
Recommendation to contact healthcare (self-care as first aid)	Interactions (e.g. food, alcohol)
–	Suitability of the medicinal product for other medicinal treatments
–	Contraindications for the use of the medicinal product
–	Storage of the medicinal product
–	Price advice

In the case of self-care in a pharmacy, depending on the client's situation, the most appropriate treatment may be a self-medication, a non-medicated alternative or referral to other social and healthcare settings, or a combination of both, Table 3 (Self-medication Recommended Practice 2024). Self-care can also give rise to drug treatment problems, where pharmacists play a key role in identifying and resolving these issues in pharmacies, Table 2 (STM30/2025 and the referenced Upper Rautio 2020).

The study commissioned by the Ministry of Social Affairs and Health (STM 9/2025) also addressed the possibility of documenting advice. Two needs for documentation were identified: communication between professionals and customer needs. Government bill (xx/2026) on the development of medication information management in phase 3 of the Kanta medication list allows communication between pharmacies and other social and healthcare providers through a warning sign on the Kanta medication list.

In order to develop guidance and advice on medical treatment, it is necessary to develop

legislation, professional models and information systems in a step-by-step approach. As a result of this development, the advice and advice provided at the pharmacy in the target mode would be personalised and interactive. It would also better complement the guidance provided by other professionals as part of the multidisciplinary drug treatment process. The package would require several developments (STM 9/2025, pp. 34-35, Table 4).

The legal obligation to provide advice to pharmacies should be clarified and the main obligations related to advice should be laid down at the level of the law, also because the Constitutional Law Committee has drawn attention to the prescribing powers of the Medicines Act and their compliance with the requirements of Article 80(2) of the Constitution (STM 9/2025, p. 24, with reference to PeVL 36/2021 vp). The study also considered that it was justified to include self-care advice as a specific mention in the provisions on advice on medicinal products, as quality self-care advice should be ensured and the supply of the self-care medicinal product should be ensured based on an assessment of the need for care. Correct use of self-medication as part of self-care would support healthcare resilience and can save costs for wellbeing services counties and society (STM 9/2025, p. 29 and referenced in STM 25/2024).

The guidance and advice provided by pharmacies would also be subject to targeted obligations to ensure quality and uniform operating practices. The pharmacy would be required to ensure uniform protocols for the provision of advice and guidance on medical treatment in the context of dispensing prescriptions and in the context of dispensing out-of-home medicinal products and medicinal products requiring additional advice in all service channels. Adequate staff skills and facilities for advice and guidance would also be key elements of quality of service. For advice and guidance, the pharmacy should ensure that confidentiality provisions and privacy are respected. The pharmacy should have access to up-to-date tools to support advice and guidance, including access to up-to-date treatment recommendations, information sources and databases for healthcare professionals, and decision support tools to identify and optimise the risks of pharmacy treatment as possible. Fimea maintains a recommendation on sources of information for pharmacists in pharmacies (Fimea, ENRD materials available: https://fimea.fi/kehittäminen/laakeinformaation_kehittaminen/laadukas-laakeinformaatio).
The pharmacy should cooperate with the wellbeing services county in its area so that the pharmacy can take regional practices into account when providing advice and guidance. The pharmacy must have sufficient knowledge of the care pathways and operating practices in the area to ensure consistent advice and guidance to customers. The prescriber and the pharmacist should also cooperate, where appropriate, to ensure that the user of the medicinal product is provided with consistent and comprehensive information about the medicinal product, is aware of the objective of the treatment and of the issues to be monitored with regard to the effects of the treatment. The amendments aim at recognising the role of pharmacies as part of the healthcare system and the important role of pharmacies in the successful treatment of patients. Efforts would be made to make more use of the skills of pharmacy staff as part of social and health care.

Schengen Certificate

The issuing of the Schengen Certificate has been interpreted as a public administrative function of the pharmacy. In a ruling on a complaint (16 June 2021, EOAK/1081/2020), the Deputy Ombudsman of the Parliament found it problematic that the fee for the performance of a public administrative task is determined solely on the basis of a price set by a private entrepreneur on a commercial basis. According to the Assistant Advocate General, the price of a fee may therefore vary significantly, which may give rise to unjustified discrimination between customers. A separate certificate is required for each journey, which means that the cost of obtaining a certificate can be significant for the individual on an annual basis.

Fimea monitors the annual number of Schengen Certificates issued by pharmacies. The number of certificates issued has increased considerably in recent years. In 2021, pharmacies issued a total of 1995 certificates, in 2022 a total of 8279 certificates, in 2023 a total of 10741 certificates and in 2024 a total of 16561 certificates. The basis for pricing may differ from one pharmacy to another. Pricing may be fixed-price, quantity-based or variable on a case-by-case basis and include a maximum price. The fee for a certificate typically ranges from EUR 25 free of charge. The time taken to draw up the certificate may vary considerably, and the experience of staff also has an impact on this duration. On average, it can take about 15-30 minutes to produce a certificate.

According to Article 124 of the Constitution, entrusting a public administrative task to a person other than an authority should not jeopardise the fulfilment of fundamental rights, due process or other requirements of good administration. There have been differences in the pricing of the Schengen Certificate between different pharmacies, which has led to unequal treatment of customers. In particular if the certificate has to be obtained several times a year. In order to promote equality between customers, legislation should set clear framework conditions for the pricing of the certificate. In some pharmacies, the certificate has been free of charge.

Pharmacy services

A pharmacy may also provide services other than those which form part of the pharmacy's statutory tasks. A pharmacy licence enables the provision of services relating to the supply of a medicinal product. For other services, the pharmacy must assess whether their production requires registration under the Act on the Supervision of Social Welfare and Healthcare (741/2023, Control Act). For example, for health services provided in a pharmacy, vaccination services have been required to be registered in accordance with the Control Act.

According to Section 4(4) of the Supervision Act, 'health service' means measures taken to determine a patient's state of health, to restore or maintain his or her health, health care, medical treatment or any other treatment using medical or dental methods or based on medical or dental sciences, performed by health professionals or performed in a health care facility, as a mobile service, by remote or digital means, at the patient's home or as an emergency medical service within the meaning of Section 40 of the Health Care Act (1326/2010). Under Section 5 of the Supervision Act, social and health services may be provided only by a service provider who is registered in the National Register of Service Providers (Soteri) and whose service unit is registered in that register. The Supervision Act lays down general conditions for service providers and activities. A health service in a pharmacy outside the scope of the pharmacy's tasks, as defined in Section 4(4) of the Supervision Act, would require registration as a health service provider in order to ensure equal standards, such as patient safety and equal conditions for organisations and professionals.

Pharmacies can provide health services to different operators: private healthcare, wellbeing services counties or directly to a private client. If a pharmacy provides a service to a wellbeing services county under its organisational responsibility, the service and the service provider are subject to the provisions of the Act on the Organisation of Social Welfare and Healthcare (612/2021, sote organising act) or, alternatively, to the provisions of the Act on the Service Voucher in Social Welfare and Healthcare (569/2009, service voucher act).

The wellbeing services county is responsible for the organisation of social and health care in its area and is responsible for the social and health care of its residents. The wellbeing services county may provide social and healthcare services itself or acquire them from a private service provider on a contractual basis, under the conditions laid down in Section 12 of the Social Security Act. The Sote Act also contains other detailed regulations affecting procurement in the wellbeing services county. These include the requirements for a private service provider

laid down in Article 14 of the Social Security Act and the contractual conditions for services laid down in Article 15. A private service provider must comply with the requirements of the Social Security Act. According to Chapter 4 of the Supervision Act, a private service provider is responsible for the lawful and contractual provision of its services and for organising self-monitoring. The wellbeing services county must also ensure, in accordance with Section 10 of the Wellbeing Services county Act (611/2021), that the other service provider providing the services for which it is responsible has sufficient professional, operational and financial capacity to provide the services.

The Social Security Act allows a private service provider providing social welfare and health care services to subcontract some of the services under the Purchase Service Agreement or some of the social welfare and health care staff providing those services. Subcontracting is governed by Sections 17 and 18 of the Social Security Act. A private service provider is partly responsible for the supervision and control of its subcontractors. In this context, the private service provider is obliged to ensure that the services provided by the subcontractor meet the legal requirements and what the wellbeing services county requires of the private service provider and that the subcontractor complies with the instructions of the wellbeing services county.

The wellbeing services county may decide on the social and health services for the organisation of which it uses a service voucher in accordance with Section 9(1) of the Act on the wellbeing services county. Section 4 of the Service Voucher Act requires the wellbeing services county to approve those private service providers whose services can be paid for by the customer using a service voucher issued by the wellbeing services county. The approval of service providers shall be subject to the conditions laid down in Article 5. The wellbeing services county must keep a list of the service providers it has approved. Information on service providers, the services they provide and their prices shall be publicly available on the internet and by other appropriate means. The wellbeing services county shall withdraw the recognition of a service provider and remove the service provider from the list if the conditions for recognition are no longer met or if the service provider requests the withdrawal of recognition.

The 2024 amending decree (202/2024) amended section 6 of the Decree of the Ministry of Social Affairs and Health on vaccination (149/2017). The section allows adults to be vaccinated by a pharmacist and a pharmacist who has been properly trained to vaccinate and acts under the direction and supervision of a doctor. In addition, Valvira (now part of the Licensing and Control Authority) has issued new guidelines to pharmacies in early October 2024 for carrying out vaccination and other health services in connection with a pharmacy (the Licensing and Control Authority). Guidelines for the registration of social and healthcare services. Available at: https://lvv.fi/sosiaali-ja-terveydenhuolto/palveluiden-rekisteröinnit. For example the exact number of squares is no longer required for a holding dedicated to vaccination activities, which must be adequate and appropriate for the activities. In addition, the pharmacist no longer has to set up a separate limited company for vaccination, but can also apply for registration under the Soteri scheme as a sole trader. A pharmacist's business name can be used to register health service activities.

Since the amendment of the Vaccination Decree and the revision of the guidelines of the Licensing and Control Authority, the vaccination service has increased in pharmacies. According to the website of the Association of Pharmacists, there are around 155 pharmacies offering vaccination activities in Finland and in 2025, more than 25500 vaccination doses were administered in private pharmacies in total (Finnish Association of Pharmacists, available at: https://www.apteekkari.fi/uutiset/apteekeissa-annettiin-viime-vuonna-jo-yli-25-000-rokotusta-for one-pharmacy most popular – health services/). Vaccination activities are carried out in

different legal forms; According to the data in the Soteri register of the Licensing and Control Authority, 11 pharmacies and 29 separate companies which are partly or wholly owned by pharmacists were registered as healthcare providers in the year. In addition, there are cascading actors on the premises of pharmacies, which can represent a significant share of the providers of vaccination services.

Other health services are also available in some pharmacies, such as measurements, ear rinsing and administration of drug injections. In addition, e.g. pharmacy digital service platforms provide a gateway to telemedicine services for customers. According to the interpretation of the current pharmaceutical authority, medical services provided on the premises of a pharmacy are prohibited. Under Section 58a of the Medicines Act, a pharmacy may also carry out other service activities related to the promotion of health and well-being and the prevention of diseases. The aim of the activity must not be to increase the use of medicinal products unnecessarily. According to the interpretation, the activities described above could not have included the diagnosis and prescription of the medicinal product in the pharmacy premises in accordance with Section 22 of the Health Care Professionals Act. On the other hand, telemedicine may have been offered as part of the pharmacy's online service.

In a pharmacy, pharmaceutical competence-based services have been provided on the basis of a pharmacy licence, i.e. the supervision of activities has been part of the annual monitoring and inspections of pharmacy services by Fimea, with the exception of vaccination activities in services provided by pharmacists. A new supervisory law on the provision of social and health services entered into force in December 2024. According to the travaux préparatoires for Section 4 of the Supervision Act, the definition of 'health service' would apply to all health and medical care provided by health care units. For non-healthcare facilities, it would only apply to the activities of health professionals. Thus, treatment within the meaning of the definition should also be provided in healthcare facilities other than actual healthcare facilities if it is provided by a health professional, such as a pharmacist in pharmacies. According to the travaux préparatoires for the Supervision Act, the activities of health professionals referred to in the Act would include oral health care, preventive care, vaccination, blood donation, physiotherapy and other physical care, prescription of spectacles and similar activities (HE 299/2022 vp, p. 71). A more precise definition of pharmacy-based service activities based on a pharmacy licence is needed, as the current legal situation has proven difficult to delineate between health services and pharmacy services. For example, a reform of the definition of medical advice and advice could make a more precise distinction between what a pharmacy is supposed to demonstrate in the chain of medical care. If services fall within the definition of a health service, the provision of services should be subject to the provisions of the Supervision Act.

Clarification of the current state of regulation would also be necessary in order to ensure that the quality standards of the services provided by the pharmacist and their supervision are adequate and at the same level as those of the health service providers when it comes to the provision of health services. The Law on Medicinal Products does not regulate the supply of medicinal products and the related guidance and advice more broadly as regards the quality of the services provided by pharmacists, self-monitoring and, for example, staff skills, premises or information systems. The conditions and quality requirements for the provision of health services are comprehensively laid down in the Supervision Act. Although, according to the authorities' interpretation, it was possible for services provided by a pharmacist to be provided on the basis of a licence to operate a pharmacy, Fimea did not, in its supervisory activities, assess the conditions under which the services were provided or, otherwise, the appropriateness of the service. Regulatory oversight has focused on assessing whether the provision of services impedes the supply of medicinal products and the provision of advice on medicinal products, as required by Section 58a of the Medicines Act. As things stand, surveillance practices cannot

be considered appropriate for patient safety or uniformity of supervision. If a pharmacist provides health services as a service provider under the Supervision Act, the provision of the service is governed by the Supervision Act. In addition, for professionals other than pharmacy professionals, the conditions for the provision of services and the supervision in the pharmacy have been based on the Supervision Act and its predecessors.

As things stand at present, it has not been possible for pharmacies to process medical data electronically on services which they have provided on the basis of a pharmacy licence. In practice, the patient data needed to provide the services have been delivered to the pharmacy in the form of paper documents or electronic security mail. As a result, the processing of data has not been smooth and has required manual work at several stages of document management. Where the service provided by a pharmacist in a pharmacy is based on the provision and registration of a health service, the activity in the provision of those services is subject to the same data management regulation as other health services.

Legislative amendments to better define the role of pharmacies and the guidance and advice on medical treatment would harmonise the requirements for the provision of health services and increase the equality of supervision. The amendment would contribute to a record of the government's programme to identify the points in the legislation that currently limit the expansion of pharmacies' activities, such as vaccination or other low-threshold health services. Efforts are being made to make greater use of the skills of pharmacy staff as part of social and health care.

The knowledge-related conditions for the provision of services by pharmacists in pharmacies can be assessed as good. The basic education of pharmacists and pharmacists has been reformed over the last ten years with the introduction of the degree reform and the new curriculum at the University of Helsinki in 2014, Åbo Akadem in 2015 and the University of Eastern Finland in 2019. The development of education in Finland is in line with international change. With the identification of medical treatments, the growth of the sick spectrum and the ageing of the population, the rational use of medicines has become more challenging and the importance of managing the harms associated with the use of medicines has become more prominent. The need for services to support prescribers, prescribers and users at different stages of the drug treatment process has been identified. The pharmacy degree reform contributes to this development. Key changes have been the increase in medication safety and clinical pharmacy training, as well as the inclusion of medication assessment skills in the undergraduate degree. The emphasis of the clinical pharmacy is on rational use and influencing of medicines, the development and evaluation of pharmaceutical services and medication safety. It requires multi-professional collaboration and collaboration with the patient. Clinical pharmacy covers all social and healthcare settings in ambulatory and institutional care, where medical treatment is part of the patient's care (Airaksinen, Marja). The importance of research and publication for the development of pharmacy. Dosis 3/2025, The European Statements of Hospital Pharmacy, European Journal of Hospital Pharmacy 2014;21:256-258). Currently, there are different types of basic pharmacy professionals in the labour market. However, professional training in the field of pharmacy is widely available through various training organisations, which helps to develop the skills of professionals in line with the services provided by the pharmacy.

2.2 Processing of data in connection with the activities of a pharmacy and the provision of services in connection with that pharmacy

Current status

In the context of the dispensing of the medicinal product and the supervision and advice of the medication, the pharmacy processes medical data (see 1.3. The tasks of the pharmacy and the

service activities carried out in the pharmacy, including the dispensing of medicinal products, advice and advice). Patient information refers to information on the patient's medical condition or functional capacity contained in the patient's medical record and other health-related documents, or to customer information on the health service provided to the patient. The definition is based on the Act on the Processing of Customer Data in Social Welfare and Healthcare (703/2023) ('the Customer Information Act'). The treatment of ePrescriptions and other medical records stored at the prescription centre is governed by the prescription act. The healthcare service provided in connection with the pharmacy also processes medical data and applies the Customer Information Act.

When dispensing a medicinal product, the pharmacies' right to information is based on Paragraph 11 of the Law on prescription. At the request of the patient or a person acting on behalf of the patient (the purchaser of the medicinal product), the pharmacy has the right to obtain from the prescription centre information on the national medication list or on the medicinal products prescribed for the patient and the related labelling. Paragraph 11 of the Law on prescription has also been applied in the context of advice and guidance to the self-care customer, where the need to take into account the entire medical treatment has arisen in the discussion with the purchaser of the medicinal product. The obligation to register the dispensation of a medicinal product in a pharmacy is also based on the prescription law. In accordance with Paragraph 12 of the Law on prescriptions, the information on the delivery of the prescription is attached to the prescription at the prescription centre.

The legislation governing the processing of medical data determines precisely which data may be processed, by whom and on what basis. According to Section 9 of the Client Information Act, the right to use the data must be based on the work activity of the social or healthcare professional and the service provided in such a way that the person is only entitled to use the necessary customer data necessary for his or her work activity. The processing of customer data shall be based on an IT-verified customer or care relationship or other task related to the organisation and delivery of the customer's social and health service. Decree of the Ministry of Social Affairs and Health (457/2024) ('the Access Decree') lays down the data that professionals and other persons processing customer data may use on the basis of their duties and the service provided.

Under Paragraph 3 of the Access Regulation, the tasks to be taken into account in the access rights of health professionals and other persons processing medical data are to be broken down as follows: (1) cross-cutting tasks in the organisation and delivery of patient health services, such as the assessment of the patient's state of health, capacity and need for care, diagnostics, the organisation of patient health services and treatment and rehabilitation, consultancy and the issuing of health certificates and official decisions; (2) limited tasks for the implementation of the patient's health services, such as the care, rehabilitation and examination of the patient's state of health or health problem and other measures in accordance with the patient's plan; (3) tasks in support of the delivery of health services; (4) tasks related to evaluating, supplying and advising on the use of medicinal products; (5) tasks of patient management.

Article 4 of the Access Regulation further classifies the services to be taken into account in the access rights of health professionals and other persons processing medical data as follows: (1) healthcare reception services; (2) hospital and inpatient services; (3) occupational health services; (4) oral health care services; (5) home care; (6) mental health care, substance abuse and addiction services; (7) emergency care and standby services; (8) advisory services; (9) student care services; (10) rehabilitation services; (11) health services provided in the context of a social service; (12) research and intervention services; (13) screening and vaccination services; (14) pharmaceutical services provided by a hospital.

Section 8 of the Access Regulation determines access to medical records in the context of the work of evaluating, supplying and advising on the use of medicinal products. As part of the task of assessing and advising on the use of medicinal products, healthcare reception services, hospital and inpatient care services, home care, mental health care, substance abuse and addiction care services, emergency care and emergency care services and hospital pharmacy services, in addition to the patient's basic data, shall have access to the patient summary. The patient summary includes information such as diagnoses, medication, risk information such as allergies, drug allergies and body-mounted devices, and procedures. In the case of the pharmacy services of a hospital referred to in Article 4, access to the medication records of the Reception Centre, in addition to the patient's basic data, is available in the context of a work assignment relating to the supply of medicinal products.

For tasks where the pharmacy does not process medical data but the data contains personal data, the EU Data Protection Regulation (GDPR) applies. In addition, the pharmacy must take into account other regulations governing information management and archiving, such as the Medicines Act and the Drug Act (373/2008).

Including pharmacy health service: in the case of a health service provided in conjunction with a processing patient information and the Customer Information Act applies. The pharmacy then acts as a private service provider in accordance with the law governing it, not in its statutory capacity (see section on services provided in a pharmacy in this government bill).

The National Institute for Health and Welfare acts as the national authority that steers, defines, monitors and develops information management and related information system services for health and social care. In the case of pharmacies, the tasks of the THL concern systems processing medical data. To the extent that the data processed in pharmacy systems are not classified as patient data, there are no national definitions of the requirements related to the systems and there is no guidance on data management to further specify general data protection and security and operational legislation.

Assessment of the status quo

Processing and recording of medical data in the context of pharmacy tasks

The objective of medical advice and guidance and the development of pharmaceutical services in pharmacies is to improve the management of patient-specific drug treatment packages, avoid risks to medication safety, increase adherence to treatment and support other healthcare activities (STM 15/2018, STM 5/2019, STM 9/2025). Advice and guidance from a pharmacist in a pharmacy on monitoring the delivery of medication, identifying problems and supporting adherence to treatment is quite feasible with currently available information (e.g. prescription centre medication data, delivery intervals in pharmacy systems) and in discussion with the client. However, in the case of healthcare activities comparable to those of a pharmacy, pharmacy professionals have access to more complete medical records. The medication information available in the pharmacy will expand as Kanta becomes available in 2027.

Pharmacological practices are developing rapidly and, increasingly, the prescriber has been able to prescribe a medicinal product for off-label use on the basis of medical judgement. For example, in such situations, it is important that advice and guidance in the pharmacy can be given on the basis of the right premise. This would require information on the intended use of the medicinal product and the objective of the treatment. The domestic study highlighted the role of the pharmacy in risk management and guidance and advice on medication. According to the study, strengthening the role of pharmacies and improving cooperation and the flow of information between hospitals and pharmacies is crucial to achieving better treatment

outcomes (K.Kvarnström, H.Tallqvist, and A.- R.Holmström, ‘From Hospital to Home: Patient Experiences With Medication Counselling for Colorectal Cancer,’ Basic & Clinical Pharmacology & Toxicology138, no. 1 (2026): e70180).

Based on their duties, the pharmacists of the pharmacy would need to make greater use of their medical records for the purposes of dispensing medicinal products and guiding and advising on medical treatment. Expanding access to information in the pharmacy would make it possible to strengthen the role of pharmacies in healthcare in the success and support of medical treatments, in line with the rapidly evolving role of pharmacy professionals within healthcare (Schepel, Lotta et al. Evolution of hospital clinical pharmacy services in Finland in the period 2017-2022: the third nationwide follow-up survey. EUR J Hosp Pharm. 2025 Aug 21;32(5):413-420. doi: 10.1136/ejhpharm-2024-004312. PMID: 39638349).

The necessary medical records in the pharmacy would continue to be deposited at Kanta’s prescription centre. The labels registered by the pharmacy will expand in phase 3 of the development of pharmacological information management, with the possibility to deposit warning and check labels for medication in a prescription centre (HE xx/2026). The THL Recording Guide should be updated to further guide the record-keeping practices with regard to the signalling of advice and guidance provided in the pharmacy at the time of dispensing the medicine, which would be visible via the Reception Centre to other healthcare providers and to the user of the medicine in Omakana.

The development of pharmacy access rights as described above would implement the governmental programme’s statement that the pharmacy reform recognises the role of pharmacies as part of the healthcare system and the important role of pharmacies in the patient’s successful medical treatment. The pharmacy also needs information from the Patients’ Data Repository when providing a health service under the Supervision Act. However, in those situations, the pharmacy would have access to the patient information system and no legislative changes would be necessary to that extent.

Ensuring smooth running and working in a context of increasing digitalisation and developing knowledge-based government requires stronger national coordination and guidance. In this context, it would be necessary for Fimea to strengthen the governance of pharmacy data management as part of its pharmacy supervision tasks and the monitoring of pharmacy activities. The supervision of Fimea to ensure the security, data protection and interoperability of solutions would be necessary in areas of pharmacy activity that would not fall within the remit of the THL.

Health service provided in connection with a pharmacy

A pharmacy would need information from the Patient Information Reserve in a situation where a health service is provided in the pharmacy in accordance with the Supervision Act. Soteri registration would require the delivery of a medicine, with guidance and advice, for a wider range of competency-based services for pharmacists, such as medication assessments. In addition, other health professionals may work in a pharmacy and the provision of services based on their knowledge requires the registration of health services in accordance with the Supervision Act. The necessary entries in the medical records would be stored in the Patient Data Repository or the prescription centre. For example, by pharmacists in pharmacies, the entries in the medication assessment would be recorded as a signal and check at the Kanta prescription centre, as proposed in Government bill xx/2026. The THL Booking Guide should also be updated in this situation to further guide bookkeeping practices also in the pharmacy. The provision of health care services by a pharmacy would constitute work for the provision of limited health services within the meaning of Article 3 of the Concessions Decree. As regards the management of information, the pharmacy would comply with the Client Information Act

and the decrees and orders issued on the basis thereof.

When providing a health service, the pharmacy would have access to a patient information system for the exploitation and recording of the data, unless the nature of the service would be such that the exception for manual recording provided for in Section 67 of the Client Information Act would apply. Therefore, the management of information relating to the provision of a service requiring the registration of health services under the Supervision Act does not require any legislative changes in the situation where the service is provided in a pharmacy.

2.3 Pharmacy licensing system and annual assessment of pharmacy activities

Current status

Authorisation to operate a pharmacy

According to Section 40 of the Medicines Act, a pharmacy establishment may be operated with the authorisation of the Finnish Medicines Agency (Fimea). Under that provision, a licence to operate a pharmacy is granted for the operation of a particular pharmacy in a municipality or part thereof. A pharmacist is defined in Section 38 of the Medicines Act as a person authorised to operate a pharmacy. Section 41 of the Medicines Act regulates the area in which a pharmacy is located, the change of the area in which a pharmacy is located and the transfer of a pharmacy if the availability of medicinal products so requires or is necessary to ensure adequate pharmacy services. In assessing the availability of medicinal products and the adequacy of pharmaceutical services, account shall be taken at least of the number of inhabitants and the population served, the pharmaceutical services already existing in the area and other social and healthcare services. Pharmacies must, pursuant to Paragraph 39, be established within the country so that, wherever possible, the population has access to medicines without difficulty.

In accordance with the Medicines Act, Fimea decides to open a pharmacy, publishes a new or open pharmacy licence and, on the basis of an overall assessment, selects a pharmacist from among the applicants. Fimea publishes a new or open pharmacy licence by publishing a notice on the Centre’s website, indicating the location of the pharmacy, the conditions attached to the licence and the size of the pharmacy’s sales of medicinal products.

In order to assess the pharmacy services in the area, Fimea may ask the municipality to assess the functioning, location and adequacy of the pharmacy services in the area. The municipality may make a proposal to Fimea to open a pharmacy and branch pharmacy, to change the location of the pharmacy and branch pharmacy or to transfer the pharmacy and branch pharmacy. Fimea must also consult the municipality if it makes changes to the authorisation of a pharmacy located in the municipality’s territory (Section 41 of the Medicines Act). Since the beginning of 2023, when responsibility for the organisation of social and health services shifted from municipalities to the wellbeing services counties, the City of Helsinki and HUS Group, Fimea has sent the wellbeing services counties for information the changes affecting the network of pharmacies in its territory. If, after 2023, Fimea had been dealing with matters relating to the establishment or location of pharmacies in Helsinki or Åland had also approached the City of Helsinki, HUS Group and Ålands hälso- och sjukvård, the public authority responsible for the organisation of primary and secondary care in the Province of Åland and its municipalities, as well as the municipalities in Åland.

A pharmacy may have separate branches, i.e. branch pharmacies, which, under Section 52 of the Medicines Act, Fimea may establish on the initiative of a municipality, an association of municipalities or a pharmacist or on its own initiative. The establishment of a branch pharmacy is subject to the condition that pharmacy services are required in the area in order to ensure the

availability of medicinal products and that there is insufficient capacity for an independent pharmacy. There are two types of branch pharmacy: branch pharmacies entitled to operate as a pharmacist and branch pharmacies subject to a licence to operate as a pharmacy. Branch pharmacies are, in principle, entitled unless Fimea has made the operation of a branch pharmacy subject to authorisation in order to ensure the availability of medicinal products. The operation of a branch pharmacy involves tax treatment under Section 7 of the Pharmacy Tax Act (770/2016). Under that section, a pharmacist may deduct from the basis of assessment of the pharmacy tax EUR 12500 per calendar month in the case of a branch pharmacy subject to deduction and EUR 4167 per calendar month in the case of a qualified branch pharmacy. In total, there are 157 branch pharmacies in private pharmacies, of which 61 are entitled and 96 are conditioned. In addition, the University of Helsinki's pharmacy has 16 branch pharmacies with rights (information from Fimea of 16 March 2026).

The Law on Medicinal Products limits the number of branch pharmacies per main pharmacy of private pharmacies. A pharmacist may be authorised to operate up to three branch pharmacies. Fimea decides on the location of the branch pharmacy, which may be amended, if necessary, on the initiative of the Centre itself or of the municipality, the association of municipalities or the holder of the branch pharmacy licence, in order to ensure the availability of medicinal products.

An independent pharmacy may, under the conditions laid down in Paragraph 53 of the Law on medicinal products, be transformed into a branch pharmacy and, under the conditions laid down in Paragraph 54, a branch pharmacy may be transformed into a pharmacy by decision of Fimea. A pharmacy may be transformed into a branch pharmacy when the pharmacy licence has become open. After the pharmacy has been transformed into a branch pharmacy, the open branch pharmacy licence may either be published or the branch pharmacy may be attached as a condition of the pharmacy licence. If the operation of a branch pharmacy is a condition for authorisation to operate a pharmacy, the matter shall be dealt with together with the authorisation to operate a pharmacy. A branch pharmacy which is a condition for authorisation to operate a pharmacy shall be announced and applied for as part of the authorisation to operate a pharmacy. If the operation of a branch pharmacy is a right, Fimea may advertise it separately and, pursuant to Paragraph 52 of the Law on medicinal products, Fimea grants a branch pharmacy licence from several applicants to the pharmacist who is best placed to operate the branch pharmacy, taking into account the location of the pharmacy, the other operating conditions and, in the case of a new branch pharmacy licence, the plans for the organisation of the branch pharmacy business. A branch pharmacy may also be transformed into an independent pharmacy if it has sufficient facilities. Pursuant to Paragraph 54 of the Law on medicinal products, Fimea may, at the request of a pharmacist who operates a branch pharmacy, grant him a pharmacy licence from a pharmacy which previously operated as a branch pharmacy, without making a separate application. Under Section 52c of the Medicines Act, a branch pharmacy must have a manager appointed by a pharmacist, who must be a licensed pharmacist or pharmacist. However, the operator of a branch pharmacy of the University of Helsinki must be a qualified pharmacist. The operator of the branch pharmacy must be notified to the Finnish Medicines Agency. The pharmacist is obliged to inspect the branch pharmacy annually and the operator of the University of Helsinki pharmacy must inspect the university branch pharmacy accordingly. The opening hours of the branch pharmacy and the range of medicinal products must correspond to local pharmaceutical needs.

The activities of a pharmacy establishment include, in addition to the branch pharmacy described above, the operation of a pharmacy's online services. A pharmacy's online service is defined in the Medicines Act as the sale of medicinal products on the basis of an order placed by a customer via the internet. Section 52b of the Medicines Act describes the general conditions for providing and maintaining a pharmacy's online service. The pharmacy's online

service can be provided by a pharmacist, the University of Helsinki's pharmacy and the University of Eastern Finland's pharmacy. The operator of the service must have a website offering medicinal products for sale at a distance. The website should contain a link to the list of legal online pharmacy services maintained by FIMEA and a clearly visible European common logo for online pharmacy services in the European Union. The sale through the pharmacy's online service is a remote service. In the current state, unlike a pharmacy, the holder of a retail licence for non-prescription medicinal products is not allowed to sell a limited range of non-prescription medicinal products remotely.

The pharmacist, the pharmacy of the University of Helsinki and the pharmacy of the University of Eastern Finland are responsible for operating and operating the online pharmacy service. The operation of the pharmacy's online service is subject to prior notification to Fimea. The prior notification shall be accompanied by a plan on how to organise the provision of advice on medicinal products. Start-up, closure and material changes must be notified to Fimea. Fimea may prohibit the start of operations or order the termination of the online service if the pharmacy's online service does not meet the quality standards required by the Medicines Act.

In addition, the pharmacy may maintain collection clubs in accordance with Paragraph 57e of the Law on medicinal products, which must be located in the area in which the pharmacy is located. The swab must be suitable for the proper and safe storage and warehousing of medicinal products.

Annual assessment of pharmacy activities

According to Section 2 of the Act on the Finnish Medicines Agency (593/2009), Fimea's task is to improve the functioning and safety of the pharmaceutical sector, pharmacy and other pharmaceutical services. As part of that task, Fimean is required, under Article 58 of the Law on medicinal products, to submit annually to the Ministry of Social Affairs and Health information on the pharmacy's margin and other aspects of the pharmaceutical tariff. In practice, Fimea has provided the information referred to in Section 58 of the Medicines Act as part of the annual pharmacy accounts analysis published annually. The financial statement analysis contains information on, inter alia, the pharmacy network, sales of pharmaceutical products by pharmacies, profitability and other business activities carried out in connection with pharmacies.

The objective of the financial statement analysis is to describe the activities of pharmacies and their financial situation over a four-year period. The analysis is based on the financial data reported by the pharmacies to Fimea, which are collected in the spring of the year preceding the publication of the financial statement analysis, following the completion of the financial statements of the pharmacies and their associated companies. Pharmacies are under an obligation to provide information under Section 89 of the Medicines Act, according to which a pharmacist, the University of Helsinki's pharmacy and the University of Eastern Finland's pharmacy must provide the Finnish Medicines Agency with the information on pharmacy activities and other business activities carried out in the same premises as the pharmacy, necessary for the development, planning and supervision of the pharmacy, the imposition of a quality control fee and the compilation of statistics. In addition, under Article 89 of the Law on medicinal products, pharmacies must, on request, provide Fimea, free of charge and without prejudice to the provisions on confidentiality, with the information and explanations relating to the import, manufacture, inspection, distribution, sale or other release for consumption of medicinal products which are necessary for the performance of the tasks assigned to the Centre.

Assessment of the status quo

Authorisation to operate a pharmacy

The current pharmacy licensing system has been in place in Finland for a long time and, in the light of Section 18 of the Constitution on the freedom to conduct a business, the system is rare in Finland compared to other sectors. At the heart of the pharmacy licensing system is that the pharmacist has personal responsibility for the operation and operating conditions of the pharmacy, both financially and professionally, and is responsible for meeting the requirements of the Medicines Act in relation to the operation of the pharmacy. In accordance with the government programme, no changes are proposed to the pharmacy ownership.

The number of out-patient pharmacies in Finland has increased moderately in the 2000s. For example, at the end of 2002, there were almost 600 main pharmacies and 200 branch pharmacies in Finland, while in March 2026 there were 648 main private pharmacies and two university pharmacies in Finland. In addition to 157 branch pharmacies belonging to private pharmacies, there were 16 branch pharmacies belonging to the University of Helsinki pharmacy. In addition, 110 pharmacy outlets were available and 199 pharmacies offered distance sales of medicinal products (Analysis of pharmacy accounts 2020-2023). Fimea will develop and inform 1/2025, 17.3.2026 Updated by Fimea). The availability of pharmacy services and the density of the pharmacy network vary regionally. In 2025, Finland had around 6800 inhabitants per pharmacy branch (including main and branch pharmacies). However, Finland does not require a minimum population for the allocation of new pharmacy numbers, but pharmacies are often established where the most significant regional centres of population are located (Competitiveness and Consumer Authority: Development of the pharmacy market. Finnish Competition and Consumer Authority, 5/2020). In terms of population, South Savo had the highest number of pharmacies at the end of 2025, with more than 4100 inhabitants per pharmacy branch. The lowest ratio of pharmacies to population was found in Uusimaa, with more than 10000 inhabitants per pharmacy branch. The branch pharmacy system is intended to safeguard the location of medicinal products in areas where there are no conditions for the main pharmacy. The establishment of new pharmacies and branch pharmacies on the basis of an economic needs test means that the number and, to some extent, the location of pharmacies is a matter for the public authority to decide.

As regards the evaluation of the pharmacy network and the preparation of decisions related to pharmacy licences, the current legislation does not take into account the wellbeing services counties that started operating in 2023, the City of Helsinki and the HUS Group, which replaced municipalities in their task of organising social and health services and coordinating services in the region. On the other hand, there were no changes in the responsibility for the organisation of services in Åland. It would be appropriate to identify the organiser of social and health services as a key actor when it comes to assessing the need for pharmacy services in their territory, as the task of organising pharmacy care is part of the task of organising social and health services and pharmacies are a key part of the pharmacy process of outpatient pharmacy care. Integrating social and health care providers into the preparation of FIMEA’s decisions on pharmacy licences would not be a new task for the regions, but would be in line with the principles of the changes introduced by the so-called SOTE100 legislative package.

In line with Prime Minister Orpo’s government programme, pharmacy regulation is being reformed responsibly and gradually, ensuring high-quality and safe pharmacy services throughout Finland. The first phase of the reform was implemented for the pharmaceutical economy from the beginning of 2026 (HE 111/2025 vp). In view of the changes made to the pharmacy tax, it is necessary to clarify the rules governing branch pharmacies.

Under the legislation in force, a branch pharmacy may be made subject to a pharmacy licence only if the pharmacy licence is open. Conditions cannot be added to the pharmacy licence issued ex post, which limits the authority's ability to react to regional changes in the need for pharmacy services. The regulation of conditional branch pharmacies was created in 2010 and there are currently a number of branch pharmacies which have previously been granted the right to operate as a branch pharmacy, even if they are designated as conditional branch pharmacies under the current Medicines Act. The authority should have the possibility to make the licensing of a pharmacy conditional on the existence of a branch pharmacy, where this is justified by the need to ensure adequate access to medicinal products for the population in the region. However, the procedure should take account of the fact that, from the pharmacist's point of view, the conversion of a qualified branch pharmacy into a condition would mean that the closure of the branch would no longer be merely a notification procedure and would therefore entail a greater financial risk for the pharmacist. An application procedure initiated by a pharmacist makes it possible to secure self-employment from the pharmacist's point of view in an appropriate manner and would not give the impression that the new obligations are an obligation imposed by the public authority.

It would be necessary, in the event that the holder of a pharmacy licence renounces the pharmacy licence and Fimea turns the pharmacy into a branch pharmacy or the pharmacist renounces a qualified branch pharmacy which Fimea considers to be important for the supply of medicinal products to the population of the region, to make the authorisation of a branch pharmacy subject to the publicity procedure. It should be possible for a branch pharmacy to be included as a condition for authorisation to operate a pharmacy by means of a public announcement procedure which would allow interested parties to express their willingness to make the branch a condition for authorisation to operate a pharmacy in their possession. It should also be noted that a subsidiary pharmacy subject to an amendment to the Pharmacy Tax Act, which entered into force at the beginning of 2026, entitles it to a higher deduction from pharmacy tax than a subsidiary pharmacy entitled to it. For this reason, pharmacies have an economic incentive to operate a conditional branch pharmacy.

As part of the development of online pharmacy activities, the need to assess the possibility for a pharmacy to locate a collection club outside the area where the pharmacy is located has emerged. In digital services, the pharmacy's customer base can be located anywhere in the country and opportunities for cross-border e-commerce are also being developed in cooperation between EU countries. In view of the nature of access to the digital service and the qualitative conditions of the service relating to the collection club of a pharmacy under Section 57e of the Medicines Act, it would not be necessary in the future to restrict the pharmacy's right to set up collection clubs to the areas it considers necessary. In addition to the supply of online pharmacies, the collection club may also be used for the supply of uncollected medicinal products, for example in a situation where the medicinal product was not available at the pharmacy at the time of the transaction and remained unsolicited. The regulation of the location of the collection club in the pharmacy was based on the location of the pharmacy in order to enable the pharmacist effectively to ascertain the proper functioning of the collection clubs. However, the regulation has not identified, for example, situations where a pharmacy is located close to the municipal border and could then serve the inhabitants of several municipalities. Amendments to the Medicines Act would be proposed on the basis of the premise that in future consideration of the proper functioning of collection clubs would be left to the pharmacy, not ex ante in legislation.

Annual assessment of pharmacy activities

There is currently no comprehensive monitoring and evaluation of pharmacy activities. The wellbeing services counties have started operating in 2023 and are responsible for

pharmaceutical treatment on their territory. The wellbeing services counties should cooperate on a number of issues related to pharmaceutical treatment and pharmacies, depending on the areas of cooperation and with national authorities. Cooperation between the wellbeing services counties and the national pharmaceutical authority is still unstructured. Fimea produces and publishes on its website information on pharmacy services such as availability, drug use and shortages, drug advice, pharmacy switching and pharmacy finances. However, there is still work to be done on the regional use of data. Fimea's annual financial analysis compiles, inter alia, the financial data, number and opening hours of pharmacies, but at present it does not systematically take into account the performance of pharmacy activities, for example in relation to pharmacy services, from the point of view of the population in the region or from the point of view of social and health services.

For social and health services other than pharmacies, according to Section 29 of the Act on the Organisation of Services, the service provider must monitor the well-being and health of the population in its area by population group, the need, availability, quality, effectiveness and equity of the social and health care it organises, the coordination of customer services, the costs and productivity of social and health care, and matters relating to staffing and use. The wellbeing services county shall compare the monitoring data with similar data from other wellbeing services counties. The National Institute for Health and Welfare produces comparative data at national level. Furthermore, according to Section 30 of the Organising Act, the National Institute for Health and Welfare is responsible for assessing annually the organisation of services by wellbeing services counties at national level, by cooperation area and by wellbeing services counties. The THL will carry out an assessment against the national targets and policy recommendations addressed to the wellbeing services counties. The assessments look, among other things, at the service needs of the population, the service system of the wellbeing services counties and the economy by service package.

With regard to pharmacy activities, it would be appropriate, in the course of development, to seek a similar estimate, in which Fimea would compile comprehensive information on pharmacy services and the economy, publish an annual estimate of pharmacy services and the economy instead of an accounting analysis, and provide the wellbeing services counties with the necessary national and regional information on pharmacy activities. Currently, the knowledge base compiled by Fimea does not allow for the evaluation of pharmaceutical services, for example on the following key themes: regional service needs, availability, quality (including medication safety, security of supply), effectiveness and equity, customer service experience, service production costs and productivity, and staffing and usage issues. Fimea has launched a project to improve the collection of data on the activities and finances of pharmacies, with a view to gradually achieving the above-mentioned objectives. In order to improve the annual evaluation of pharmacy activities, it would be appropriate to amend the Medicines Act to support the development work in Fimea. The evaluation of pharmacy activities and the knowledge base needed for it should be developed in a step-by-step, long-term and systematic manner. In parallel to these developments, a further review of the legislation may be necessary at a later stage.

2.4 Qualitative and functional requirements for the operation of pharmacies

Current status

The Medicines Act imposes qualitative and functional requirements on pharmacy operations. Under Paragraph 55 of the Law on medicinal products, a pharmacy and a branch pharmacy must hold in stock a quantity of medicinal products corresponding to the average need of its usual customer population of at least two weeks, together with the equipment and supplies necessary for the use of the medicinal products and the need for bandages. The pharmacy and

the branch pharmacy must also stock the cheapest medicines. In order to ensure the availability of medicinal products, the pharmacy and branch pharmacy shall be kept open in such a way that customers can easily obtain their medicinal products. The Law on Medicinal Products also contains requirements regarding the quality of medicinal products and to ensure that they are released for consumption with sufficient expertise and that the pharmacy's premises are adequate. For his part, the pharmacist must ensure that the medicinal products supplied from the pharmacy, the branch pharmacy, the pharmacy's outlet and the pharmacy's online service are of sound quality and that the sale or release for consumption of the medicinal product is duly authorised. Under Paragraph 56 of the Law on medicinal products, a pharmacy and a branch pharmacy must have a sufficient number of qualified pharmacists. The pharmacist must ensure that all the staff of the pharmacy are adequately involved in further training. The pharmacy, the branch pharmacy, the pharmacy service and the premises used for the pharmacy's online service must be suitable for the sale and storage of medicinal products. The facilities used for the preparation and examination of medicinal products must be suitable and equipped for that purpose. Article 15 of the Decree on medicinal products lays down more detailed requirements for farms. The pharmacist must take appropriate measures to prevent unauthorised persons from having access to the premises of the pharmacy.

The high-quality provision of pharmaceutical services also requires that the necessary documentation be provided so that the activity can be traced where necessary. The documentation is provided for in Section 57a of the Medicines Act, according to which a list of prescriptions must be kept in a pharmacy and a branch pharmacy each calendar year. That list shall include information on the medicinal product supplied and its quantity, the user of the medicinal product or the establishment for which the medicinal product is prescribed and the prescriber. The transfer of a pharmacy to another pharmacist requires specific regulation, which safeguards continuity of services and the rights of data subjects. As regards document management, Article 46 of the Law on Medicinal Products provides that, in the event of the transfer of a pharmacy to another pharmacist, all documents held in accordance with the law and regulations are to be handed over free of charge to the new pharmacist. Fimea's regulations on dispensing the medicine and operating online pharmacies also impose documentation requirements.

In order to guarantee the quality of pharmaceutical services, the Medicines Act also regulates service channels other than the operation of the main pharmacy. Under Paragraph 52 of the Law on medicinal products, a branch pharmacy must have a manager appointed by a pharmacist. Each year, the pharmacist must inspect the branch pharmacy and the operator of the University of Helsinki's pharmacy must inspect the university's branch pharmacies. Article 20 of the Decree on Medicinal Products specifies the requirement, provided that the pharmacist or the qualified pharmacist appointed by him must inspect the branch pharmacy and the pharmacy's outlet at least once a year. A record of the inspection shall be kept. In addition, a pharmacist must inspect an online pharmacy every year. The pharmacy's service channels, in particular the online service and the use of the pick-up club, are also characterised by specific considerations relating to the transport and storage of medicinal products. The pharmacist must ensure proper storage and transport conditions for medicinal products supplied through the pharmacy's online service. In accordance with Paragraph 57a of the Law on medicinal products, the collection club must be suitable for the proper and safe storage and warehousing of medicinal products. The pharmacist is responsible for the proper functioning of the collection club. The pharmacist is responsible for the proper transport conditions and storage of the medicinal products in the collection club until the customer collects the medicinal product from the collection club.

Under Paragraph 58a of the Law on medicinal products, the sale of products other than medicinal products or the provision of services in a pharmacy, a branch pharmacy or a

pharmacy outlet must not impede the supply of medicinal products or the provision of advice on medicinal products. Fimea's regulations on the dispensing of medicinal products (2/2016), the online pharmacy service (2/2011), the notification of defects and suspected falsified medicinal products (2/2019) and the dispensing of medicinal products on the basis of a European prescription (1/2020) also set qualitative and functional requirements for pharmacy operations. The requirements concern, inter alia, the provision of advice on medicinal products, storage and transport conditions, outsourcing of activities, handling of product defects, premises, the range of medicinal products, the performance and documentation of inspections under the responsibility of a pharmacist. In addition, Fimea has issued guidance letters on pharmacy activities, including reporting information system incidents and information security incidents, ensuring critical functions for the safety of medicines and medication in the pharmacy, implementing pharmacy substitution, and the range of medicinal products used for mechanised dispensing.

Assessment of the status quo

Legislation and regulations set quality standards for pharmacy operations. However, the Law on medicinal products does not lay down general principles for ensuring the quality of pharmaceutical activity. Compared to the conditions for the provision of social and health services, the Supervision Act sets out the conditions for service providers and activities. These set out the main principles regarding premises, operating environment, equipment and information systems (Article 8). As part of the conditions, a position is also taken on staff (Article 9) and on the quality conditions of the service and responsibility for the quality of the service (Article 10).

A key element in improving the quality of social and healthcare services and customer and patient safety is risk analysis, monitoring processes and structures, and learning from incidents. Self-monitoring is carried out to ensure the quality of services and patient safety in health and social care institutions. At the heart of self-monitoring is the self-responsibility of the service provider for the proper functioning of the service and the quality of the services it provides, as well as customer and patient safety. Provisions on self-monitoring of social welfare and health care are laid down in Chapter 4 of the Supervision Act. The whole consists of self-monitoring by the service provider (Articles 23-26) and self-monitoring by the producer (Article 27). One element of self-monitoring is incident reporting and learning procedures. Self-monitoring can play a very important role in the daily life of operators and, for example, operating devices can play a key role in ensuring patient safety (Incident Investigation Centre: Delay in detecting patient non-viability due to telemetry malfunction, 23 October 2024, T2024-01. Under Article 29 of the regulation on self-monitoring, the service provider must immediately inform the service provider and the supervisory authority of any defects in the service provider's own operations or those of its subcontractor which are likely to endanger the safety of customers and patients, or of any incident, accident or incident which has seriously jeopardised the safety of customers and patients, and of any other defect which the service provider has been unable or is unable to remedy by self-monitoring.

In the regulation of pharmacies, self-monitoring is not used as a concept, but internal controls are identified instead. Pharmacies must operate in accordance with the Customer Information Act, which provides, inter alia, for self-monitoring of data security and data protection. In addition, Fimea has instructed pharmacies to draw up terms of reference and to carry out inspections of the pharmacy's core activities in order to ensure the quality and safety of the service. In these cases, however, there has been a lack of regulation at the level of the law and action has been based on the Fimea Order. In its investigation T2023-01, the Safety Investigation Authority recommended Fimea to ensure that self-monitoring by pharmacies is developed in order to promote medication safety.

According to the prescribing regulation (1088/2010), the health and social care unit must have a method for monitoring prescriptions and reporting and handling medication errors. According to the travaux préparatoires for the Regulation, such a method can both remedy potential problems and provide feedback on the quality of the activity. The purpose of the Regulation is to ensure that monitoring is carried out both at patient level and at regional level. A diary of prescriptions should be kept in the pharmacy, but there is no broader obligation in the Medicines Act to monitor the performance of tasks or deviations. On the other hand, Fimea's order to supply medicinal products requires that any discrepancies in supply be documented and handled in a pharmacy in accordance with the pharmacy's instructions. In addition, Fimea has issued a guidance letter to pharmacies to ensure critical functions for the safety of medicines and medication (FIMEA/2024/002625). In the guidance letter, Fimea requires that deviations be handled immediately in such a way as to minimise potential harm. In addition, the reasons that led to the incident shall be assessed and, where necessary, the function and the instructions shall be amended to prevent similar incidents. Deviations are dealt with in a documented manner in a pharmacy. Near misses are also dealt with in a documented manner. In these situations, any deviation has been detected and corrected before it causes harm. Dealing with near misses provides important information on vulnerabilities to incidents and can lead to proactive policy development. Fimea recommends that medication errors and near misses be reported to the available national incident reporting systems. The use of a national system makes it possible to monitor incidents and identify risks in a comprehensive manner and to take these into account when developing activities.

In some regions, pharmacies and social services have had the opportunity to send each other notifications about incidents they detect and to monitor the progress of their notifications in another service. Hazardous event means an event that endangers the safety of a patient and causes or may cause harm to the patient (Stakes and Centre for the Development of Medicine Care Rohto: Patient and medication safety vocabulary. Working papers 28/2006, available at https://urn.fi/URN:NBN:fi-fe201204193972). Pharmacies have reported prescribing deviations to the STE units, such as incorrect dosage instructions, missing prescriptions and many valid prescriptions for different strengths. In addition, pharmacies have observed anomalies in areas such as up-to-date information on medication, information flows and information systems. The notifications reported by pharmacies have been saved by the Finnish Association of Pharmacists (SAL). In the social and healthcare sector, notifications are stored for each wellbeing services county.

A single reporting repository is a key source of information to identify hidden weaknesses in processes and structures and to develop risk management tools. For example, in the HUS group, medication safety work based on research and analysis of reported anomalies has been long-term. Progress has been made in reducing drug allocation and administration anomalies and, most recently, development is focused on the systematic prevention of drug prescribing anomalies (Kallio MM, kupu-Huhtala A, Kvarnström K, et al. Effects of pharmacist-conducted Medication order verification in a hospital setting: a systematic review European Journal of Hospital Pharmacy Published Online First: 18 March 2026. doi: 10.1136/ejhpharm-2025-004825).

Some service providers have published medication safety data sheets to prevent adverse events in social care, healthcare and pharmacies. A number of medication safety data sheets, reports and publications have also been produced to support the development of activities, based on the pharmacy notification material compiled by the Finnish Pharmacy Association (available at: https://valo.apteekki.fi/tutkimus-ja-kehittäminen/julkaisut-ja-raportit/). The Association of Pharmacists in Finland has produced medication safety data sheets on, among other things, the supply of a medicinal product classified as a narcotic drug and dealing with a situation in which a prescription has been issued to a wrong person. The latest research publication

concerns self-medicinal products, according to which pharmaceutical advice provided by pharmacies plays a key role in ensuring the safety of self-medication. According to the study, the majority of incidents involving self-medication, i.e. 69 %, were related to the customer's own activities. However, 80 % of these were near misses, where advice from pharmacy staff prevented the mistake from proceeding (University of Eastern Finland, available at: https://www.uef.fi/fi/artikkeli/apteekkien-neuvonta-estaa-suurimman-osan- for self-administration vigilance incidents).

In order to ensure the continuous development of pharmacy operations and the safety of medication, incidents (client and near misses) in pharmacies should also be fully reported. Situations reported in the pharmacy should be addressed and necessary corrective or development measures taken. In order to ensure continuous self-development in all pharmacies, the Medicines Act should require the pharmacy to have a system for reporting medication incidents. In addition, the pharmacy should have procedures for handling and learning events to the extent required.

In the longer term, it might be appropriate for the incident reports reported by pharmacies to be compiled at national level for the pharmacy service, similar to those compiled by the social services providers. In addition, it would be important for pharmacies and social services providers to be able to report to each other. These would require an assessment of the responsibilities of the authorities and a national notification system. The Customer and Patient Safety Centre shall draw up an overall plan and roadmap for the development of national data production on adverse and incident events. A mapping exercise is also underway to identify the needs for the development of guidance for medical treatment and care.

2.5 Online services

Current status

The distance marketing of medicinal products within the European Union is governed by Directive 2001/83/EC of the European Parliament and of the Council on the Community code relating to medicinal products for human use, the provisions of Article 85c of which are implemented at national level in the Medicines Act. According to Section 52b of the Medicines Act, pharmacists, the pharmacy of the University of Helsinki and the pharmacy of the University of Eastern Finland may also provide the services of a pharmacy through an online service. Section 38 of the Medicines Act defines a pharmacy's online service as the sale of medicinal products on the basis of an order placed by a customer via the internet. The provisions on the pharmacy's online service also apply to the sale of medicinal products by other means of distance communication. Under Section 54f of the Medicines Act, which will enter into force in 2027, certain non-prescription medicinal products may also be sold by operators other than pharmacies on the basis of a retail licence for non-prescription medicinal products. However, it is not possible for those operators to sell medicinal products online.

The pharmacy's online service allows the dispensing of self-care and prescription-only medicines. Under Section 52b of the Medicines Act, prescription-only medicinal products may be dispensed from a pharmacy's online service only on the basis of an electronic prescription in accordance with the Medicines Act. Under that section, Fimea may issue orders concerning, inter alia, the supply of medicinal products by means of an online service, the packaging and checking of consignments of medicinal products and the selection of medicinal products.

The range of the pharmacy's online service should be sufficient, taking into account the different therapeutic groups, and the cheapest medicinal products available should also be available. The product information provided on the web service must comply with the provisions of the Medicines Act on the marketing of medicinal products. Order 2/2011 of

Fimea on the online services of pharmacies excludes medicinal products that are subject to a medical prescription and, in addition, medicinal products that mainly affect the central nervous system may be supplied only in the smallest pack size. Under Paragraph 58 of the Law on medicinal products, the price of a medicinal product for self-care must be the same for all pharmacy establishments and online services.

In accordance with Section 52b of the Medicines Act, the maintenance of a pharmacy's online service is subject to prior notification to the Finnish Medicines Agency. In addition, the Authority shall be informed of the commencement, cessation and material changes of operations. The section also imposes a number of obligations on pharmacists in relation to the pharmacy's online service. In particular, the pharmacist is responsible for operating the pharmacy's online service and managing the online service. Online service activities may be carried out only in premises managed exclusively by a pharmacy or pharmacist.

The pharmacist must check the pharmacy's online service on an annual basis. The pharmacist must ensure proper storage and transport conditions for medicinal products supplied through the pharmacy's online service. Fimea's order on the pharmacy's online service states that the pharmacist is responsible for the proper transport conditions and storage of the medicinal products in the take-away disc until the customer collects the medicinal product from the take-away disc under Paragraph 57e of the Law on medicinal products. In the case of transport of medicinal products, care must be taken not only to preserve the quality of the product but also to ensure that, during transport, sensitive medication information cannot be accessed by third parties. The pharmacy must also package the medicinal product in such a way that it is not apparent from the packaging that it contains the medicinal product. The packaging must be visible if it has been opened during transport. In addition, the pharmacy must ensure that the customer receives the medicinal product. The delivery of orders for medicinal products via an online service to a customer may be outsourced by a pharmacy to a transport company which either takes the medicinal product to the customer's home or to a collection point.

The provisions of Chapter 6 of the Consumer Protection Act (38/1978) on distance selling shall apply to the online service activities of a pharmacy. The provisions on the pharmacy's online service also apply to the sale of medicinal products by other means of distance communication. Further provisions on the provision of advice in connection with the use of an online service and on charges to customers for online service activities may be issued by government decree. The Finnish Medicines Agency may issue instructions to pharmacies on the content and making of prior notification, as well as on pharmaceutical advice, packaging and checking of consignments of medicinal products, transport, outsourcing of activities, returns, handling of product defects, information on medicinal products provided on the pharmacy's online service, storage of medicinal products, supply of medicinal products via the online service, premises, technical implementation, selection of medicinal products, management, and performance and documentation of the inspection of the online service activities.

Fimea's web service regulation contains provisions on the technical implementation of the pharmacy's web service activities, the provision of information on medicinal products, the verification of the web service and customer identification when dispensing prescription-only medicinal products. According to the order, the pharmacist must ensure that no third party has access to the customer's data in the online service and must ensure that communications between the customer and the online service and between the online service and the pharmacy are protected. A non-disclosure agreement shall be concluded with the partners involved in the technical implementation, covering all persons involved in the implementation of the web service. The pharmacist is responsible for the technical implementation of the web service, i.e. the processing of data in the web service, the software used and the communication links. The

pharmacist is also responsible for ensuring that the operation of the pharmacy meets the requirements of data protection regulation and is secure.

Assessment of the status quo

In 2024, the total turnover of the online pharmacy service was approximately EUR 44 million. The turnover of the online service of university pharmacies accounted for almost 70 % of total turnover. The online pharmacy service was provided by almost 250 pharmacies at the end of 2024, compared to 199 pharmacies in 2026 (information provided by Fimea on 17 March 2026). The total turnover of the online service of private pharmacies in 2024 was approximately EUR 13.5 million. This averaged EUR 41850 per pharmacy (median EUR 7300 per pharmacy, maximum EUR 1.9 million). On the basis of the turnover per pharmacy, the pharmacy's online activity is, as a rule, small in scale, with the exception of individual larger operators. The change in the number of online service providers in recent years can be explained by the fact that the smallest online pharmacy operators would have left the market. In Finland, online pharmacy activity has not developed into a large scale activity, which may be partly due to the fact that development and marketing require significant investment. However, the expansion of online activities could lead to a number of benefits for medicine users and society. For example, price competition between pharmacies could increase, which, according to studies, is currently moderate (Piira, Jussi). Price competition for non-prescription medicines on the Finnish pharmacy market. Pro gradu thesis. University of Eastern Finland 2024. Available at: https://erepo.uef.fi/server/api/core/bitstreams/6ffbde61-fdd6-40a9-9e11-bd5e98e66a51/ content). The low level of price competition may in part be explained by the fact that it may be difficult for a consumer to compare the prices of products between pharmacies. As online price comparison is substantially easier for the consumer, improving the number of online pharmacies and the conditions under which they operate could improve the consumer's position in pharmacy transactions. Allowing online sales by holders of retail licences for non-prescription medicinal products would also increase price competition for medicinal products.

With the development of online pharmacy activities, the work of pharmacists in a pharmacy could be better geared towards monitoring treatment and solving problems when dispensing a medicine. In order to make this possible in a context of limited resources, it would be appropriate to develop remote pharmacy services as a whole on a long-term basis and to encourage more customers with small health problems and strong resources to deal as independently as possible, for example in an online pharmacy. In general, the key benefits of e-commerce can be seen from a customer's perspective as being time- and place-neutral, as well as the possibility of self-delivery, which, if well implemented, could lead to more online transactions. Well-implemented online activities are smooth and safe for the customer and efficient for the service provider. However, as things stand at present, the regulation of the pharmacy's online activities does not allow, for example, flexible self-medication or independence from time and place in relation to prescription-only medicine. Guidance and advice on medication with digital solutions is also still modest. One of the obstacles is the limitations of the transmission of data related to prescriptions and reimbursements of medicines by national data management services to the online service platform for viewing by the customer. For this reason, in the case of prescription-only administration, the customer and the pharmacist must be at the same time in the process of selecting the medicinal product to be dispensed and in the process of calculating the reimbursement.

There are few restrictions in the Medicines Act and the Decree on how the online pharmacy service is organised in practice. Fimea's regulation of online pharmacy activities, on the other hand, provides strong guidance to operators. The Fimea Order was drawn up in 2011 and since then there has been significant technological progress. In the context of the preparation of the

assessment of the current state of play, several needs for changes to the Fimea Order have been identified in order to enable operators to develop the online service, increase customer orientation and improve the efficiency of service processes. Such development opportunities include, but are not limited to, half-way transactions, strong authentication, checking orders for self-medication and collected medicines, and enabling teleworking. In addition, the impact of the Fimea Order on data management should be assessed. Fimea's prescription restricts the range of medicines that can be supplied through the online service. At present, the customer has to go to a brick-and-mortar pharmacy if the medicinal product he needs has to be classified as a narcotic drug or has to be packed in larger sizes for a medicinal product that mainly affects the central nervous system. This can be particularly challenging for customers who struggle to arrange half-time or face challenges such as going to a pharmacy. A strong identification of the customer at the time of dispensing, the lack of information on the medicinal products contained in the packaging after the product has been packaged, the traceability of the transport and the requirement to identify the recipient of the order would militate in favour of making it possible to supply those products via an online pharmacy. However, as the range may widen, the organisation of transport should be assessed separately and subcontracting, for example, could be restricted for medicines classified as narcotics. Following the adoption of the legislative amendments, the reform of Fimea's ordinance concerning the pharmacy's online service becomes relevant. This work has the potential to significantly streamline the online service and create the conditions for long-term development.

As things stand at present, the pharmacy's online service and other remote transactions are not governed as a whole by the provisions of the Client Information Act or recognised in national guides to digital social services and their development, such as the General Guide to the Development of Digital Social Services (THL 2/2026, available at: https://yhteistyötilat.fi/wiki08/spaces/JULYDSK/overview). The development of remote pharmacy services should be more clearly steered in the future. It is appropriate to regulate pharmacy transactions on stone yards and online on the basis of uniform principles. The regulation of information systems and applications depends on how operators organise the digital service process. In the future, it might be appropriate to allow for different ways of implementation by operators, but to ensure, including through specifications and controls, that all solutions deliver safe medication and transactions, as well as customer rights. Although the applications and operating models of the online service, which are separate from the pharmacy's systems for dispensing medicinal products, are not currently regulated by the Client Information Act, they must comply with the general principles of health data processing and data protection. Particular attention should be paid to the way in which information containing advice on medicinal products, dosage instructions and order and delivery confirmations containing information on medicinal products is provided to the purchaser of the medicinal product. In the course of its supervision, the EDPS has identified shortcomings in the processing of personal data in relation to monitoring technologies used on the e-pharmacy website (Office of the EDPS, Decision of 27 May 2025, available at: https://www.finlex.fi/fi/viranomaiset/tietosuojavaltuutettu/2025/2473). The decisions of the College of Sanctions and the Assistant Supervisor are not final (situation as at 16.4.2026).

When assessing the potential for developing online pharmacy activities, the resources required should be taken into account, e.g. for the provision of advice, in particular in view of the challenges posed by the transfer of information described above. It is unlikely that it would be profitable for a small pharmacy operator to maintain a wide opening of the service online in the event of a low number of orders. Customer acquisition, which requires the expansion of online activities, can also be a significant cost for a small operator. In order to increase online activity, opportunities for cooperation between pharmacies should be assessed. At present, a pharmacy cannot distribute activities related to the online dispensing of a medicinal product to other pharmacies, which can be seen as one of the obstacles to the growth of online pharmacy

activity. In an online pharmacy, the process involves, for example, identifying the customer, giving advice on the medicine, affixing a delivery note to the prescription centre and sending the medicine to the customer. The provision of online services could be improved if more pharmacies could work together to supply the medicine. However, cooperation should ensure the continuity of information between the collaborating entities and that the customer knows which pharmacy is using the service. This may require changes to the labelling of the dispensing of the medicinal product in the prescription centre. On the other hand, there would be no need to allow cooperation in the field of brick-and-mortar pharmacies. If a pharmacy is so small that the resources of the pharmacy are not sufficient to provide all the steps required to supply the medicine, such as advice, the ability of the pharmacy to operate as an independent pharmacy should be assessed instead of allowing cooperation.

Overall, the data management reform package allowing for the development of online pharmacy activities is comprehensive. A step-by-step approach to this work, while ensuring predictability of national development, would be appropriate in order to prepare operators for the development of new business and the investments needed to do so. The package is broader than pharmacies, including commercial providers of information on medicinal products and sales outlets for a limited range of self-care medicinal products.

With regard to data management, the above shall also apply to the development of a limited online service related to the self-medication portfolio and related data management.

2.6 Mechanical dispensing

Current status

In outpatient dispensing refers to the process and service whereby a pharmacy delivers tablet- and capsule-shaped medicines regularly consumed by the customer, packaged as single doses, usually in batches of two weeks. As a general rule, medicinal products are packaged in single doses mechanically. Customers served by a delivery service are often multi-medicated and often live in a nursing home or are in home care. The dosage distribution activity is divided into two groups of services: the packaging of dispensed medicinal products in single-dose bags and the supply of dispensed medicinal products from a pharmacy to customers.

Hospital pharmacies and pharmaceutical centres can deliver patient medicines per dose, machine-packaged, to wards and to public health and social care institutions in their area (e.g. residential care, hospital beds). Hospital pharmacies provide two types of services: (1) unit dose distribution, where a single sachet is dispensed with one dose of a medicine (unit dose) and these unit packs are bundled into patient-specific packs at the time of administration and identified; and (2) multi dose distribution, where a sachet is dispensed with all the medicines of a single patient at the time of administration and the bag is identified, i.e. treated in the same way as an outpatient treatment.

Provisions on dosage distribution in the Medicines Act are limited. Paragraph 12a of the Law on medicinal products lays down the procedure for authorising the distribution of doses by mechanical means in pharmacies and hospital pharmacies and Paragraph 15 lays down the general conditions for the distribution of doses by mechanical means. Under Paragraph 12a of the Law on medicinal products, the mechanical dispensing of doses in a pharmacy and the activity of manufacturing under contract are subject to authorisation by Fimea. Authorisation shall be granted if the activity complies with the requirements laid down in section 15. The authorisation may be subject to conditions concerning the manufacture, supply and use of the medicinal product and other conditions necessary for the safety of medicinal products. Under the second paragraph of that section, a pharmacist may arrange for the automatic dispensing of doses on the basis of a contract in another pharmacy authorised for the automatic dispensing of

doses.

The distribution of doses is also subject to qualitative requirements. Under Article 15 of the Law on medicinal products, the mechanical dispensing of doses is subject to the condition that the staff are sufficiently familiar with the manufacture of medicinal products and that the production facilities and equipment necessary for that purpose are appropriate. The activity must also comply, where applicable, with good manufacturing practice for medicinal products in accordance with Section 11 of the Medicines Act.

Article 37a of the Law on medicinal products lays down the wholesale prices of medicinal products, which 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. Paragraph 2 provides for an exception for the mechanical dispensing of medicinal products. According to that provision, a person making a mechanical dispensing of medicinal products may be granted a discount for a medicinal product used for the dispensing of medicinal products which is included in the list of interchangeable medicinal products referred to in Section 57c and in the reference price group referred to in Chapter 6, Section 18 of the Health Insurance Act. A reduction may be granted if the fixed reference price changes and the medicinal product used at the time when the change takes effect is more expensive than the new reference price. The discount shall be granted for a maximum period of 30 days following the change in the reference price.

The mechanical dispensing of medicinal products by hospital pharmacies is not subject to price regulation for outpatient care, but the range of medicinal products used for dispensing is based on the hospitals' own range of basic medicinal products. In the case of the supply of medicinal products, suitable medicinal products are selected for dosage distribution, as a general rule from among the products selected. Where necessary, the procurement of medicinal products for dosage distribution may be the subject of separate competitive tendering in order to obtain the products and packaging formats best suited to the physical characteristics of the dosage distribution alongside those intended for normal use.

Fimea has authorised four pharmacies to be supplied with mechanised dispensing medicinal products, three of which also sell the dispensing medicinal products to other pharmacies under contract. Contract-manufacturing pharmacies rent premises, equipment and personnel to produce dosage distribution from a company separate from the pharmacy, the dosage distribution unit. Nevertheless, the dispensing unit operates under the responsibility of the pharmacy. The dispensing unit attached to the University of Helsinki pharmacy is part of the pharmacy's group of companies and not a separate company. Unlike other pharmacies licensed for dosage distribution, the pharmacy of the University of Helsinki distributes dosage only to its own dosage customers and does not operate as a contract manufacturing pharmacy for dosage distribution. As part of pharmacy supervision, Fimea regularly monitors and inspects the pharmacies that package the dispensed medicines.

In 2025, dispensing was carried out in five hospital pharmacies and in the penal medicine centre. In addition, two hospitals have the capacity to start dosage distribution.

The dispensing of medicinal products in dose distribution shall be governed by the same provisions as those governing the usual dispensing of medicinal products. Fimea's regulation on the supply of medicinal products specifically regulates the particularities of the supply of mechanised medicinal products. A pharmacist or pharmacist of a pharmacy supplying medicinal products to a customer in a dispensing unit inspects the medicinal products dispensed in a dosage dispensing unit in order to make them ready for supply. In this case, check that the dispensed medication corresponds to the medication prescribed for the customer and that the medication is distributed correctly, e.g. by checking the 1st day sachets. The

pharmacy must ensure that the medicines have been ordered correctly and that the medicines necessary for the customer have not been missed. Urgent medication changes should be taken into account at the time of delivery. At the time of submission of the prescription, the date of submission shall be documented. The delivery date is defined for dosage-distributed medicinal products as well as for other medicinal products to be supplied. Delivery date means the time at which the dosage-distributed medicinal product is delivered to the customer, duly checked. The delivery information to be attached to the prescription centre must be based on the actual verification by the pharmacist or pharmacist of the medicinal products to be delivered. (Fimea Order 2/2016, p. 15).

In a hospital pharmacy, the process of mechanical dispensing is largely similar to that of outpatient care. The medicinal products to be dispensed are ordered by medical staff according to a pre-agreed ordering schedule via an electronic ordering system. Before being placed in production, pharmacists check orders, such as when medicines are taken and any combinatorial effects, and then the orders are transferred to the production of dosage distribution. The finished dispensing bags are described and checked by means of a dedicated device. The supply of dispensed medicinal products to customer units takes place in the context of the supply of other orders for medicinal products. The Customer Service checks the correspondence of the dispensed medicines with the patient's medication list and manages the dosage of the medicine.

Social and health policies have guided municipalities and steer existing wellbeing services counties towards deinstitutionalisation of older people and shifting service provision to community-based care, i.e. increasing home care and round-the-clock residential care, affecting the volumes of dosage distribution in hospitals as customers decline. Only in specific cases can medicinal products be dispensed from a hospital pharmacy to an outpatient patient, e.g. from a hospital or institutional care. Moreover, hospital pharmacies do not supply medicinal products to residential care units within the meaning of the Social Welfare Act.

The number of outpatient delivery customers has increased significantly over the last decade. According to a request for information from Fimea to the dosage distribution units, there were 102958 customers in the summer of 2023. In spring 2025, a total of 117989 customers were distributed. In 2022, the total cost of dispensing medicines amounted to EUR 95.9 million, which represented 3.6 % of the cost of outpatient prescription medicines. At the end of 2024, 638 pharmacies provided mechanical delivery services and 191 pharmacies provided manual delivery services. In 2024, the total turnover of dispensing fees in pharmacies was EUR 18.4 million, with an average of EUR 31170 and a median of EUR 15755.

In the current state, machine-dose distribution is not subject to separate data management regulation, but to general health data processing legislation and data management regulation for pharmacies in the Customer Information Act and the Prescribing Act. In addition, Fimea's provisions on dispensing and mechanised dispensing must also be applied to data management. The personal and medication data of customers circulating in the context of machine-dose distribution between different operators are subject to the GDPR. The actors involved in the machine-dose distribution have different roles through which their roles and responsibilities in data management are defined. In the case of dispensing, the public and private social and healthcare organisation, the private medical practice and the pharmacy providing the dispensing service act as data controllers. The Dose Distribution Unit does not act as a registrar but as a data processor. The Machine Dose Distribution Unit operates under a contract with a pharmacy, where a contract for the processing of personal data is required between the pharmacy and the Machine Dose Distribution Unit (controller/processor). If the customer of a machine-based dispensing service has refused to disclose prescription data, that refusal cannot be overlooked by the abovementioned contract for the processing of personal data. A machine-

based dispensing service requires the explicit consent of the end-user of the service, so that the pharmacy can forward prescription information to the machine-based dispensing unit.

Assessment of the status quo

On behalf of the STM, Fimea carried out a study (STM 30/2025) on the development needs of the mechanical dosage distribution service. In preparing the report, Fimea took into account the perspectives of stakeholders such as dosage distribution units, wellbeing services counties and private service providers, community pharmacies, the Ministry of Social Affairs and Health, the Medicines Prices Board (hila), Kela, THL and representative organisations on development needs.

According to the study (STM 30/2025), the current legislation on mechanical dispensing is insufficient and does not identify the entities that actually carry out the dispensing operations, i.e. the dispensing packaging operations. The activities of dispensing units are not directly comparable to those of pharmaceutical factories, pharmaceutical wholesalers or pharmacies, which are recognised by the current Medicines Act as independent operators in the supply of medicinal products. The activity of packaging in the dispensing sector has grown into a large-scale activity carried out independently by the dispensing units, even though it is carried out by a pharmacist who has been granted a mechanical dispensing licence under the Medicines Act. Similarly, in the case of a machine-based dosage distribution service provided by hospital pharmacies, one dosage distribution unit in practice serves a wide range of customers and it may be appropriate in the future to agree on a wider cooperation and centralisation of the service (VN 8128/2025). In order to develop the mechanised dosage distribution service, it would be necessary for the Medicines Act to clearly identify the dosage distribution units as a separate operator in their own right, including the conditions for authorisation, the person responsible for the activity and the operating boundary conditions. Clearer legislation would make it easier for operators to anticipate changes in their activities and clarify the implementation of controls, which would also improve the legal position of the dispensing units.

In the current state, mechanical dosage distribution is provided in outpatient care, hospital pharmacies and other entities governed by public law. It would be appropriate to continue to make it possible for those responsible for the current situation to provide a dosage distribution service and to operate on the basis of a separate authorisation procedure.

Shortcomings in the legislation give rise to a lack of clarity as regards the conditions imposed on operators of dosage distribution packaging and regulatory control, as the regulation does not clearly guide packaging operations. The current Medicines Act specifies that, where appropriate, good manufacturing practices for medicinal products should be taken into account in packaging operations. In addition, packaging operations must be carried out by suitably qualified staff and appropriate facilities and equipment must be provided. Dosage distribution packaging activities have many features of industrial pharmaceutical manufacturing that require quality assurance and extensive control of the packaging process. The size of the packaging activity of medicinal products is significant, which constitutes a key patient safety risk in case of potential quality issues in the packaging activity, for example in case of packaging or documentation errors. Monitoring these matters is challenging as the Medicines Act does not clearly spell out the operational requirements. Control weaknesses have been identified in areas such as quality systems, functionality of information systems and data security.

The study (STM 30/2025) found that there are no legal provisions on the range of medicines used for dosage distribution. In order to safeguard the position of the user of the medicinal product, the general starting points for the composition of the dosage distribution range should

be laid down by law. On the basis of the information provided by Fimea's pharmacy supervision, there are situations in which the customer's right to be supplied with the cheapest interchangeable medicinal product is not satisfied in the case of a machine-based dispensing service. The Authority has identified similar situations in several products and has highlighted the current state of affairs in the Machine Dose Distribution Survey (STM 30/2025).

The starting point for determining the range to be used for dose distribution should be that the range is in line with the therapeutic recommendations. Hospitals have a similar objective in their selection of basic medicines. In the case of out-patient treatment, in addition to this, priority should be given to the selection of authorised medicinal products covered by health insurance and covered by the exchange of medicinal products. This would ensure that the efficacy and safety of the medicinal products supplied in dosage is ensured for the users of the medicinal product and that the price level corresponds to the medicinal products normally supplied in the pharmacy. However, the regulation of the range of medicines in the dispensing sector should not be too strict and the specificities of the service should be taken into account in both outpatient and hospital settings. The composition of the range should take into account the appropriateness of the range of medicinal products for dosage distribution, the suitability of the products for dosage distribution, the composition of the range on the basis of competitive tendering and the fact that it is not possible to update the range in outpatient care within the reference price system cycle as a result of competitive tendering. The physical durability and adequate shelf-life of the product outside the original packaging should also be ensured by the marketing authorisation holder or by the packaging operator in order to ensure the quality of the medicinal product used by the customer.

The composition of the range of medicines should take into account those involved in the implementation and prescribing of medicines. On the one hand, this dialogue would ensure the composition of the range according to the products actually used by the serving customers, but on the other hand, it would increase the understanding of the limited range of the serving, as it would not be possible to keep all products in the range of the serving. For example, the exclusion of low-demand products from the range of medicines is justified. The inclusion of these products in the dosage distribution range is not appropriate or economical and may lead to unnecessary losses of medicinal products. Effective interaction and dialogue would also be important in the event of a sudden change in selection, for example due to a lack of availability of medicines.

It is appropriate to use large packaging for dosage distribution packaging operations. The use of these packages would be encouraged if the legislation allowed marketing authorisation holders to introduce into the Finnish market appropriate pack sizes for dosage distribution from the EU/EEA that would comply with the Finnish marketing authorisation but would be labelled in a foreign language. In the case of portion distribution, packaging is handled only in portion distribution units and does not reach the portion distribution customer, as is the case with labelling in a foreign language. For this reason, it is not necessary for packaging intended solely for dispensing in portions to bear the full labelling or package leaflet in Finnish and Swedish, as is required for the packaging of medicinal products under the current legislation. Marketing authorisation holders have stated that the marketing authorisation for dosage dispensers would be streamlined if they did not incur separate costs when applying for dosage dispensers as part of the marketing authorisation.

However, an authorisation to derogate from the terms of the marketing authorisation, the so-called "exceptional authorisation", is not a suitable procedure to allow trade in portion dispensers to be imported from other EU countries. A waiver for marketing authorisations means a batch-by-batch and/or time-limited deviation from the marketing authorisation for the supply of a critical product to Finland in order to ensure availability. However, it is possible to

accept a package in a foreign language as a permanent marketing authorisation through a national IB (C.I.z) application when Fimea has granted a marketing authorisation for the product. This could possibly be the case for large unit packets. In addition, substitutability of packaging should be applied for.

In the current state, outpatient units in the field of mechanical dispensing have held a wholesale licence for medicinal products. These undertakings could already have imported the packaging they needed for the distribution of portions, but this possibility does not appear to have been used. This appears to be due to the obligations of the importer under the Medicines Act, as well as to the administrative processes relating to the substitutability of packaging.

The study (STM 30/2025) identified a number of development needs for the data management of machine-dose delivery in outpatient settings. National data management definition and guidance should take into account the specificities of dosage distribution in the future. Information systems and integrations between them should allow for the automated transfer of data between different actors in a secure manner, thus reducing human error and improving the security and fluidity of the process. The various checks, warnings and blockings built into the systems could support the execution of the work and improve the safety of dosage distribution if information management were developed in an overall and nationally coordinated manner. Customer and patient information related to dosage distribution should flow smoothly and safely between treating entities, pharmacies and dosage distribution entities. The inter-operability of the systems would ensure the integrity and correctness of the information, which is important for a smooth service and effective dosage distribution. A smooth process reduces the manual transmission of data and the risk of errors.

Information on whether a person belongs to a dosage distribution, information on the total up-to-date medication of the dosage distribution customer and information on the medication checks or assessments carried out will be available to all actors in real time when the changes in phase 3 of medication information management (HE xx/2026) are implemented in national and local systems and new approaches are introduced. The introduction of a master medication list is also the basis for the development of data management and medication safety in the field of mechanical dispensing. The next steps in the development of data management for mechanical delivery should be pursued in a coordinated manner and, at a later stage, the need to steer the data management for mechanical delivery units more closely than the current general data management and data protection regulation should be assessed.

The study (STM 30/2025) also proposed changes to the pricing of medicinal products in the machine-dose dispensing service. Further preparation concluded that price changes would not be feasible without a broader assessment of the reference price system. In addition, support for the development of a database on medicinal products would be needed to maintain price information on medicinal products.

The legislative amendments relating to the machine-based dispensing service would implement the government programme’s objective of further developing the dispensing of medicinal products in order to increase medication safety and the efficient use of human resources.

2.7 Vertical integration

Current status

Vertical integration refers to the combination of different levels of a sector’s value chain with the same trader or group. Vertical integration can lead to efficiency gains and economies of scale, for example through logistics restructuring and centralised operations. The main benefit of vertical integration is better management of the value chain, often leading to significant cost

savings and efficiency gains.

Vertical integration can also have detrimental effects on the business environment. Such effects depend on the regulatory environment of the business environment, the companies operating in the market and other market conditions. For example, a large integrated player may crowd out smaller competitors in distribution or pricing. An integrated operator may be incentivised to favour either its own products or its own distributors. Small, non-integrated operators may lose their market position or even exit the market, which may lead to less competition and negative effects for the consumer.

The Medicines Act contains rules limiting vertical integration. Under Paragraph 43b of the Law on medicinal products, a pharmacy licence may be granted to a pharmacist. This means that no authorisation can be granted, for example, to a medicine tube, a medicine manufacturer or a health company. It follows from Paragraph 43b of the Law on medicinal products that it is not possible to carry on activities subject to a pharmacy licence in the form of a company, but that the exercise of the activity of a pharmacy is tied to a pharmacist as a person. Furthermore, under Paragraph 54f of the Law on medicinal products, the holder of a retail licence for a limited range of self-care medicinal products cannot be a pharmaceutical company, a wholesaler or an intermediary in medicinal products. However, the holder of a retail licence could be an undertaking in the social services sector, such as, for example, a private medical centre.

Assessment of the status quo

In Finland, vertical integration between the wholesale and retail levels of pharmaceutical distribution could pose different challenges. This is partly due to single channel distribution agreements between pharmaceutical manufacturers and wholesalers. In Finland's single-channel distribution, all the products of a given pharmaceutical manufacturer are typically distributed to pharmacies via only one medicine barrel. In practice, therefore, pharmacies must conclude distribution agreements with all the wholesalers so that the pharmacy can offer its customers a sufficient range of products as required by law.

Vertical integration between wholesalers and pharmacies, such as partial or total ownership of pharmacies by a wholesaler, would be problematic under single-channel distribution agreements. For example, it could lead to a closed distribution chain for the products of a given manufacturer of medicinal products, in which a pharmaceutical wholesaler might favour the pharmacies with which it has a shareholding in its distribution. This could in turn reduce the availability of these products in other pharmacies.

According to a well-established interpretation by the authorities, pharmaceutical and wholesale activities should be kept separate. However, there are no restrictions in the regulation of the current situation that would prevent the grant of a wholesale licence for medicinal products to a person or entity holding a retail licence for medicinal products. Thus, a pharmacist holding a licence to operate a pharmacy could apply for a wholesale licence and a licence should be granted to a qualified applicant. Pharmacists have not applied for wholesale pharmacy licences, which may be due to the fact that operators in the sector are generally small and the economies of scale resulting from vertical integration are small compared to the costs involved in meeting the conditions for wholesale pharmacy licences.

Vertical integration is present in the Finnish pharmaceutical market, at least in veterinary medicine and mechanised dosage distribution. Veterinary clinics have their own tumours through which they obtain the medicines they distribute at retail level. In the case of mechanised dispensing, each undertaking producing mechanised dispensing services holds a wholesale licence (STM 30/2025 Development needs for mechanised dispensing of medicinal

products, study, p. 25, Table 1). The companies producing the mechanised dosage distribution are owned by the two largest pharmaceutical tubers (Oriola Oyj and Tamro Oyj), UHP and the pharmacists of private pharmacies. In addition, the Association of Pharmacists in Finland is the holder of the authorisation for the distribution of medicinal products to pharmacies.

Possible scenarios to strengthen vertical integration

It is possible that for a limited range of self-care medicinal products, vertical integration in the supply of medicinal products will increase. One of the objectives of the regulatory package for a limited range of self-care medicinal products was to enable increased price competition associated with self-care medicinal products and therefore benefits for consumers. A limited range of self-care medicinal products is subject to the maximum price set out in Section 4a of the Government Decree on the Pharmaceutical Tariff. Price regulation that differs from other self-care medicines makes it possible to negotiate discounts on the purchase of medicines. This may increase incentives for vertical integration arrangements.

Under Paragraph 54f of the Law on medicinal products, the holder of a retail licence for a limited range of self-care medicinal products could not at the same time be the holder of a wholesale licence for medicinal products. However, vertical integration in the supply chain of a limited range of para-pharmaceuticals could occur in the future, for example, through the actual involvement of the grocery retail chain in the retail sale of para-pharmaceuticals on the basis of a retail licence by applying for a wholesale licence for the importation and distribution of pharmaceuticals to retail outlets. If a logistics company in a grocery store applied for a wholesale medication licence, it could both distribute products from a limited range of self-medication products to retail outlet licensees and, for example, offer an online sales platform to retail outlets. However, the product purchased online would be sold at each point of sale, as the retail licence is granted on a site-by-site basis. However, as described above, vertical integration could occur in the future, for example in the grocery trade chains.

Similarly to a limited range of self-care medicinal products outside pharmacies, a shift towards vertically integrated dispensing of medicinal products would also be possible in pharmacies. Some pharmacy operators, mainly dosage distributors, and a company owned by the Finnish Pharmacists' Association currently hold a pharmaceutical wholesale licence. However, developments in this area are difficult to predict.

Pharmacy operators have also accumulated on a common online sales platform. On the platform, a customer's order can be redirected, for example, to the pharmacy that can deliver it most quickly. However, these are not vertical integration, since the online sales platforms used by the pharmacies were separate traders from the pharmacies and the medicine vouchers.

The need to limit vertical integration

As part of the development of pharmacy activities, in a context where no changes are proposed to the ownership, corporate form and chain activities of pharmacies, no need for legislative changes that would change the current regulatory landscape of vertical integration has been identified. Pursuing the benefits of vertical integration could lead to more multi-channel distribution of medicinal products, with positive pro-competitive effects. On the other hand, the categorical prohibition of vertical integration in the provision of medicinal products raises implementation concerns.

In the case of mechanised dosage distribution, a ban on vertical integration could lead to changes in the ownership structure of all companies producing mechanised dosage distribution. A legislative proposal leading to such a development would be problematic, at least from the point of view of the continuity of the operation of the mechanical delivery service and the

protection of property. A similar situation with regard to the protection of property could arise in the case of veterinary medicinal products.

If, in the case of a limited range of self-care medicinal products, vertical integration were to be based on a stronger delimitation of the current regulation (Section 54f of the Medicines Act), this could reduce the scope for greater price competition. As described above, this development could also have positive effects on the Finnish pharmaceutical market. At present, out-of-home medicines are purchased from medicines vouchers, which have mainly exclusive distribution agreements with pharmaceutical manufacturers. Each pharmacy and retail outlet must therefore conclude a contract with several pharmacies in order to obtain a full range of products. If new companies applying for wholesale licensing were to enter the market or existing wholesale licensing holders changed their business strategy, multi-channel pharmaceutical distribution would increase. The change would increase competition between operators, but the impact on costs for different operators would be difficult to predict, as the single channel system may also have cost-effective features compared to the multi-channel system.

In the case of an autotherapy portfolio, the adverse effects of possible further vertical integration may be limited. Negative effects could, for example, be related, for a short time, to the adequacy of medicines on the Finnish market, as stocks of imported medicines could be spread over several medicines. It should also be noted that, even in the event of availability challenges for medicinal products in a limited range of self-care medicinal products, these cannot be considered as critical for the protection of public health due to the limited scope of the range.

If, at a later stage of development, the range of out-of-pharmacy medicinal products were to be extended, the rules on ownership of pharmacies were to be amended, the operation of pharmacies in the form of public limited companies and the chain of pharmacies were to be allowed, it would be appropriate at the same time to assess the possible beneficial and harmful effects of vertical integration and the need to control adverse effects by means of legislation.

2.8 Pharmacy agreement

Current status

The pharmacy contract procedure is an approach aimed at ensuring the safe treatment of patients in situations where normal practices are not sufficient, such as the delivery of treatment for withdrawal and replacement of opioid addicts. The pharmacy agreement is concluded between the patient and the doctor or treatment unit treating him and the procedure is currently carried out by restricting the supply of the medicine from the pharmacy. Under the contract, the patient undertakes that he will only be able to collect the medication for ddmmyyyy or narcotics from the pharmacy designated in the contract. The designated pharmacy is authorised to inform other pharmacies of the validity of the contract, in which case the other pharmacies shall refrain from supplying the medicinal products concerned. In addition, the pharmacy may pass on to the patient’s treating physician information necessary to assess whether the treatment has been provided. The contract may also have been used to support the distribution of medicinal products as a preventive measure to prevent addiction in patients taking medicinal products that mainly affect the central nervous system (ddmmv) or medicinal products containing substances classified as narcotics. The possibility of dispensing medicinal products through a pharmacy instead of a unit of care has facilitated the daily life of the user by allowing medicinal products to be collected from an out-patient pharmacy rather than from an entity of substance use. The total number of pharmacy contract customers is currently 10998 (compared to 10724 in 11/2024).

The pharmacy agreement is governed by Section 55b of the Medicines Act. The data

management solution for the pharmacy contract procedure was implemented in 2013 as an information service operated by the Finnish Association of Pharmacists, intended as an interim solution, because implementation as part of Kanta services was not possible at that time. The current implementation of the pharmacy agreement does not allow for the development of activities in line with national pharmacy data management principles (STM 8/2024). Needs for the development of the pharmacy contract procedure have been identified and described in the Information Management Solution Statement produced by THL (THL 12/2023).

Assessment of the status quo

As part of Kela's Kanta services, the approach to a prescription centre would primarily be to restrict prescription and dispensing only when this is necessary for the organisation of the treatment. As things stand, all pharmacies have access to information on the pharmacy contract, but only the contracted pharmacy is aware of its exact content. If the contracted patient tries to purchase medicinal products for ddmmyyyy or narcotic drugs from a pharmacy other than his own, the pharmacy system will inform the supplier of the medicine about the existing pharmacy contract and the contracted pharmacy recorded therein. Pharmacies other than the contracted pharmacy do not see which medicinal products are covered by the customer's contract and refuse to supply the medication for ddmmyyyy or narcotics and refer the patient to the contracted pharmacy. The fact that the content of the contract or the restrictions contained therein, such as those relating to a single product, are not visible to the pharmacy may cause problems or, at the very least, delay the provision of appropriate treatment by preventing the supply of all medicinal products for ddmmyyyy and narcotic drugs.

From a physician's point of view, a restriction on the visibility of a pharmacy contract may be detrimental to treatment situations. The existence and content of a pharmacy agreement shall be known only to the parties to the agreement. A doctor who has no knowledge of a pharmacy contract may prescribe medicinal products without being aware of the contract, but the pharmacy would not be able to supply them. This can complicate the proper planning of treatment and delay its delivery. In addition, in the absence of information on the existence of a pharmacy agreement during institutionalisation, the patient may be treated with medicinal products that make it difficult to follow up or replace the patient.

The current range of medicines covered by the agreement is linked to the list of drugs and drugs and cannot be extended to other misused medicines. In addition, the agreement cannot be limited to specific individual medicinal products, which would make the procedure more accessible to patients who are not dependent on opioids or medicinal products. The Medicines Act as such does not limit the conclusion of the agreement to ddmmyy and narcotic drugs only, but the system operated by the Finnish Pharmacists' Association has been implemented only for ddmmyy and narcotic drugs, so the use of the agreement to control the use of other medicines is not practicable.

Additional extension needs have been identified in the contract procedure. It is not necessary to limit treatment by law to only one pharmacy or one doctor for all patients to be treated, but it should be possible to stagger the contract procedure according to the patient's need for support. In some cases, a pharmacy contract such as the current one and a permanent care relationship with the same physician or care unit are necessary, but in many cases the model of a single physician or a single supplying pharmacy is unnecessarily restrictive.

In the case of care organisations, problems may also arise if no replacement is appointed for the treating physician in the pharmacy contract. In this case, no other doctor can comment on the contract, make changes to it or even prescribe the medicinal products covered by the contract. At worst, if a doctor leaves the organisation, the contract cannot be changed or even

terminated.

The pharmacy contract procedure has been described as stigmatising because it specifically targets the category of abusers of medicinal products. The pharmacy agreement, by its very name, has been perceived as having become the hallmark of the child, and the hallmark of the pharmacy unnecessarily accompanies the patient, even if the pharmacy agreement was concluded for different reasons.

3 Goals

The amendments to the Medicines Act proposed in the government bill are part of the pharmaceutical reform on the basis of the roadmap. According to Orpo's government programme, the regulation of pharmacies will be reformed in a responsible and gradual manner, ensuring high-quality and safe pharmacy services throughout Finland. As part of the reform, the role of pharmacies is recognised as part of the healthcare system and the important role of pharmacies in the successful treatment of patients. According to the government programme, the safety, effectiveness and relevance of medication treatments for older people and people with multi-morbidity will be improved through medication guidance and overall medication assessments. In addition, according to the government programme, special attention needs to be paid to drug treatment packages for the elderly and for high-volume pharmaceutical users. A key means of achieving these objectives is to reform the functions and activities of pharmacies, the licensing system for pharmacies and the qualitative requirements for their activities.

In line with the government programme, dosage distribution of medicines will also be further developed to increase medication safety and the efficient use of human resources. With regard to the development of dosage distribution, the authorisation of packaging activities will be renewed, clarifying the role of the dosage distribution units as part of the supply of medicinal products, ensuring quality of operations and patient safety. The regulation of the range of medicinal products in the dispensing system would ensure that the range of dispensing is in line with commonly used treatment practices.

In addition, the operation of online pharmacies is being developed through a reform of the regulation of the online service, enabling cooperation between pharmacies in accordance with the government programme. The development of online pharmacy activities aims at streamlining the customer's dealings with the online service.

As a matter of priority, the pharmacy agreement would be transformed into a prescribing policy rather than a single pharmacy delivery model. Changes to the pharmacy agreement's data management solutions would aim at improving the flow of information between pharmacies and healthcare.

4 Proposals and their effects

4.1 Key suggestions

It is proposed that the content of pharmaceutical services be clarified as to what activities should be carried out in a pharmacy. The proposals aim to establish uniform principles for the requirements of pharmacy operations and to safeguard the position of the user of the medicine, so that a uniform service can be obtained independently of the pharmacy. Clarification of the content of pharmaceutical services will also support further assessment of the need for and adequacy of funding for the provision of services. The legislative changes related to advice and counselling on medicinal products aim to improve the effectiveness of advice by supporting the success of pharmaceutical treatments based on individual needs with the skills of pharmacists

in the pharmacy. A more precise definition of guidance and advice on medicinal products will also clarify the conditions for the development of services that go beyond this. The proposed changes to the regulation of pharmacy activities would highlight the role of pharmacies as part of the pharmaceutical treatment process vis-à-vis other social and healthcare services.

The presentation proposes to make more use of the expertise of pharmacists in pharmacies as part of successful medical treatment and to support both self-care by clients and self-care co-designed with a healthcare professional.

Changes to the regulation of pharmacy contracts are proposed to support the success of pharmaceutical treatment. It is proposed to amend the provisions of the Medicines Act on the pharmacy agreement, which governs the dispensation of the medicinal product, to direct the prescription of the medicinal product and to focus on one health service unit. In the first place, the contracted medicinal products could be collected from any pharmacy, unless a restriction to only one or a limited number of pharmacies would be justified. Furthermore, in order to prevent pharmaceutical losses and to control distribution, it would normally be necessary to concentrate the supply of the distributed packaging in one pharmacy only. The Act would also be amended as regards the data management of pharmaceutical contracts, including by transferring the maintenance of contracts from the server of the Finnish Pharmacists' Association to a prescription centre operated by Kanta. It is proposed to change the title of the pharmacy agreement to a pharmaceutical agreement.

The aim of the proposals is to ensure high-quality and equal pharmacy services in Finland by clarifying the operational requirements. It is proposed to add to the Medicines Act provisions on the qualitative and functional requirements for pharmacy operations by introducing obligations to support patient safety with regard to the pharmacy's operating procedures. and incident reporting and handling.
The draft amendments also safeguard the equal position of customers by adding to the Medicines Act a Government decree-making power on price regulation for issuing the Schengen Certificate.

The proposal also proposes changes to the pharmacy licensing system that would contribute to the well-functioning of the national pharmacy network and ensure its social sustainability. The aim is to reform the regulation of branch pharmacies to better reflect actual regional needs and to involve the providers of social and healthcare services in the region in the evaluation of the pharmacy services needed in the region. It is proposed to exempt pharmacy pick-up clubs from location regulation.

Presentation propose a retail licence for para-therapeutics
enabling the online service of the holders. In addition, remote pharmacy services would be streamlined through the development of a pharmacy: Regulation of the online service and provision
conditions. The amendments would allow for more flexible cooperation between pharmacies for the supply of the medicinal product. The conditions for competition on the price of medicines would be strengthened by allowing a different pricing from that of a brick-and-mortar pharmacy in an online pharmacy through an amendment to the Medicines Act.

In addition, amendments are proposed to the Medicines Act aimed at identifying the mechanical dispensing activity as a separate activity from the pharmacy activity, which would clarify the position of both dispensing operators and customers as part of pharmaceutical treatment and regulatory supervision.

4.2 Principal impacts

4.2.1 Economic impacts

4.2.2 Economic impact on the state's finances and public finances

The proposal is estimated to have indirect financial implications for the state or public finances due to changes in the use of medicines. The reduction in unnecessary use of medicines due to guidance and advice on customer-oriented medication, better collaboration and operational practices between pharmacies and social and health services may reduce the financial burden on the state and health insurers due to reduced reimbursements under Kela. The proposal may also have implications for the success of pharmaceutical treatment, as further assessed in section 1.11.5 on the financial implications for health and social care.

The bill's proposals for changes to the regulation of branch pharmacies may have a limited impact on the tax revenue of the State. The possibility for Fimea to convert a qualified branch pharmacy into a pharmacy licence would be streamlined, which could lead to more qualified branch pharmacies becoming a condition of a pharmacy licence. This may have an impact on the collection of pharmacy tax, since the operation of a branch pharmacy on which authorisation to operate a pharmacy is conditional gives rise to a higher deduction from the basis of assessment for pharmacy tax than the person entitled. However, the impact is likely to be limited, as it would not be the primary means of maintaining a nationwide network of pharmacies and the righting branch pharmacy can only make the authorisation of a pharmacy conditional on it if it is justified by the need to ensure the continuity of the pharmacy services in the region. Decisions to make the authorisation of a branch pharmacy subject to authorisation would be taken on a case-by-case basis.

The proposed solution for data management in the pharmaceutical contract would require the development of national data management services. This proposal includes the phase 3 part of the pharmaceutical contract, for which the development costs for Kela's Kanta services are estimated at around EUR 0.4 million. The total cost of the development of phase 3 of pharmaceutical data management in Kanta services is around EUR 4 million for the period 2026-2029. The costs will be covered by Article 4.23.33.01.25 of the State budget. Kela estimates that the maintenance costs of the Kanta system are already included in the existing maintenance costs of the system, i.e. no new maintenance costs will arise from the development of phase 3.

4.2.3 Economic impact on households

The proposal is estimated to have financial implications for customers using medicines. The aim of the amendment is to improve the success of medicinal treatments, which can improve the financial position of the customer through reduced use of medicinal products or through the ability to work and function resulting from the success of medicinal treatments. For example, nationally harmonised guidance and advice on medication can increase the success of medication and, as a result of changes in the regulation of mechanised dispensing and the consolidation of modus operandi, moderate changes in the cost of medication for clients using the service can be supported.

Competition on the price of para-pharmaceuticals would be strengthened by extending the pharmacy's obligation to offer the cheapest para-pharmaceutical, as well as by allowing different prices for the different service channels of the pharmacy and an online service of non-pharmacy retail outlets for para-pharmaceuticals. This change may improve the financial position of the user of the medicine if prices of out-of-home medicines were to fall. The proposal may therefore have positive effects on the position of households. The change may also, to a limited extent, increase unnecessary consumption of para-pharmaceuticals and thus

weaken the position of households, as advice and advice on pharmaceutical treatment and therefore support for product selection could not be provided through the online service of retail outlets in the same way as through the online service of a pharmacy.

The cost of customers using medicinal products containing narcotic drugs or psychotropic substances and travelling abroad may be affected, depending on what the pharmacy requesting the Schengen Certificate has considered to be the cost of drawing up the certificate. The impact on the population is likely to be small, as the proposed pricing is based on an estimate of the cost value, i.e. mainly the cost of working time, which seems to have been the basis for the pricing of pharmacies in many cases also in the current state.

4.2.4 Financial implications for pharmacies

The proposed definition of the functions of pharmacies would have implications not only for the operation of pharmacies, the activities of public authorities, i.e. licensing and registration practices and supervision, but also for the evaluation and supervision of pharmacy activities. The definition of the pharmacy's tasks would give transparency to the pharmacy's activities and clarify the core tasks of the pharmacy and the principles under which pharmacy activities are carried out. The changes are estimated to have a limited economic impact on pharmacies, as the core functions of pharmacies would remain unchanged.

In the case of pharmacies providing services other than those provided on the basis of a pharmacy licence, registration with Soteri is required. The registration fee consists of the fees of the service provider and the service entity, and the amount of the fee varies according to the type and size of the company. For example, depending on the size of the pharmacy or whether it is applied for to a separate limited company, the fee for the provision of health services in one outlet would range from a minimum of EUR 1060 to a maximum of EUR 1800. It is also possible to apply for a single service unit registration at a cost of EUR 1280, including a one-stop shop, a maximum of four service sectors and a maximum of five service providers. The 'Soteri' registration fee may further dissuade pharmacies from developing health services in regional cooperation, e.g. pharmaceutical-based reception or assessment services, which, as things stand, have been limited in their provision. On the other hand, it should be noted that a significant number of pharmacies already provide health services on a partnership basis. The clarification of the conditions for the provision of services may also increase the willingness of some pharmacies to provide health services and at the same time increase demand for them if, for example, cooperation were to be agreed within the wellbeing services county. If there were a significant increase in health service activities in pharmacies compared to the current situation, this would have the effect of strengthening the pharmacy's economy.

The changes proposed in the presentation to streamline the web service business would have the effect of improving the profitability of the web service business. The proposed changes to the implementation of the online service will make it easier for all pharmacies to offer their services online. It would be possible for pharmacies to provide the online service with lower investment and maintenance costs if it were produced in cooperation. The online service also increases the efficiency and flexibility of the pharmacy by allowing the customer to place part of the order independently and by allowing the pharmacy to direct its employees to handle online orders when there are fewer customers in the stonehouse. The scope for an online pharmacy to operate would also be improved by expanding the location of pick-up clubs, which can facilitate the provision of an online service outside the area in which the pharmacy is located. The pharmacist should continue to ensure that pick-up clubs are adequate, so it can be assumed that, despite the easing of regulation, pharmacies would not place them very far away from the area in which they are located. The effects on competition between pharmacies in this respect are likely to be limited. On the other hand, the extension of price competition for self-care medicinal products that can be enabled by the online service may increase competition

between pharmacies. The online service of holders of retail licences for non-pharmacies for non-prescription medicinal products can also reduce the share of pharmacies in the sale of non-prescription medicinal products and increase price competition between different operators. However, the impact is likely to be limited, as non-pharmacy retailers have a significantly narrower range of self-medication than pharmacies.

The increase in customers' purchases of medicinal products via the pharmacy's online service may have different economic consequences for different pharmacies. Pharmacies that invest in the provision of an online service and the smooth running of the service process as well as customer orientation, or that agree to cooperate with different actors, may benefit from increased sales of medicines and other products through the online service. On the other hand, sales of pharmacies which do not develop their activities in relation to an online service may be reduced if their customers switch to purchasing medicinal products and other pharmacy products from another pharmacy's online service. It would not be possible to predict which pharmacies will benefit or suffer from the increase in the online service and the pharmacy would be able to influence the change through its own activities.

The proposed changes to the operation of online services may lead to changes in the market, concentrating demand on those pharmacies that invest and develop their services and reduce the number of players in the online pharmacy market. This may weaken competition in the longer term. On the other hand, in the current situation, the online services activities of pharmacies are already highly polarised, with a high concentration of large-scale activities due to the need for investment and the operating environment of the pharmacy system. Enabling cooperation through a legislative amendment can bring new pharmacies into the online pharmacy business and thus increase competition in the market. New business models can improve the service and also support proximity services by allowing pharmacies that, as independent operators, would be too small to invest and meet the customer service requirements of the network to join the online service. On the other hand, enabling cooperation may lead to the concentration of some entities involved in online service activities, for example in platform solutions or medical advice and advisory services.

The proposed change in the presentation to the monitoring of the performance of the pharmacy's tasks and to the reporting and handling of incidents may have an economic impact on the pharmacy. The potential need for investment in a pharmacy may be related to convergent handling of monitoring, reporting and changes, costs of staff induction and training, or costs of purchasing an information system. However, the overall impact is estimated to be limited and, as regards the incident procedure, only a small number of pharmacies would be affected, as currently almost all pharmacies have incident reporting and handling procedures in place (STM Working Group Report VN/14650/2023). Plan of measures to ensure medication safety and treatment success in a pharmacy for biological medicinal products on-going in the case of exchange of medicinal products. Available at: https://api.hankeikkuna.fi/asiakirjat/7ee12781-84ec-4157-9980-0f6514035aad/e2263b92-e22e-4075-a067-2df0d88f4d6a/RAPORTTI_20250509082610.PDF). The general monitoring of the pharmacy's tasks should already be an essential part of the monitoring, continuous development and management of the business as it currently stands.

The proposed changes to the content of guidance and advice on pharmaceutical treatment provided by pharmacies may entail induction and training costs for pharmacy staff. On the other hand, it should be noted that Fimea's order for the supply of medicinal products already contained obligations relating to the content of the advice on medicinal products, which corresponded to the clarifications proposed. Moreover, under the Law on professionals, pharmacists are already required to maintain and develop their own professional skills on an

ongoing basis and, under the Law on medicinal products, the pharmacist must ensure that all the staff of the pharmacy are adequately involved in further training. The cost of training and induction for pharmacies would depend on how the above-mentioned obligations would have been fulfilled in the past and, for example, on when the pharmacists completed their initial training. It would also be relevant when the staff of the pharmacy would have obtained their basic degree, as the university education reforms over the last decade or so have made the skills targets for degrees more supportive of the skills needed for the proposed changes.

Changes in the content of medical advice and advice may also alter the pharmacy's financial position due to increased competition in the quality of the service, which may affect the number of customers. Although the aim of the proposal is to harmonise pharmacy activities, it would also mean that customer-focused advice could vary from one pharmacy to another in terms of its content. On the one hand, pharmacies that maintain staff skills and invest in a customer-oriented service would benefit financially, and on the other hand, pharmacies that do not provide guidance and advice to the same level of service may suffer from increased competition. The ability of a pharmacy to develop a transactional experience, as well as guidance and advice in an online pharmacy, may also have an impact on the number of customers, which is quite typical of business activity in general.

4.2.5 Economic impact on public health and social care

Problems related to the use of medicines entail significant costs for health and social care. According to a domestic study, the cost of work to resolve anomalies in pharmaceutical treatment has been estimated at around EUR 15.5 million per year. (Kanninen JC, Ojala R, Ahonen J, Kautiainen H, Holm A, White V. The Financial and Workforce Impact of Medication Errors in the Finnish Public Healthcare System: A Pilot Study. Health Serv Insights. 2026, doi: 10.1177/11786329261427522.). The modus operandi and data management of the different actors in the medication process has been developed over time, including through the introduction of the Kanta medication list through the expansion of the information content of the medication list during this government term (HE xx/2026). The changes proposed in this proposal support the objectives of the development of the Kanta medication list and contribute to the strengthening of the economic impact assessment that has already been carried out in this context.

In western countries, drug-related harm affects an estimated one in five patients treated in hospitals, and in Finland it is estimated that it accounts for up to a quarter of on-call visits by older people (Laatikainen, 2020). Drug-related adverse events in healthcare). It is also estimated in the literature that greater commitment to pharmacotherapy improves the effectiveness of medication and reduces other use of healthcare services, in particular for chronic diseases (OECD Health Working Paper No. 105 (2018)). Investing in Medication adherence Improves health outcomes and health systems efficiency. Adherence to medicines for diabetes, hypertension, and hyperlipidaemia). According to the literature, adherence to treatment varies depending on the disease and the therapeutic class. For example, according to a recent publication, the commitment to treat asthma in Finland is good (Salmela, Petri, frost, Johanna., Juntunen, Pekka et al. Adherence to asthma Medication and asthma control in Finland. BMC pulm Med (2026). Available at: https://doi.org/10.1186/s12890-026-04223-0). However, adherence to psychiatric patients is estimated to be significantly lower (Misdrahi, David, Tessier Arnaud et al. Evaluation of adherence patterns in schizophrenia using electronic monitoring (MEMS(R)): a six-month post-discharge prospective study. Schizophr Res 2018; 193:114-8).

The proposal would clarify the customer-focused nature of the information and advice provided on the dispensation of a medicinal product and clarify that the activities of a pharmacy should constitute a safe, high-quality, effective and economic entity for the user of

the medicinal product and for health and social care and society. Advice and advice provided in a pharmacy should in all circumstances strengthen the advice provided in healthcare. In addition, the discussion in the pharmacy may revert to issues that remain unclear to the user of the medicinal product. The changes have the potential to improve the success of medication treatments, reduce the use of unnecessary medication, reduce the number of on-call visits due to medication problems. In Finland, it is estimated that pharmaceutical work by pharmacies reduces the use of public health services by EUR 855 million per year (study commissioned by the Association of Pharmacists: The value of pharmaceutical work carried out by pharmacies. Eior Oy, 2024). In particular, the evaluation will look at the impact of self-care and prescription-only counselling and the revision of deviations and interactions. The extent of the impact will depend on the extent to which pharmacies have already acted to influence the above-mentioned issues when supplying the medicinal product. In addition, the determination to promote cooperation between pharmacies and health and social care in different regions as a result of the changes will be key. The treatment of anomalies found in a pharmacy, as proposed in the presentation, will support the identification and learning of problems related to the use of medicines.

If the skills of the pharmacy's staff are not maintained or there is no agreement in the wellbeing services county on outpatient medication guidance and advice as required by the proposed changes with the pharmacy operators, it is possible that customer-oriented advice provided by pharmacies may also mean that it is different from advice provided in healthcare. This risk may increase in particular for medicinal products that are off-label, compassionate or prepared in a pharmacy. Conflicting medication guidance and advice can reduce the chances of successful medication and thus increase costs for social and health services. However, the impact is estimated to be small and its realisation would require the pharmacy to breach its obligations, e.g. to cooperate with the wellbeing services county or to maintain the skills of its staff.

The impact of the proposals is also linked to the way in which, in addition to legislative developments, other means are put in place to support the implementation of pharmaceutical advice in different regions that meets customer needs. These include national information guidance and support for increased regional cooperation between wellbeing services counties and pharmacies. At national level, implementation of pharmacological practices and advice, adherence to treatment and reported pharmacological incidents are not yet monitored, but there are ongoing development projects aimed at supporting knowledge-based leadership in the development and cooperation of regional practices.

The proposed changes to the mechanical dispensing system may have an impact on the functioning of health and social care. The proposal proposes to clarify the operational requirements. Dose distribution activities should contribute to ensuring patient safety, which would have been identified by regulation as the role of a specifically required responsible person. If properly implemented, mechanised dosage dispensing can support the success of multi-medicine treatment and reduce the working time of medical staff involved in the dispensing of medicinal products, as well as reducing errors in dispensing.

4.2.6 Financial impact on grocery and non- grocery stores

The changes proposed in the presentation to enable the online service of a retail licence holder for over-the-counter medicinal products would improve their ability to expand their service channels for the sale of over-the-counter medicinal products. The amendment may increase the sales of medicinal products by the operators concerned and price competition between them. The size of the change will depend on the range of products to be sold, i.e. the extent to which pharmaceutical companies seek authorisation to sell out-of-pharmaceuticals outside pharmacies for medicinal products for which this would be possible. The proposed change to

the extension of the sales channel for over-the-counter medicines could increase the current consumption of these medicines, which would benefit pharmaceutical companies financially.

The proposed change in the presentation of the online service of the retail licence holder for self-care medicinal products requires the development of information systems and data management to support online transactions. No separate regulation is proposed for data management and the service should comply with the General Data Protection Regulation. Thus, the marketing authorisation holder of a limited range of self-care medicinal products must ensure, through technical and operational solutions, that data protection and security, as well as the rights of data subjects, are respected in the online service it provides. In the context of the sale of a limited range of self-care medicinal products, a customer registry will be created to store personal and medicinal product data of a high-risk nature. In addition to the processing and storage of data, attention shall be paid to the proper transmission of ordering and delivery confirmations containing personal and medicinal product data. In practice, an appropriate way to provide such information could be, for example, an electronic mailbox where a customer who purchases medicinal products online logs in and through which he or she can obtain the above-mentioned information, which is inherently risky.

Enabling cooperation within the pharmacy's online service, including with operators outside pharmacies, may create new business activities, for example for qualified sole proprietors in the pharmaceutical sector. The proposed changes would allow the pharmacy to agree, for example, on the implementation of medication advice and counselling on its online service with a company that is capable of providing advice. Allowing cooperation could broaden business opportunities in the pharmacy sector, where the number of operators is limited. At the same time, cooperation may require investment in the necessary information systems and data management. If a pharmacy provides medical advice and advice on the dispensing of a medicinal product in cooperation with another operator, all the actors involved in the dispensing of the medicinal product must have uniform protections for the datasets processed and procedures to ensure technical security. The procedures and processing of information should correspond to what is required of a pharmacy in relation to the dispensing of a medicinal product.

The proposed changes to the mechanical dispensing of medicinal products may have an impact on the financial position of the companies providing the service. However, the regulatory authorisation conditions, the operational quality requirements and the principles of portfolio building would not change the status quo in terms of requirements and therefore the economic impact on existing operators is assessed as negligible. If, as a result of the proposed regulation, there were changes in the range of medicinal products in the dosage distribution unit which would weaken its financial position, the costs could be passed on in the supply chain in the form of fees charged to the pharmacy or to the purchaser of the dosage distribution service. The proposed changes do not entail separate development costs related to data management or information systems, which is equivalent to a regulatory activity. In the future, the pharmacy and the mechanical dispensing unit it operates will have to ensure the proper implementation of data protection and security and data subjects' rights. The Dose Machine Distribution process shall comply with the general legislation related to the processing of health data and systems and policies shall comply with the requirements of the Data Protection Regulation and the GMP guidelines.

The proposed data management solution for the pharmaceutical contract would remove the maintenance responsibility and related costs of the Finnish Pharmacists' Association in relation to the proxy server for pharmacy contracts and the related contract, support and access management procedures.

4.2.7 Impact on people and society

The changes proposed in the proposal aim to clarify the tasks and organisation of pharmacies so that they form a safe, high-quality, effective and economic entity for the user of the medicinal product and for health and social care and society. More precise guidance and advice on medical treatment would make it possible, on the one hand, to use the expertise of pharmacists in pharmacies to support the success of medical treatment and, on the other hand, to identify problems with medical treatment in the context of advice and advice on the supply of medicinal products. The proposed changes can reduce the burden of treatment for the medicine user (Mikkola, Heidi et. al. Understanding medication-related burden from patient perspectives: a qualitative study testing the applicability of the conceptual model among chronically ill outpatients in Finland. BMJ Open. 2023 Dec 1;13(12):e077214. Available at: https://doi.org/10.1136/bmjopen-2023-077214) and improve the success of medical treatments (Jokelin, Elisa et al. Clinical and economic outcomes of multidisciplinary team members in primary care: a scoping review. BMC Health Serv Res 25, 1025 (2025). Available at: https://doi.org/10.1186/s12913-025-13243-1), where the input of pharmacists is used for customer-oriented advice.

It is proposed that the pharmacy, when dispensing the medicinal product, should provide the pharmacist with the opportunity to give advice and advice on the treatment of the medicinal product with a view to its correct and safe use and to support the success of the treatment. Under the current rules, when dispensing medicinal products, the advice and guidance of the pharmacist's staff must be aimed at ensuring that the user of the medicinal product is aware of the correct and safe use of the medicinal product. It would always be possible for the customer to obtain advice. The proposed wording would continue to allow the user of the medicine to choose whether or not to seek advice. If the proposed change in the presentation would lead to a greater refusal of advice on the part of the users of the medicinal product, the proposal may reduce the support that users of these medicinal products receive for the implementation of the treatment. On the other hand, it should be noted that, in practice, as it stands at present, advice may have been refused and the proposal should not be expected to change the situation immediately. Refusal to give advice could be low-risk in situations where medication has been well established for a long time and in a good balance of care. Refusal to give advice may also be due to the sensitivity of the case, where the willingness to receive advice may be strengthened if it is offered, for example, as a written chat service. It is also possible that the proposed amendment would allow pharmacies to better focus on guiding and advising those who have a heightened need for assistance to support the success of medical treatment. Such persons would be, for example, persons with multi-morbidity who have access to several different medicinal products or persons starting to use a new medicinal product. Users who face challenges in maintaining a balanced treatment and are reluctant to receive oral advice and counselling can also benefit from new ways of accessing information to support their treatment. The changes would allow the pharmacy to develop means of guidance and advice, which could help to allocate the pharmacy's resources to advising those who would most benefit from it. Different language groups could benefit from such solutions, including the accessibility of counselling services as a competitive advantage for the pharmacy.

Pharmacies must continue to offer advice to anyone who so wishes. Refusal to give advice may be accentuated in the case of an order for a medicine in an online service, since if advice is not immediately available, it can be seen as a delay in obtaining the medicine. The impact would be difficult to assess in advance and much would depend on how pharmacies would actually implement their obligation to provide advice. It would also be possible for pharmacies to support the use of a medicinal product, in particular through an online service, beyond the advice and guidance provided by a professional, through various digital solutions. In the context of regulated prices for medicinal products, the importance of the quality of the

pharmacy's service in the customer experience is emphasised, which, in the case of advice, would mean appropriate support for the user of the medicinal product.

A number of different proposed changes will improve customers' access to medicines. Changes to the regulation of branch pharmacies will improve the availability of medicinal products in the area where the branch pharmacy is located, online sales by the holder of a retail licence for non-prescription medicinal products will improve availability, as will changes to the pharmacy's online service. In an online service, enabling collaboration can improve the customer's ability to order both self-care and prescription medicines from the pharmacy's online service, as pharmacies would be better able to maintain the service more widely during opening hours. The quality of advice and other services in the online service can also be improved when it is possible to co-operate. Liberalising the location of pick-up clubs may increase the number of clubs or change the location of existing clubs to suit the needs of customers. The change can make it easier to collect the medicine ordered and thus to access it.

The proposed amendments to FIMEA's prescribing mandate on the notification and handling of product recalls and the handling of product defects and suspected falsifications of medicinal products will improve pharmaceutical safety and patient safety more broadly. The current situation of the users of the medicinal product would be improved by strengthening the legal basis for safety precautions for the medicinal product.

The proposed changes to the assessment of the functionality, location and adequacy of pharmacy services, so that the current municipal role is transferred to the entity responsible for the organisation of social and health services, in order to ensure the compatibility and functionality of pharmacy services with other social and health services. For example, it would be possible for a wellbeing services county, as part of its organisational role, to assess where pharmacies should be located and how the outpatient pharmacy treatment process should be organised, including pharmacies. The proposed changes could improve the success of the customer's medical treatment and access to medicines if the wellbeing services county manages to better integrate pharmacy services into the customer's care pathway (e.g. Kvarnström, Kirsi et al. From Hospital to Home: Patient Experiences With Medication Counselling for Colorectal Cancer. Basic & Clinical Pharmacology & Toxicology, 138(1), 2026. Article e70180. Available at: https://doi.org/10.1111/bcpt.70180).

The proposed amendment on the monitoring of pharmacies' own activities and the reporting and handling of detected anomalies would strengthen the continuous improvement of pharmacy practices and the strengthening of the assurance of medication safety. The obligation to compile and handle a near miss situation also improves the possibility of pre-establishing medication safety practices and thus prevents adverse events in medication for the user of the medicinal product. The impact is partly linked to the development of national incident data collection and information guidance. The proposed changes would strengthen local work. For the time being, there is no official body that collects information on medication-related incidents and directs medication safety assurance at national level.

Changes to the information management solution of the medicinal product contract included in the presentation can help the patient to cope with life situations where normal prescribing and dispensing procedures are not sufficient, for example due to the risk of abuse or for any other reason. Changing the pharmacy contract procedure from the server of the Finnish Association of Pharmacists to the Kanta services would allow more flexibility in the use of contract information. The change would concern not only the transfer of maintenance but also the fact that the pharmaceutical contract would in future be a contract between the patient and the health institution and that the supply of the contracted medicinal products would not necessarily be tied to a single pharmacy. Both changes would make the patient's position

easier. The amendments would not change the nature of the agreement, which would still be drawn up by mutual agreement between the parties. With the support of the pharmacovigilance agreement, the success of the treatment of patients can be improved and the risk of misuse of medicines reduced, thus reducing the costs and harm of medicines and creating better conditions for the success of the treatment.

Data protection implications

In the context of the sale of a limited range of self-care medicinal products, a customer registry will be created to store personal and medicinal product data of a high-risk nature. There are specific comments on how to deal with them.

The processing of personal data in pharmacy and pharmacy contracts under this Government proposal falls within the scope of Regulation (EU) 2016/679 of the European Parliament and of the Council on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation). The proposals would have implications for the protection of personal data.

The Finnish Association of Pharmacists ('the SAL') operated a proxy server for pharmacy contracts and was responsible for the related contract, support and access management procedures. The use of the pharmacy agreement for the treatment of patients required a separate register of persons maintained by the Association of Pharmacists on the basis of a separate agreement. It is proposed that the maintenance of pharmacy contracts should be transferred by means of a one-off operation from the Association of Pharmacists in Finland to the prescription centre for Kanta services of the Social Insurance Institution of Finland. The pharmacy contracts would be transferred in one go from the SAL to the prescription centre on 1 October 2028, i.e. only one IT system would be operational after the entry into force of the Act.

Under the proposed transitional provision, pharmacy contracts could be concluded until 30 September 2028. The new contracts would be concluded as pharmaceutical contracts under the prescription law as from 1 October 2028. Before the entry into force of this Act, personal data on pharmacy contracts held by the Finnish Pharmacy Association would, following the proposed amendment to the Act, be transferred to the Social Insurance Institution of Finland, its prescription centre for Kanta services, on 1 October 2028. After the transfer of the data, the Social Insurance Institution would act as the controller of the personal data in the pharmacy agreement within the meaning of Section 18 of the Act on prescriptions. The Finnish Pharmacists' Association's right to the processing of personal data based on data controllership ceases when the data is transferred on 1 October 2028.

The healthcare service would be obliged to deposit the contract with the prescription centre as of 1 October 2028. The master medication list thus centralises some information on outpatient medication at national level in a prescription centre. From a data protection point of view, the introduction of the Kanta medication list, already implemented by previous legislation, means that the information is automatically visible every time the medication is handled by a professional and that the patient loses partial control as a result of the patient's right to opt out of the medicine. The information flows through automated system queries and the minimisation of processing is made more difficult. As donation bans would apply to an existing medicinal product and not to an individual prescription, the patient will no longer be able to block the view of the individual prescription, but the effect of the ban will be extended to the entire continuum of the medicinal product. Patients should understand the broader impact of their bans when the system implements less fine-grained controls than in the past. In addition, some of the information prescribed by law would always be displayed independently

of any prohibitions.

The amendment would mean that the number of persons authorised to view data would increase in proportion to the current situation. An increasing number of health and social care professionals would be allowed to process the same data, which could increase the complexity of access management and the risk of data being processed in situations where it is not necessary, as well as the number of staff that could see sensitive data. The burden of access management and logging could increase. This could lead to the risk that the worker will see information that he or she does not need for his or her care tasks and that abuses may be more difficult to detect with increasing use rates. In addition, controls could become more complex. The attractiveness of a central repository and therefore the risk of misuse may increase.

The rights of data subjects are set out in Articles 15 to 22 of the GDPR. The rights which the data subject may exercise in each case depend on the legal basis for the processing of personal data in Articles 6(1) and 9(1) of the GDPR. Where the processing of personal data is based on point (c) of Article 6(1) and point (h) of Article 9(2), data subjects have the following rights under the GDPR: the right to information about the processing of personal data (Art. 13-15), the right of access (Art. 15), the right to rectification (Art. 16), the right to restriction of processing (Art. 18) and the right not to be subject to automated decision-making without lawful justification (Art. 22).

The government proposal would not affect the data subject's rights under the GDPR. Instead, the proposal would affect the patient's right under the prescription law to refuse information related to the pharmacy and medicinal product contract.

The proposed provisions will be assessed against the principles of lawfulness, appropriateness, transparency, purpose limitation, data minimisation and accuracy, storage limitation and integrity and confidentiality. The principles have already been implemented in the current Client Information Act and are not affected by the presentation as such, although the proposed limitation of the patient's right to obtain a prohibitory injunction has an impact on the extent to which the information can be disclosed in accordance with Section 13 of the Act on prescriptions.

The processing of pharmacy and pharmacy contract data would be based on Article 6(1)(c) GDPR (legal obligation of the controller) and Article 9(2)(h) GDPR (processing necessary for the provision of health or social care or treatment or for the management of health and social care services and systems on the basis of Member State law). In addition to those grounds, the treatment in a pharmacy for the supply of medicinal products is based on the request of the patient or of a person acting on his or her behalf, in accordance with Paragraph 11(1) of the Law on prescription.

Article 9(3) of the GDPR requires that processing for the purposes set out in point (h) be carried out by a professional who is subject to an obligation of professional secrecy under the law of a Member State. Section 17 of the Health Care Professionals Act (559/1994) lays down the obligation of confidentiality for health professionals. Article 90 of the Law on medicinal products lays down the obligation of professional secrecy for pharmacists and their assistants. As regards the processing of customer data, pharmacies are subject to the principles of Chapter 2 of the Client Information Act on the processing of customer data. Thus, pharmacies must comply with the obligation of professional secrecy laid down in Section 4 of the CIA and the obligation of professional secrecy and prohibition of exploitation laid down in Section 5 of the CIA. Provisions on professional secrecy of social welfare professionals are laid down in Section 15 of the Act on the Status and Rights of Customer of Social Welfare (812/2000).

The fair and reasonable processing of personal data in relation to the purpose of the processing

is achieved by tying the right of social and healthcare professionals and other persons processing customer data to the customer data necessary for the performance of their statutory tasks. The definition of access under the Client Information Act and the Client Information Regulation, in accordance with their statutory tasks, protects the legitimate expectations of data subjects with regard to the processing of personal data in the health and social care sector.

The principle of transparency requires that information about the processing of personal data is provided to the data subject in a clear and comprehensible manner. As regards the provision of information on nationwide information system services, the Medicines Ordinance refers to Section 68 of the Client Information Act, according to which the service provider must provide the customer with information on his or her rights and the nationwide information system services relating to his or her customer data and their general operating principles.

The principle of purpose limitation requires that the purposes of the processing of personal data are defined in advance and that personal data are collected only for specified, explicit and legitimate purposes. Healthcare customer data is processed in accordance with the Client Information Act in force and the prescription act for the performance of statutory tasks. An additional requirement for the disclosure of information on the national medication list is the prohibition right under the prescription act. A new exception to the patient's right to obtain a prohibitory injunction is proposed.

In accordance with the principle of data minimisation, personal data must be adequate, relevant and limited to what is necessary in relation to the purposes for which they are processed. The processing of customer data is limited, on the one hand, by the definition of access rights and, on the other hand, by the verification of the context or the care relationship.

The personal data processed shall be accurate in relation to the purposes for which they are processed and shall be updated as necessary. According to the CIA, the integrity, integrity and non-repudiation of documents must be ensured in the processing, transmission and storage of customer data.

Personal data shall be kept only for as long as they are necessary for the purposes for which the personal data are used. The retention periods for customer documents are laid down in the Annex to the Client Information Act.

The principle of integrity and confidentiality requires that the processing of personal data ensures appropriate security of the data, including protection against unauthorised or unlawful processing and against accidental loss, destruction or damage, using appropriate technical or organisational measures. Technical and organisational measures already in place in the CIA prevent abuse and unlawful access to customer and medical data. The service provider or other registrar processing customer data shall maintain a register of users of its information systems and customer registers used for processing customer data and their access rights. Under the current Client Information Act, in the electronic processing of customer data, persons processing customer data, service providers, IT equipment and nationwide information system services must be reliably identified. The Customer Information Act lays down provisions on the use and disclosure of customer information and on the monitoring of the logs collected. The collection and logging of access and release logs shall ensure that the data subject or any other person performing the logging control is able to verify a posteriori who has accessed his or her data and to address potential abuses. The Customer Information Act already lays down requirements for social and healthcare information systems, which also apply to Kela's national information systems. The Act contains provisions on information security plans, the implementation of information security self-monitoring, the registration of social and healthcare information systems, monitoring after information systems have been put into operation, and essential requirements for information systems, such as the demonstration and

certification of compliance of information systems and the assessment of information security. In addition, the Client Information Act contains provisions on the supervision and inspection of health and social care information systems.

In this proposal, it is proposed to restrict the patient's right to obtain a prohibitory injunction under Section 13 of the Act on prescriptions. If the patient were able to exercise his right of prohibition in relation to the pharmacy and pharmaceutical contract, that would, by its very nature, lead to the termination of the contract in a comparable situation, since the information in the contract would not be available either to other prescribers or to the dispensing pharmacy. That limitation in national law on the patient's right to restrict access to his or her health data would be intended to prevent the pharmacy or pharmaceutical contract between the patient and the health service from being nullified. The restriction concerns a limited use of data; information in the pharmacy and pharmaceutical contract when prescribing or dispensing a medicinal product for ddmmyyyy and narcotic drugs.

In the case of pharmacies, the visibility of information on medicinal products for ddmmyyyy and narcotic drugs would correspond to the extent of the right to information of those who prescribe those medicinal products. The proposed limitation of the patient's right to an injunction for pharmacies would be justified by the fact that it would also be necessary to know about other ddmmyyyy and narcotic drugs at the time of dispensing due to their harmful interactions.

4.2.8 Authority effects

The proposed changes would not add to the tasks of the authorities or would require an immediate increase in resources. However, the implementation of extracts may require, in the initial phase, the concentration of resources, including the updating of instructions and instructions. Fimea should also provide guidance and advice to pharmacy and dispensing operators on the proposed legislative change. It would also be appropriate for the Licensing and Control Agency to inform operators of proposals falling within its remit.

In the longer term, the proposals as a whole would provide greater clarity, streamline the work of public authorities and increase their predictability. For example, key issues related to mechanical dosage distribution in the past have been subject to regulations or instructions, which has led to interpretative challenges. The Act has not identified dosage distribution as an activity that it has created, which has been attempted to manage through regulations and instructions, and has led to a challenging legal situation in practice. Clearer regulation would also lead to greater consistency in the supervision of operators and thus in their activities by providing a clearer description of, for example, the expectations and quality requirements for such activities.

The proposed amendments would also clarify the authority's powers and possibilities to steer the network of pharmacy services, e.g. in the consumption of branch pharmacies and in making the pharmacy licence a condition. However, after the entry into force of the Act, there may initially be applications to change the branch pharmacy, which may cause a temporary workload in Fimea.

The proposed changes would create a need to update several of Fimea's prescriptions, such as on-line pharmacy services, dispensing of medicines and product defects. In the future, it may be appropriate to support the execution of certain matters by an instruction from an authority rather than by an order. The proposed amendments would allow for new prescribing powers, e.g. in relation to machine-dose distribution. This will temporarily increase the need for resources for the Authority's activities, but may streamline the Authority's work over a longer period of time.

The consolidation of the pharmacy functions and the organisational details proposed in the proposal, in order to achieve a safe, high-quality, effective and economic entity for the user of the medicinal product and for health and social care and society, will create development needs for the supervision and information management of pharmacies. It would be appropriate to do this in an orderly, long-term manner. As a result of this development, Fimean could, for example, need to provide guidance on metrics and criteria relating to the quality of pharmacy operations, given the lack of information on quality of service. Fimean could also need to provide guidance on cooperation between pharmacies and social and health services.

This development is also linked to FIMEA's task of providing the Ministry of Social Affairs and Health with the necessary information to assess the financing of pharmacy activities (pharmaceutical tax). Fimea is already in the process of developing the financial data provided by pharmacies, as well as the collection of other data related to pharmacy activities, which will support the implementation of the changes proposed in this proposal.

The regulatory impact assessment has to take into account that Fimea's statutory task is to improve the functioning and safety of the pharmaceutical sector, pharmacy operations and other pharmaceutical services, and the changes proposed in this proposal would only clarify Fimea's tasks in relation to pharmacy operations.

The changes proposed in the presentation may increase the need for FIMEA and the Licensing and Control Authority to cooperate in monitoring and coordinating the information guidance provided, for example, on the website. The provision by pharmacies of services other than those provided on the basis of a pharmacy licence would be subject to registration under Soteri. In cooperation with the online pharmacy service, part of the tasks related to the supply of the medicinal product could also be carried out in cooperation with the Soteri registered operator. The supervision of the cooperation would be carried out between two different authorities, with Fimea supervising the pharmacy and the Licensing and Control Authority supervising the Soteri-registered company. The main responsibility for co-operation on e-commerce would remain with the pharmacy and Fimea would have the possibility to refuse co-operation if it were not regulated. A similar cooperation in supervision is already required at present when Fimea supervises pharmacy operations and the pharmacists working in the pharmacy at the Licensing and Control Authority.

4.2.9 Employment effects

The proposals in the proposal may have some employment-related implications. The proposed regulation of cooperation on the pharmacy's online service could increase the demand for work such as advice and counselling on medicinal products and increase the activity of the companies providing those services, while some of the steps involved in the supply of a medicinal product could be carried out in cooperation with another company. Digital solutions for online services may also increase compared to today, affecting the companies providing them. On the other hand, the proliferation of digital solutions in some pharmacies may mean more efficiency than at present and fewer staff or changes in the organisation of staff work. It is also possible that investing in an online service would mean increasing the number of staff in the pharmacy. The proliferation of online services could also mean a diversification of tasks in the pharmacy sector.

Sales of pharmacies which do not develop their activities in relation to an online service may be reduced if their customers switch to another pharmacy for the purchase of medicinal products and other pharmacy products. This could lead to a need to reduce staff in pharmacies where sales of medicines would fall from the current level. It is also possible that collaboration in the online service would to some extent change the current functioning of the cooperating pharmacies, with a greater focus on pharmaceutical logistics, if the advice related to the supply

of the medicinal product is provided in a collaborative manner. This can have a negative impact on staff retention and attractiveness. It would not be possible to predict which pharmacies will benefit or suffer from the increased use of the online service and the pharmacy would be able to influence the change through its own activities.

4.2.10 Impact on municipalities and wellbeing services counties, regional development and rural impact

The changes proposed in the presentation have an impact on the functioning of municipalities and wellbeing services counties. The task of assessing the functionality, location and adequacy of pharmacy services would be transferred from the municipality to the entity responsible for the organisation of social and health services. However, it might be appropriate for the wellbeing services county to consult the municipality concerned in its assessment. The proposed amendment will ensure compatibility and functionality of pharmacy services with other social and health services and improve the ability of the wellbeing services county to influence pharmacy services in the region. This change may also lead to closer cooperation between wellbeing services counties and pharmacies. Cooperation can streamline processes and, for example, support the design of the service network.

This change may reduce the ability of municipalities to influence pharmacy services in their area. On the other hand, it should be noted that there should be structures for cooperation between municipalities and wellbeing services counties in the region and it should be possible for the wellbeing services county to continue to consult the municipality in its assessment. Municipalities continue to play a role in promoting health and well-being, as well as regional knowledge, which can also be useful for assessing the pharmacy services of the population in the wellbeing services county. It should also be noted that decisions on the authorisation and location of pharmacies would remain the responsibility of Fimea.

The proposed changes may have an impact on rural areas. Changes in the regulation of branch pharmacies can improve the conditions for maintaining a branch pharmacy and thus the availability of medicines in rural areas. Changes to the online collaboration may affect the operation of pharmacies in rural areas, so that by participating in the collaboration, the current level of sales of medicinal products can be increased for rural customers who would in principle order their medicinal products online, but the closest pharmacy has not offered the online collaboration. On the other hand, if the use of the online service becomes more widespread than at present, it is also possible that the financial position of a rural pharmacy would be weakened if its customers switched to buying medicinal products from another pharmacy’s online service. This deterioration would be evident in a situation where rural pharmacies fail to develop their business and cooperation with other pharmacies or the wellbeing services county.

4.2.11 Information Management Effects

The presentation has data management implications for Fimea and Kela’s Kanta services. The Ministry of Finance’s Recommendation on the Assessment of Change Effects of Information Management (VM 2024:21) has been applied in the assessment of the Change Effects of Authorities’ Information Management. The data management implications have been assessed for the following amendments: enabling collaboration in the pharmacy’s online service, transferring the data management of the pharmacy and pharmacy agreement to Kanta services, Fimea’s authorisation and changes in the data management of control activities for the online service of a limited range of self-care medicinal products and for machine-dose distribution, and the change in Fimea’s data access rights for machine-dose distribution. The above-described changes have an impact on the data content, system architecture and data flows of the Kanta recipe centre, as well as on the registers maintained by Fimea.

Enabling cooperation on online pharmacies

Enabling online pharmacy collaboration requires new information from the prescription centre on how to dispense the medicine to the customer. In addition to the new data field, the change would require the prescription centre to record the medicinal product for dispensation at different times and by different organisations and individuals. This would allow for the monitoring and traceability of the process in situations where the pharmacy dealings of the user of the medicinal product involve collaboration as permitted by the amendment to the Medicines Act. If the supply of a medicinal product is divided into two parts, there would be a pharmacy in which the customer starts dealing with the medicinal product, in accordance with the proposed amendment to the Medicines Act, with overall responsibility for the process of supplying the medicinal product. This would mean that the pharmacy is also the controller for the supply and delivery of the medicinal product on all labels. Similarly, the operator with whom the pharmacy cooperates on a contractual basis would be the data processor. This processor of data relating to the supply of a medicinal product should have access to information systems in accordance with the Medicines Act or the Social Security Act and the Customer Information Act.

With the proposed amendment, the dataset of the Reception Centre will be expanded, improving the coverage of medicine supply data at local and regional level. For example, the new data field may allow the production of an indicator on the security of medicines supply from the dataset of the prescription centre.

Agreement on pharmacies and medicinal products

With the proposed changes, the maintenance of pharmacy contracts would now be transferred from the responsibility of the Finnish Pharmacists' Association to the responsibility of the Social Insurance Institution (Kansaneläkelaitos) in the national information management service for Kanta services, to be maintained in a prescription centre.

According to Section 18 of the Act on prescriptions, the Recipe Centre is a joint register of the Social Insurance Institution, pharmacies and ePrescription providers and independent prescribers. The responsibilities of the registrars would also be shared with regard to information in pharmacy and pharmaceutical contracts in the same way as provided for in Article 18.

The Social Insurance Institution is responsible for the availability and integrity of the data in the prescription centre, the intactness of the data content and the storage and destruction of the data. The responsibility for the maintenance and other processing of personal data in pharmacy contracts based on the data controllership of the Finnish Pharmacy Association ceases when the data is transferred on 1 October 2028. The pharmacy agreements are deleted from the SAL's server in accordance with practical processes to be defined after the end of the SAL's custody responsibility.

The model of the pharmaceutical contract would be different from the model of the pharmacy contract. Instead of prescribing the medicine, the contract would be concluded with a healthcare institution with which the patient has a care relationship. The healthcare service would be responsible for the content of the contract. The healthcare unit would be obliged to store the pharmaceutical contract at the prescription centre through a new contract service (interface) in accordance with Section 12c of the Medicines Act. The new contracted service would be limited to contract management and healthcare use only. The Healthcare Service Unit would act as joint controller with Kela in accordance with Section 18 of the Act on prescriptions and would therefore be responsible for recording the accuracy of the data in the pharmaceutical contracts.

The pharmaceutical contract would guide the dispensing of the medicinal product in the pharmacy. The user of the medicinal product could use any pharmacy, unless the medicinal product contract concentrates his activities in a single pharmacy or in a limited number of pharmacies. The supplying pharmacy would be responsible for the accuracy of the delivery data stored in the prescription centre, including in relation to the contract for medicinal products and pharmacies.

An approach based on legislation would take account of the fact that, if a customer were to enter a pharmacy after 1 October 2028 with a pharmacy contract under the old law, the pharmacy would liaise with the care unit and invite a new contract to be concluded. The pharmacy agreements would run until 30 September 2030, i.e. they would remain in force for two years from the entry into force of the Act in the absence of a new pharmaceutical agreement. During a transitional period of two years, all contracted customers should, in principle, have some form of healthcare contact with the healthcare facility where the contract information would be updated.

The legislative approach would also take into account the situation where the patient would still have a pharmacy contract, but the prescriber would not see the need to conclude a new pharmaceutical contract, but would not have the right to terminate the pharmacy contract as it was concluded with another doctor. However, the non-terminated pharmacy contracts would expire by 30 September 2030 at the latest under the proposed amendment to the Law on prescriptions.

The interoperability of information systems and the exploitation of data would be carried out in accordance with the legislation in force for pharmaceutical and pharmacy contracts (including the Customer Information and Prescribing Act). The Recipe Centre and the pharmacy systems would be produced at the same time on 1 October 2028, with the aim of having a national contract interface (web interface) at the time of entry into force of the Act, where healthcare would be able to manage contracts (conclude new pharmaceutical contracts and terminate pharmacy contracts). The new contractual service maintained by the Social Insurance Institution of Finland for the management of pharmaceutical contracts would be regulated in the Client Information Act.

Fimea's registers and right of access

The changes would make it possible to sell certain non-prescription medicines outside pharmacies also on-line. Operators should notify Fimea before starting to sell self-care medicines online. Fimea maintains a register of sales outlets for a limited range of self-care medicines. Adding information about the web service would be a change to the register maintained by Fimea.

The proposed amendments would result in the creation of a new register of mechanical delivery concessionaires in Fimea. As part of the authorisation control, Fimea would gather new information on the operators of mechanical delivery. Key information would be the name, contact details and responsible person details of the company providing the machine-dose distribution. The proposals would extend Fimea's access rights to information to mechanical delivery licensees, who, notwithstanding confidentiality provisions, would have to provide Fimea, free of charge, with the information necessary to carry out its tasks. Fimea would be the controller of the datasets consisting of the information described above. The information collected would be used in Fimea for the supervision of the mechanical dispensing, the processing of licences and other Fimea tasks under the Medicines Act and the Act on the Finnish Medicines Agency.

The new authorisation register would contain personal data that would be retained on a

permanent basis. The rights of the data subject would respect the rights of the GDPR. The change would have no impact on the public access or confidentiality of documents. The information in the register would be treated confidentially. Fimea is bound by an obligation of confidentiality under the Act on the Openness of Government Activities (621/1999) and the Act on the Finnish Medicines Agency. The register would compile the data for the purpose of electronic processing. The data would be protected by data access management, technical protection of databases and servers, physical protection of premises, access control, communication security and data backup. Access and processing rights are granted on the basis of the duties involved. Fimea is also obliged to keep statistics relating to its field of activity, publish indicators and make estimates. The information in the register could be used and published as part of these governmental tasks.

As the construction of a new licensing system, register or control has not yet started, issues related to data management and register changes will be clarified during the implementation of the Act. However, Fimea has several similar registers of operators. This would be a new dataset for operators, which could be implemented either by creating a new register or by extending the existing register of operators. In addition, the proposed amendment would also have implications for other Fimea registers, such as, for example, wholesale registers, as well as for reporting on, inter alia, the distribution of sales by operator and region, the evolution of sales and market shares.

5 Other implementation options

5.1 Options and their impacts

The main objective of the legislative changes proposed in the proposal is to seek to establish uniform principles for pharmacy activities. The current state of regulation is sometimes unclear or incomplete, which justifies the adoption of uniform principles. The principles have been defined largely on the basis of maintaining the status quo, with a view to clarifying, to the level of the law, the pharmacy's functions, which in the past were based on official regulations or on the operators' own initiative. The objectives of the regulatory changes are to ensure the most equal, effective, safe and high-quality operation of pharmacies. An alternative to the proposed regulation would have been to increase the requirements for pharmacy operations beyond the current ones, e.g. to strengthen medication safety and adherence to treatment. However, this would have meant additional obligations for pharmacy operators and additional operating costs. This option would have been challenging in the current context, as from the beginning of 2026, the financial regulation of pharmacies was changed and fiscal savings targets were implemented. Another option would have been to ease the pharmacy's current obligations, but this would undermine the position of users of medicines and their access to support for successful treatment. Moreover, this option would not be appropriate due to the significant challenges to the success of pharmaceutical treatments, which, according to studies, still generate avoidable costs.

The proposal clarifies the status of the services provided in the pharmacy and states that services other than those strictly related to the supply of the medicinal product require the pharmacy to register with Soteri. An alternative model would be that all services based on the pharmaceutical competence of the pharmacy could have been provided under a pharmacy licence, e.g. pharmacy assessment and various hospitalisation services. However, this was abandoned in the course of the preparation of the presentation, as the situation was found to be problematic from the point of view of competitive neutrality in the conduct of business. In addition, this situation would have led to a different authority being involved in the registration and supervision of the same service, depending on whether the service is provided in a pharmacy (Fimea) or, for example, by a pharmacist as a self-employed person (Authorisation

and Supervision Authority). The chosen model also clarifies the regulation of data management in relation to the use of patient data and allows for a smooth further development of the necessary extension of the use of patient data in pharmacy operations.

The cooperation that could be made possible by the online pharmacy service could have been limited from the proposed one, so that only pharmacies could cooperate on the online service, also in place of other Soteri registered operators. However, the broader option chosen is justified not only from the point of view of the freedom to conduct a business, but also because it is actually possible to carry out some of the steps involved in the supply of a medicinal product outside the pharmacy, provided that there is cooperation with an operator who satisfies the requirements of the Medicines Act, such as those relating to pharmaceutical personnel and tools, and those relating to information management under the Client Information Act.

As regards the development of the management of pharmacy contracts, one alternative to the proposed regulation would have been to leave the legal situation unchanged. In that case, the transfer of contract management to Kanta services, which was a longer-term and more permanent objective, would not be achieved.

5.2 Foreign law and other means used abroad

Pharmacy systems and regulation differ from one country to another. In principle, the operation of a pharmacy is subject to authorisation or registration and the services are provided by a pharmacist. A key function of pharmacies is the distribution of prescription medicines and patient guidance. The way in which each country organises health services and finances medical care has an impact on the organisation and regulation of pharmacy activities. In the inventory of foreign legislation, countries were selected in which the way pharmacy operations are organised is in line with practice in Finland, as well as countries that deviate from this.

5.2.1 Pharmacy activities and functions of pharmacies

Sweden

The basic statutory task of an outpatient pharmacy is to ensure the availability of medicinal products and products to consumers as soon as possible, to provide expert and personalised advice and information, to carry out and inform the exchange of medicinal products and to adapt its stock to consumer needs so that as many customers as possible can be served directly (Law 2009:366). Trade in medicinal products shall be conducted in such a way that they do not harm people, property or the environment and that their quality is not impaired.

The general requirements for the operation of pharmacies have recently been amended, including as regards the provision of advice on medicinal products. The regulation will enter into force in September 2028 (Act 2025:923). The regulation requires one or more pharmacists to be present during the opening hours of the pharmacy. Premises should be functional and privacy-preserving when giving advice. Medicinal products and other products shall be delivered to the customer as soon as possible. A responsible person must be appointed for the pharmacy. The pharmacy must also carry out self-monitoring and maintain a self-monitoring programme. The pharmacy shall offer the customer the possibility of partial payment for medicinal products and reimbursable products and shall provide personalised advice on medicinal products by qualified staff independent of the manufacturer. The customer shall be informed of the pharmacy at which the medicinal product is available if delivery is not immediately possible. The activity must meet the requirements of other regulations (e.g. data management, drug control, pharmacovigilance regulation, veterinary medicines regulation)

Pharmacy activities are subject to age control. Non-prescription medicines with the only active

substance nicotine (nicotine medicines) cannot be sold to people under 18 years of age. When selling nicotine medicines, you must ensure that the consumer is at least 18 years of age. The sale of syringes or needles to persons under 20 years of age is only allowed if the purchaser can prove that the products are necessary for his or her own medical use or that of a member of his or her family.

Norway

[To be completed after consultation.]

Iceland

[To be completed after consultation.]

Denmark

In Denmark, the basic tasks of pharmacies fall into six categories: access to and distribution of medicines, pharmaceutical safety and advice, environmental liability, data generation and institutionalisation, training and skills support, and quality management of operations (LBK 703/2023).

The pharmacy is mainly responsible for the sale of medicines to consumers. In addition, the pharmacy supplies dosage-distributed medicinal products. A key part of the pharmacy's role is to advise on and promote the safety of medicines. The pharmacy provides consumers, healthcare professionals and public authorities with information on medicinal products, their use, storage and prices, as well as information on possible cheaper interchangeable medicinal products and price differences. The pharmacy provides guidance to people with chronic diseases and advises consumers on how to report adverse drug reactions to the authorities. The pharmacy is also obliged to comply with risk management programmes for medicinal products and to notify the authorities without delay of suspected or potentially falsified medicinal products.

The pharmacy contributes to environmental and social responsibility by receiving pharmaceutical waste from consumers for its proper disposal. In addition, the pharmacy produces and supplies to the authorities, in accordance with the regulations, information in a machine-readable format on the sale and distribution of medicinal products, supporting healthcare planning, monitoring and statistics.

The pharmacy may also issue the necessary certificates for travel within the Schengen area. As part of skills development and ensuring continuity of pharmaceutical supply, the pharmacy provides practical training and internships for students. The quality and effectiveness of the pharmacy's activities are supported by the obligation to set service objectives in accordance with the official instructions and to ensure that they are implemented.

In Denmark, pharmacists can operate in pharmacies with a knowledge-based extended remit, including to ensure the continuity of medical care and the replacement of the machine dispensing service (LBK 1008/2024, BEK 688/2020).

Pharmacies must provide patients with medication chats designed to support patients' understanding of, adherence to, and appropriate use of their medication (BEK 1563/2024). The pharmacy shall record and report the number of discussions of medicinal products that have taken place, as well as those cases where the discussion has not taken place within the prescribed time limit.

Denmark is currently running a nationwide and free-of-charge experiment with the telephone

helpline (BEK 1324/2025). The service will answer questions related to medicines from healthcare professionals and relatives dealing with patients' medication. Pharmacies can apply to provide a telephone helpline. The Agency shall coordinate the whole.

Netherlands

In the Netherlands, pharmaceutical services are part of the public regulated health system. As a rule, pharmacies are private, guided by national regulations to ensure the distribution of medicines, patient safety and professional qualifications. Self-medication can be sold by trained healthcare sellers, who have the right to sell self-medication and the obligation to provide advice outside the pharmacy. In exceptional cases, prescribers may also dispense medicines if pharmacy services are not available. Sales of medicinal products fall into three categories: medicinal products subject to medical prescription which are supplied only in a pharmacy or by a doctor authorised to operate a pharmacy, medicinal products for self-care which may be sold only in pharmacies and in a shop operated by a person with separate competence for the sale of health products, and medicinal products for general sale which may also be sold outside pharmacies. The purpose of classification is to reconcile the availability and safety of medicinal products.

The provision of pharmaceutical services requires both the registration of an organisation and the legal registration of professionals. Pharmaceutical services are registered together with other health services. Registration (Online Suppliers of Medicines) is also required for the online service. Only qualified operators can sell medicinal products online and are included in an official list of authorised online operators.

The pharmacy's main tasks are the dispensing of prescription-only medicinal products on prescription, the sale of non-prescription medicinal products, the proper storage and, where appropriate, the preparation of medicinal products, advice to patients on the correct and safe use of medicinal products, the promotion of safety of medicinal products and the prevention of errors.

In the Netherlands, the quality of pharmaceutical care in community pharmacies has been measured annually through quality indicators since 2008 (Teichert Martina, et. al. Quality indicators for pharmaceutical care: a comprehensive set with national scores for Dutch community pharmacies. INT J Clin Pharm. 2016 Aug;38(4):870-9. doi: 10.1007/s11096-016-0301-x. Epub 2016 Apr 23. PMID: 27107583; PMCID: PMC4929158). The metrics are widely research-based and developed in collaboration with pharmacies, public authorities, researchers and patient organisations. Analysis on the basis of metrics is compiled on a regular basis.

Estonian

The general tasks of pharmacies are laid down in the Medicines Act (Ravimiseadus). According to the Law on Medicinal Products, a pharmaceutical service means the retail or supply of medicinal products which includes advice on the appropriate and rational use of medicinal products and on the safe use and storage of medicinal products for the user of the medicinal product. Pharmaceutical services also include the manufacture and distribution of medicinal products. In principle, pharmacy services can be provided only by pharmacists and pharmacists in a licensed pharmacy.

United Kingdom

The NHS (National Health Service) is a public health system in the United Kingdom (UK) divided into four regional divisions in England, Scotland, Wales and Northern Ireland. The system provides most of the healthcare, including pharmacy activities. Laws and regulations

are binding on the UK as a whole. In addition, each region has its own complementary regulation. The National Institute for Health and Care Excellence (NICE) develops national recommendations and provides guidance to improve the quality of health and social care, including on medication safety and effectiveness of medication. The General Pharmaceutical Council (GPhC) is an independent professional regulatory authority established by law that issues standards, guidelines and regulations for pharmacies, such as personnel, pharmaceutical manufacturing and remote services (available at: https://www.pharmacyregulation.org/pharmacies/standards-and-guidance-registered-pharmacies).

In the UK, pharmaceutical services are an integral part of the NHS. Pharmacies operate as publicly funded, but privately provided, health services whose mission is not only to supply medicines, but also to promote medication safety, continuity of care and access to healthcare. The National Health Service, Pharmaceutical and Local Pharmaceutical Services Regulations 2013. The Regulation determines who is allowed to provide pharmaceutical services, where and under what conditions, how activities are monitored and how the remuneration and fees for the service are determined (separate Drug Tariff). Regulations can also be found in the Medicines Act 1968 and the Health Act 2006.

A pharmacy is an operator authorised to provide NHS pharmaceutical services as defined by law and contractual conditions (The National Health Service, Pharmaceutical and Local Pharmaceutical Services, Regulations 2013). The majority of pharmacies are private service providers operating under a contractual relationship with the NHS. The agreements are the key determinants of the content of pharmaceutical services. The doctor can also dispense medicines and online pharmacy operations are possible. There are three baskets of pharmaceutical sales in the UK: prescription medicines, self-care medicines sold by pharmacies and also medicines sold elsewhere in the retail trade (general sales list).

All NHS contracted pharmacies are obliged to provide at least the following basic services: 1) dispensing prescriptions, 2) counselling and self-care guidance and safe delivery of medication, and 4) repeat dispensing. The NHS maintains contractual terms defined by region (England, Scotland, Wales and Northern Ireland (e.g. NHS England Pharmacy Quality Scheme). Pharmacies may also offer additional reimbursable services on a contractual basis if they fulfil separate requirements, such as: (1) New Medicine Service, (2) Influenza vaccination, (3) Pharmacy First, (4) Discharge Medicines Service. In addition, regional authorities, separate from the NHS, and programmes such as continuity of care, can finance services related to substance abuse, palliative care, prevention and health counselling.

In pharmacies, incident reporting is mandatory. Pharmacies must comply with NHS patient safety strategies and contractual obligations regarding quality and safety work. The NHS encourages pharmacies to engage in evidence-based activities, improve medication safety, monitor high-risk medicines and develop customer experience as part of the NHS England Pharmacy Quality Scheme. For example, NHS England and NICE maintain guidelines on patient-level drug management (NHS England Medicines optimisation, NICE Medicines optimisation).

5.2.2 Online pharmacy activities in different countries

In 2021, the Nordic competition authorities published a report (Joint Nordic Report) examining online pharmacies and distance sales of medicines from a competition perspective. The STM has published a progress report on the regulation of online pharmacy activities and distance sales of medicines in the Nordic countries (STM 31/2021).

In all Nordic countries, online pharmacy activities and distance sales of medicines are based on

a three-tier regulatory approach. The law sets fundamental rights and restrictions (who can sell what can be sold, licensing requirements). The Decree clarifies the application of the law (e.g. distance selling practices, delivery, transport). Regulations and instructions issued by public authorities specify detailed technical and operational requirements (advice, identification, website, data protection).

The regulation of online pharmacies varies from one Nordic country to another, affecting the market in Sweden and Denmark allowing pharmacies operating only online, which have rapidly reached a share of 10-20 % of the pharmaceutical market in Sweden. In contrast, pharmacies operating only online in Denmark had not achieved a significant market share. In other Nordic countries, operating online pharmacies requires a brick-and-mortar pharmacy licence and online pharmacies are not allowed.

In all Nordic countries, pharmacies are allowed to sell self-medication online. Sweden, Norway and Denmark also allow online sales of non-pharmacies (e.g. retailers), subject to certain conditions. In Sweden, an online shop does not require a licence but requires a notification to the authority. In Norway and Denmark, authorisation or notification from the authorities is required and only a limited list of medicinal products is allowed. In Iceland, the online sale of non-prescription medicines is only allowed to pharmacies.

Pharmaceutical pricing has been partially liberalised in other Nordic countries, except Denmark. The exemption has increased the possibility for consumers to compare prices not only between online pharmacies, but also between online pharmacies and brick-and-mortar pharmacies.

Sweden and Denmark have recently reformed their regulation of online pharmacy activities. In Sweden, provisions have been specified to ensure that, in the case of distance selling, among other things, the medicinal product meets the requirements of the legislation of the country in which it is sold (Act 2009).

The operation of online pharmacies is regulated in more detail by decree and by order of the pharmaceutical authority. The information system requirements for the web service in Sweden are specified in the Act (2009:366) on the marketing of medicinal products and the Decree (2009:659) detailing this. The E-hälsomyndigheten maintains a national list of medicinal products, to which pharmacies also have access in respect of prescriptions for patients and other information necessary for dispensing a medicinal product.

In recent years, pharmacy activities in Denmark have undergone a number of reforms. In 2021, the E-Commerce and Medicines Supply Regulation was reformed (BEK 2467/2021). A number of changes were made, including: pharmacies and other authorised operators are required to make a separate notification to the pharmaceutical authority about the start and end of online sales of medicinal products, detailed content and identification requirements were imposed on websites, including the official EU online sales logo and the extension of regulation to online sales of veterinary medicinal products, which were previously less regulated. In addition, from 1 July 2025, the pharmacy was required to attach written medical advice material to the supply of a prescription-only medicinal product. The material must be personalised (including age, sex, posology, indication, etc.), going beyond a simple repetition of the package leaflet or the web link, and be part of the delivery of the medicinal product, including when the product is collected at the point of delivery after an online order.

The amendment to the Danish Pharmacy Act (LBK 703/2023) strengthened and clarified the position of online pharmacies compared to the previous one. Pharmacy activities can be carried out exclusively online, but are subject to specific restrictions and conditions. In addition, provisions on who may use the designation ‘apotek’, under what conditions and how this also

applies to digital services and domain names, have been added and specified in the Pharmacy Act. The aim has been to prevent misleading marketing and strengthen consumer protection online.

As a result of the operational change, Denmark has reformed its regulations governing data management in remote services in 2023 and 2024 (LBK 339/2023, BEK 827/2024). The changes provided the legal basis for a safer and smoother online supply of medicines. Provisions on electronic prescriptions and their use for online delivery were set out in full, requirements for dosage delivery and remote delivery were specified, and the ability of public authorities to react to supply and availability disruptions was improved (e.g. by limiting the quantities to be delivered at once, including online).

In addition, Denmark provided clarifications in 2024 on the operating conditions and responsibilities of the online service (BEK 816/2024). The amendments strengthened the requirements for organisational separation, i.e. operating under the pharmacy's own responsibility and on its own account, and not just being part of a larger retail, logistics or e-commerce group, while the pharmacy itself is responsible for the quality, safety, advice and responsibilities of the authorities, including in digital activities. In addition, the pharmaceutical liability for distance selling was clarified and the supervision of pharmacies supplying medicinal products by post and their subcontracting chains was clarified.

Estonian

As in the Nordic countries, the operation of online pharmacies in Estonia is subject to authorisation by the pharmaceutical authority on the basis of an application. Distance selling covers medicinal products for human use as well as veterinary medicinal products for self-care. Online pharmacy activities must comply not only with pharmaceutical legislation, but also with legislation on information society services, contract law and consumer law.

The pharmacy shall offer uniform conditions of sale and supply throughout the territory of Estonia, in particular as regards delivery charges. The medicinal products must be delivered to the customer within three working days of the confirmation of the order, unless the customer requests a later delivery or the delay is due to circumstances beyond the control of the pharmacy.

United Kingdom

In the United Kingdom, online pharmacies do not constitute a separate activity but are subject to essentially the same requirements as pharmacies providing physical services, supplemented by specific requirements relating to remote services. The web service shall be registered with the medicinal products authority. GPhC Instruction (2025) specifies requirements for an online service, in particular: the use of telemedicine and digital channels, the provision of medical advice and risk assessment without physical contact, patient identification and access to information, and the sharing of responsibilities and professional judgement in remote services.

General Sales List (GSL) medicines can also be sold remotely. Online sales must comply with the approved marketing authorisation and packaging restrictions, e-commerce regulation, consumer protection, etc. Remote service requires registration with the Medicines Authority's authorised online sellers register.

[To be completed after consultation.]

5.2.3 Mechanical dispensing

Sweden

In Sweden, mechanical dispensing is subject to authorisation and is part of the pharmacy business. A prescription from the pharmaceutical authority directs the activity. The Order concerns the application for authorisation of a mechanical dosage distribution, the implementation of the dosage distribution, personnel and skills, facilities and equipment, returns, complaints and recalls, self-monitoring and quality system, and documentation and archiving.

Denmark

In Denmark, in the case of a machine-based dispensing service, the customer must be provided with written medical advice material, but only for the first delivery of a new medicinal product and for the first delivery after a change to the prescription for dispensing.

Netherlands

In the Netherlands, mechanical dispensing is not regulated as a separate service, but is considered to be part of the preparation and supply of pharmaceuticals by a pharmacy. It is therefore subject to the same essential rules as other pharmacy activities and the manufacture of medicinal products by pharmacies. In addition, the activity is guided by a separate standard defining requirements for, inter alia, the packaging and identification of medicinal products, the information systems and software used (prevention of errors, timeliness of data), verification procedures (automatic and manual checks), change management when medication is changed in the middle of a dosage distribution period and quality assurance and documentation.

The standard aims to minimise the risks associated with dosage distribution and is also used to monitor the service.

[To be completed after consultation.]

5.2.4 Pharmaceutical contract

The Swedish Medicines Agency’s order restricts the right to prescribe and dispense certain medicinal products from a pharmacy in order to ensure patient safety. The prescription requires that certain medicinal products may only be prescribed by a doctor with specific qualifications. Narcotic drugs intended for the treatment of opioid addiction may be dispensed from a pharmacy only, as a general rule, on the basis of a medical prescription issued by a qualified prescribing pharmacy and issued at an establishment engaged in the treatment of drug-assisted opioid addiction and duly registered.

[To be completed after consultation.]

6 Opinion feedback

[To be completed after consultation.]

7 Explanatory memorandum for each provision

7.1 Act amending the Medicines Act

Article 12a. The current section 12a regulates the requirement for a licence for machine-based dosage distribution and contract preparation in pharmacies and hospital pharmacies. It is proposed that the section be amended so that authorisation requirements for mechanical dispensing are laid down elsewhere in the Medicines Act. The current regulation on contract manufacturing would remain in place.

Article 12b. It is proposed to lay down in a new Section 12b the requirements for the authorisation of a machine-based delivery system and the conditions for the authorisation of a delivery unit. The mechanical dispensing of medicinal products is an approach whereby a pharmacy or a hospital pharmacy delivers the patient's medicinal products in machine-distributed packaging per dose. Mechanical dispensing is the repackaging of pharmaceutical products which is separate from the operation of pharmacies or hospital pharmacies. Under subsection 1 of the section, the mechanical dispensing of doses is subject to a licence issued by the Finnish Medicines Agency.

Authorisation should be granted by the Finnish Medicines Agency if the conditions laid down in points 1 to 3 of paragraph 2 of the proposed article are met. According to paragraph 1, the granting of a concession for a dose distribution unit would require the applicant for the concession to be a public law body, a sole trader or a legal person registered in the commercial register pursuant to Section 3 of the Trade Register Act (564/2023). In addition, according to the proposed paragraph 2, the granting of a licence for a dosage distribution unit would require the applicant to have appointed a responsible person with sufficient knowledge of the mechanical dispensing service for medicinal products or of the industrial manufacture of medicinal products. The requirement to designate a responsible person would be consistent with the industrial manufacturing of medicinal products. The role of the responsible person would be laid down in a new Section 12 g. According to the proposed paragraph 3, the premises, equipment and personnel of the dosage distribution unit should comply with the conditions laid down in the Medicines Act and the acts adopted on the basis thereof. The requirements for the facilities, equipment and personnel involved in the activity would be largely in line with the conditions for the industrial manufacture of medicinal products.

The proposed section would mean, for the purposes of the current legal situation, that the authorisation of a mechanical unit for the distribution of doses could be obtained not only by the entities currently authorised by law (pharmacy and hospital pharmacy) but also by other entities which have already actually provided them with a packaging service for the distribution of doses. It would not be proposed to allow the holder of a Dose Distribution Unit licence to supply medicinal products to users of the medicinal product or to social and healthcare institutions. The proposed regulation would not change the current situation, where the supply and release for consumption of medicinal products require a separate authorisation or right.

Article 12c. It is proposed to regulate the application for a concession for a dose distribution unit in a new Section 12c. According to subsection 1 of the section, the authorisation for the supply of mechanised doses should be applied for in writing from the Finnish Medicines Agency. According to subsection 2 of the section, the documents accompanying the application or the application should include the applicant's basic details and details of the dosage distribution unit, the person responsible and a description of the premises, equipment and personnel of the dosage distribution unit, as well as an estimate of the extent of the activity. The information would be relevant for the assessment of whether the applicant for authorisation fulfils the conditions attached to the authorisation. Subsection 3

proposes to provide for a regulatory power for the Finnish Medicines Agency. The authority could issue instructions on the content, form and attachments of the application.

Article 12d. According to the proposed Section 12d, the licence of a dosage distribution unit would be valid indefinitely.

According to subsection 2 of the section, the licence holder should notify the Finnish Medicines Agency in writing of any changes in the licence holder and in the implementation of the mechanical dispensing system that materially affect compliance with the conditions of the licence. The change to be notified to the authority would include, for example, a significant increase in production volumes, the purchase of new packaging machinery or the introduction of new technologies. The change should be implemented unless, within 60 days of receipt of the notification, the authority has requested further information on the matters referred to in this section or has prohibited the change of activity.

Article 12e. The concession holder of the Dose Distribution Unit should ensure compliance with the requirements of the proposed Section 12e. In practice, the licence holder should organise its activities in such a way as to ensure compliance with the obligations, for example through regular audits of operations and information systems to ensure compliance.

According to subsection 1 of the proposed section, the dosage distribution unit should operate in accordance with the Good Manufacturing Practice (GMP) for medicinal products, the purpose of which is to ensure that medicinal products are always manufactured in a safe, uniform and regulatory manner. In the case of mechanised dispensing of medicinal products, it would not be necessary to apply all good manufacturing practices governing the industrial manufacture of medicinal products. The activity of machine-based dispensing services consists, in principle, in the repackaging of a medicinal product in sachets on a per-user basis. The general GMP requirements for pharmaceutical quality systems, personnel, facilities, equipment, documentation, production, quality assurance, service purchase, complaints and product recalls and inspections would apply. In addition, in the case of mechanical dispensing, the guidelines on Good Manufacturing Practices (GMP) for the industrial manufacture of medicinal products should be applied with regard to risk management.

According to subsection 2 of the section, the licensee of a dosage distribution unit should ensure the suitability of the premises and equipment of the dosage distribution unit for the activities of the dosage distribution service. Non-pharmaceutical regulation could also become obligations that the Dose Distribution Unit should take into account in its activities, e.g. data protection regulation. The consent holder should also ensure the adequacy and competence of the personnel providing the service and the fulfilment of the operational quality requirements. In addition, the consent holder should ensure appropriate handling, protection, integrity and other factors affecting the quality of the information systems used and the data contained therein. The concession holder of the Dose Distribution Unit should also be responsible for incident handling, including identification, reporting, clearing, corrective and preventive action and documentation of incidents.

Subsection 3 proposes to provide for a regulatory power for the Finnish Medicines Agency. The authority could issue more detailed regulations on the requirements for industrial manufacturing operations.

Article 12f. Under the first paragraph of the proposed section, the Dose Distribution Unit would be allowed to purchase medicinal products for its activities from a pharmaceutical factory or from a wholesaler of medicinal products and to agree on the conditions for the purchase of medicinal products. It is proposed that the Dose Distribution Unit has a clear and autonomous right to obtain medicinal products. The Dose Distribution Unit could operate

directly with pharmaceutical laboratories or wholesalers without any separate restrictions.

The purpose of subsection 2 of the proposed section is to describe the general principles that would guide the composition of the range available to the dosage distribution unit. Products used in dosage distribution should be suitable for dosage distribution. The Dose Distribution Unit would itself determine the range of medicines it uses, as well as the approaches to portfolio management, as is the case under the current regulatory framework. The formulation of the range of medicinal products to be used in a dose distribution unit should take into account national treatment practices and economics from the point of view of society and the user of the medicinal product. In the case of machine-based dispensing of out-patient care, the selection of medicinal products covered by health insurance and authorised for marketing, which are covered by the exchange of medicinal products and the reference price system, should, in principle, be made when making the selection. Departures from the starting point should be justified, as dosage distribution is mainly financed by public funds and the choice of medicinal products cannot be influenced by the user of the medicinal product or by the pharmacy supplying the medicinal product. National treatment practices should be taken into account when making the selection, thus supporting the fulfilment of the therapeutic needs of the user of the medicinal product.

The purpose of subsection 3 would be to oblige dosage-distributing units to ensure continuity of medical care for users of the service in the event of a planned or sudden change in the range of medicinal products. Interaction with healthcare, pharmacies and, where appropriate, public authorities in relation to selective management would facilitate exchanges and support continuity of medical treatment. The Dosage Distribution Unit should seek to be proactive, e.g. in the event of shortages.

Paragraph 4 provides for the right of a pharmacy and a hospital pharmacy to obtain medicinal products from a dosage distribution unit. Unlike the wholesale distribution of medicinal products, mechanised dispensing distributes medicinal products from entire sales packages to individual bags. It is not proposed to change the pricing of medicinal products distributed in accordance with Section 37a, which is established in the case of mechanical dispensing. The pharmacy would continue to purchase the medicines mainly at a fixed wholesale price. The pharmacy or hospital pharmacy would be responsible for the delivery of the dosage-distributed medicinal product to the user of the medicinal product, in which case the status quo would be maintained.

Article **12 g.** It is proposed that provision be made for the responsibilities of the person responsible for the dosage distribution unit and for restrictions on the performance of other tasks. According to subsection 1 of the proposed section, the responsible person should be responsible within the entity for the compliance of the packaging operations with the law. Medicinal products packaged must be of sound quality. In addition, the responsible person is responsible for ensuring compliance with the provisions and regulations laid down under the Medicines Act and the Act.

It is proposed in subsection 2 that provision be made for the qualification requirements for the position of responsible person appointed by the concession holder of a dosage distribution unit with regard to university degrees and professional experience. The responsible person should be an authorised pharmacist. The responsible person should have pharmaceutical competence, knowledge of social and healthcare and of the medication reimbursement system for health insurance in order to be able to fully assess the impact of dosage distribution activities on patient safety, continuity of care and the economy of medication. In addition, the responsible person would be required to have been involved for at least one year in the packaging or quality assurance of medicinal products or in the industrial manufacture of medicinal products in the context of dosage distribution.

In accordance with the third paragraph of the section, the person responsible appointed by the holder of the concession for the dispensing unit could not, when acting in that capacity, be the manager responsible for the wholesale distribution of medicinal products or the pharmaceutical factory of another company, or be a pharmacist, the operator of a hospital pharmacy or a pharmaceutical centre, the manager of a military pharmacy or the operator of a pharmacy or a branch pharmacy, or the holder of a retail licence for non-prescription medicinal products, a member of its management or the person responsible for the sale of non-prescription medicinal products. The regulation would mainly be similar to the other responsible person regulations in the Medicines Act.

As the responsible person is a key actor in the quality assurance of the dosage distribution unit, the authorisation holder should notify the Finnish Medicines Agency without delay in the event of a change of person.

Article 12h. It is proposed to add a new Section 12h to the Medicines Act, which would provide for an obligation for the dosage distribution unit to appoint a new responsible person within the meaning of 12 g if the Finnish Medicines Agency finds that the responsible person is performing his or her duties inadequately in such a way that it may pose a risk to patient safety. A compromised patient safety could occur, for example, through repeated occurrences, documentation, processes or significant deficiencies in the devices and systems used. Mechanical dispensing involves a heightened duty of care compared, for example, with the packaging activities of a pharmaceutical factory, since dispensing consists of the targeted packaging of several different medicinal products for an individual patient, usually within a two-week cycle, and the medicinal products are delivered as such to the user of the medicinal product. There are several possibilities for errors in the mechanical dosage distribution process and even minor deviations or negligence in the process may endanger medication or, more broadly, patient safety.

Article 12i. The section would lay down the conditions for withdrawing the authorisation of a dosage distribution unit. According to subsection 1 of the section, the Finnish Medicines Agency should withdraw the licence of a dosage distribution unit if the holder so requests. The withdrawal of the authorisation would be subject to the condition that the dose-distribution unit has ensured that the patient safety of the customers using its service is not compromised. When withdrawing an authorisation, the authorisation holder should adequately demonstrate that it has contributed to ensuring patient safety in its customer base, for example by ensuring continuity of pharmacological treatment before the termination of the activity.

Subsection 2 of the section would lay down discretionary grounds for the authority to withdraw the authorisation. Situations leading to the withdrawal of an authorisation should be of significant severity and therefore dosage distribution could no longer be considered safe. Under the first subparagraph of subsection 2 of the section, the Finnish Medicines Agency could revoke the licence of a dosage distribution unit if the conditions for granting the licence are no longer met. This could be the case, for example, if the quality requirements assigned to the activity, for example in terms of facilities, equipment or systems, are non-compliant, if the dosage distribution unit does not have a sufficient number of suitably qualified staff, or if the dosage distribution unit has not appointed a person responsible for its activity. Under subsection 2(2), the Finnish Medicines Agency could withdraw the authorisation of a dosage distribution unit if the holder of the authorisation has repeatedly or seriously infringed the provisions laid down in or pursuant to the Medicines Act. For the purposes of this paragraph, it should be assessed whether the continuing non-compliance or individual breach is sufficiently serious to compromise the safety of the dosage distribution service.

According to subsection 3 of the proposed section, the permit holder should be given a reasonable period of time to remedy the omission or omission referred to in subsection 2,

paragraphs 1 and 2 of the section, if it can be remedied. The permit authority could revoke the permit if the permit holder has not remedied the deficiency or omission within the deadline. The purpose of the proposed regulation would be to support the possibility of regulatory compliance and to create the conditions for action by public authorities.

According to subsection 4 of the section, the Finnish Medicines Agency could issue a written warning to the holder of the authorisation in the situations referred to in subsection 2 instead of withdrawing the authorisation if the withdrawal of the authorisation would be disproportionate in the circumstances. For example, a single instance of non-conformity, unless the gravity of the non-conformity is otherwise due, would not be sufficient to trigger the consideration of withdrawal of the authorisation. The provision on written warning would oblige the authority so that, if the conditions of the provision are met, the written warning should always be given instead of the withdrawal of the authorisation. It would not be possible for the consent holder to plead unfairness if more than two written warnings had previously been issued.

ARTICLE 15. It is proposed that the section be amended so that the conditions for the authorisation of a dosage distribution unit are laid down elsewhere in the Medicines Act. The current regulation on contract manufacturing would remain in place. It is proposed to amend subsection 1 of the section in order to remove the reference to automatic dosage distribution.

30 Article **o.** The section regulates the reporting of product defects and suspected falsified medicinal products. It is proposed to add to subsection 2 of the section a power to issue an order concerning the handling of product defects and suspected falsified medicinal products. As the law currently stands, the power to issue orders covers only the procedure for notifying them. In addition, it is proposed to add a prescribing power to the Medicines Act regarding the notification and handling of the recall of a medicinal product. For the rest, it is not proposed to amend the section.

31 §. The section governs the right of a pharmaceutical company to supply pharmaceutical substances and preparations. In the current state of the Medicines Act, it is not possible to sell or otherwise hand over pharmaceuticals from a pharmaceutical factory and its own pharmaceuticals to a dosage distribution unit. It is proposed to amend subsection 1 of the section in order to include the dosage distribution unit among the operators to whom the pharmaceutical company may supply medicinal products. For the rest, it is not proposed to amend the section.

32 §. The definition of wholesale distribution of medicinal products is laid down in the section. It is proposed to amend subsection 1, paragraph 2 in order to include the dosage distribution unit among the entities to which a wholesaler could distribute medicinal products. It is also proposed to add the holders of retail licences referred to in Section 54f of the Medicines Act and those entitled to sell nicotine products to whom the wholesaler can already distribute medicinal products as the law currently stands. For the rest, it is not proposed to amend the section.

Article 38b. The proposed article would be new. The purpose of this section would be to specify and consolidate the main tasks of pharmacies and how these tasks should be carried out. The tasks of a pharmacy would refer to what activities in the pharmacy and in its branches, including the online service of the pharmacy, should be carried out. No new tasks would be assigned to the pharmacy, nor would the established division of tasks in prescribing and dispensing be changed.

Paragraph 1 would bring together the essential functions that unite all pharmacies. Under points 1 to 2 and 4 of the first paragraph of that article, the tasks of the pharmacies are to ensure the supply of medicinal products, including the provision of advice and advice on

medicinal treatment, and to ensure the storage and accessibility of the equipment, consumables and bandages necessary for the use of medicinal products and medicinal products, as provided for in Article 55 of the Law on medicinal products. The pharmacy's task would be to supply medicinal products not only to the public but also to social and healthcare institutions. Guidance and counselling on medication is part of the supply of the medicine and is particularly important in ensuring medication safety and supporting adherence to treatment when supplying medicines to the public.

The purpose of subsection 1(3) would be to clarify the role of pharmacies in supporting self-care by the customer and planned self-care with a healthcare professional. For example, a pharmacy should provide a self-care assessment of the need for care, supported by a pharmacy professional, to recommend and guide the customer on the use of a specific self-care product, or support the customer in self-care without selling the product, or refer the customer to healthcare as appropriate. According to point 5 of subsection 1 of the proposed section, the pharmacy should also carry out other specified tasks. As things stand at present, this is the case, for example, with the issue of a Schengen certificate under Article 55a of the Law on medicinal products. In addition, the pharmacies of the University of Helsinki and the University of Eastern Finland have separate responsibilities.

The purpose of subsection 2 would be to lay down the essential principles for the performance of the pharmacy's statutory tasks. A pharmacy should seek to carry out the tasks assigned to it by law in such a way that its activities constitute a safe, high-quality, effective and economic entity for the user of the medicinal product and for the health and social care sector, as well as for society.

The activity of the pharmacy directly affects the user of the medicinal product when the pharmacy advises on the correct and safe use of the medicinal product or when the pharmacy carries out an exchange of medicinal products. The outpatient drug treatment process may involve a wide range of professionals and organisations, and as part of this process, the pharmacy is integrated into the social and health services system. The activities of the pharmacy should support doctors, nurses and other socio-professionals involved in the pharmaceutical treatment process. Establishing the functions of the pharmacy and the principles governing the exercise of those functions in accordance with subparagraphs 1 and 2 would require adequate cooperation between the pharmacy and the provider of social and health services. This cooperation would relate, for example, to R & D in the outpatient drug treatment process and other network work in the region. It could be appropriate to agree on regional practices that specify common national approaches in order to streamline pharmaceutical treatment processes and ensure the success of pharmaceutical treatments. This would ensure, for example, that, for each wellbeing services county, the pharmacy's advice and advice on medication is consistent with the advice and guidance provided in the social and healthcare sector.

According to subsection 3, the performance of the tasks of pharmacies should be based on evidence and good management and operational practices. The purpose of this paragraph would be to confirm that the performance of the pharmacy's tasks is based on national management guidelines, such as the 'Fair Care' recommendations or, if sufficient scientific evidence is not available, on the best available evidence and generally accepted practices in the light of the situation. The aim would be to guide the range of services and self-care products offered by pharmacies, as well as the way the pharmacy operates according to national approaches, e.g. in relation to guidance and advice on medical treatment or information management and documentation.

The purpose of subsection 4 of the proposed section would be to clarify the responsibilities of the pharmacy for the services it provides. The proposal should not extend the responsibilities of

the pharmacy. It is proposed that the pharmacy should be responsible for the adequacy of the bundle of services and ensure that the arrangements meet the conditions set for them throughout the contract period when it provides dosage delivery services, contract manufacturing or other similar services on a collaborative basis. This would mean, for example, that the pharmacy could agree with the dosage distribution entity on a dosage distribution service and that, in such a case, the pharmacy would be responsible to the end-user customer for the overall supply of the medicinal product and the other dosage distribution service.

ARTICLE 41. The section regulates the number and location of pharmaceutical services. It is proposed that subsections 1-2 and 4 of the section be amended so that the entity responsible for the organisation of social and health services in the area is identified not as the municipality but as the assessor of the performance, location and sustainability of pharmacy services, since pharmacy services are an essential part of outpatient pharmacy treatment. Pharmacy services should be taken into account by the organisation of other social and health services in the region as part of the coordination of services for out-patients.

The proposed amendment is a key consequence of the establishment of the wellbeing services counties and their statutory tasks. The main objective of the amendment would be to update the legislation to reflect the new structural landscape and organisational responsibilities, not to interfere with the content of the legislation or to add new tasks to the wellbeing services counties. This amendment would be in line with the principle of the changes introduced by the SOTE100 package.

In accordance with Section 8 of the Act on the Organisation of Social Welfare and Healthcare (612/2021, the Act on the Organisation of Social Welfare and Healthcare), the wellbeing services county is responsible for the organisation of social welfare and health care in its territory and is responsible for the social welfare and health care of its residents. According to Section 4 of the Social Security Act, the wellbeing services county must plan and deliver social welfare and healthcare with the content, scope and quality required to meet customers' needs. The wellbeing services county must ensure the accessibility of the social and healthcare services for which it is responsible. The wellbeing services county could base its assessment at the request of the Finnish Medicines Agency on, for example, a report under Section 29 of the Act on the Organisation of Social Services.

It would be possible for the organisation of social and health services in the region to seek the opinion of the relevant municipality in support of its assessment. Under Section 6(1) of the Act on the organisation of social services, one of the tasks of a municipality is to promote the well-being and health of its inhabitants. The municipality has the primary responsibility for promoting well-being and health insofar as this task is linked to other statutory tasks of the municipality. Local knowledge of the municipality can serve as a complementary source of information for the organisation of social and health services in the region. The aim of the proposed amendment would not be to change the current territorial regulation of pharmacies in the Medicines Act. The Finnish Medicines Agency could still decide to open a new pharmacy in an area adjacent to a municipality, a part of a municipality or a social or healthcare institution.

Under Section 27(30) of the Self-Government Act (1144/1991), the Finnish Government has legislative powers in matters relating to the qualifications of persons providing health care and medical care, the establishment of a pharmacy, medicinal products and pharmaceutical products, narcotics and the manufacture of poisons and the determination of their intended use. The proposed amendments to Articles 41 and 52 relating to the pharmacy licensing system fall within the national legislative competence. However, as regards the pharmacy licensing system, the proposal is also linked to the competence of the Åland Islands, where, according to

Section 18(12) of the Self-Government Act, the Province has legislative competence in matters concerning health and medical care, with the exceptions provided for in Section 27(24), (29) and (30); burial and, under point 13, social assistance; a licence for the serving of alcoholic beverages.

Åland is responsible for the organisation of social and healthcare services in its own territory. In Åland, under the authority of the Provincial Government, Ålands hälso- och sjukvård ÅHS is responsible for health care. The 16 municipalities in the province are partly responsible for social services. For the rest, it is not proposed to amend the section.

ARTICLE 52. Provisions on branch pharmacies are laid down in Section 52 of the Medicines Act. It is proposed that subsections 1 and 5 be amended so that the establishment of branch pharmacies or the area in which the branch pharmacy is located could be initiated by the entity responsible for the organisation of social and health services in the area instead of the municipality or association of municipalities. This change would be based essentially on the statutory responsibility of the wellbeing services county for the organisation of social and health services.

It is proposed that subsections 2 and 3 of the section be amended to allow for the publication of the conditional branch pharmacy and the selection of the operator of the branch pharmacy in the same way as a qualified branch pharmacy, where this would be necessary to ensure the continuity of pharmacy services in the area on the basis of an assessment by the Finnish Medicines Agency. The Finnish Medicines Agency should base its assessment on the conditions laid down in the Medicines Act for the establishment of a branch pharmacy. The need for pharmaceutical services is assessed in particular on the basis of Sections 39 and 41 of the Medicines Act. The use of the publicity procedure for conditional branch pharmacies should, in principle, be limited to situations where it is deemed necessary. That could be the case, for example, if there were no open pharmacy licence in the vicinity of the branch pharmacy which is the subject of the proceedings, which could be linked to the branch pharmacy.

It is proposed to change the order of subsections of the section so that the subsection containing the Government's power to issue regulations is moved from subsection 6 to subsection 7. It is proposed to provide in subsection 6 that the Finnish Medicines Agency may make the authorisation of a branch pharmacy entitled to a pharmacy licence conditional on the pharmacist's initiative if this is justified by the need to ensure the continuity of the pharmacy services in the region. The Finnish Medicines Agency should base its assessment on the conditions laid down in the Medicines Act, such as the conditions under which a subsidiary pharmacy can be established. This could be the case, for example, where a pharmacist has the right to operate a branch pharmacy which was granted before 2010, but under the current Medicines Act would be defined as a conditional branch pharmacy. In 2010, amendments were made to the regulation of branch pharmacies, creating a regulation in the Medicines Act for the branch pharmacies that are a condition. For the rest, it is not proposed to amend the section.

Example

If a pharmacist were to appeal against a licence to operate a pharmacy granted to him and if, in Fimea's view, a branch pharmacy was important in order to safeguard the pharmacy services of the population of the region, that branch pharmacy could be made subject to a licence to operate a pharmacy in order to ensure the availability of medicinal products. On the other hand, in a situation where the holder of a pharmacy licence announces the closure of a qualified branch pharmacy and Fimea considers that it is important in order to safeguard the pharmacy services of the population of the region, Fimea could publicise the branch pharmacy and attach it to the licence of another holder of a pharmacy licence. The regulation of the number and

location of pharmacies is strongly interlinked and together they aim to ensure a nationwide network of pharmacies.

Article 54j. The proposed new section would concern the sale of a limited range of self-medication on-line. The sale of medicinal products belonging to a limited range of self-care medicinal products by the holder of a retail licence for self-care medicinal products would also be tied to a retail licence in the case of an online service. The retail licensee should ensure that its activities meet the requirements of data protection regulation and provide an adequate level of data security. Particular attention should be paid to the delivery of order and delivery confirmations containing information on medicinal products to the purchaser of the medicinal product. The online service should meet the conditions laid down by law. According to the proposed Section 54j, the operator of an online service should have websites on which medicinal products are offered for sale at a distance. The website should contain a link to an up-to-date list of legal pharmacy online services maintained by Fimea, as well as the common logo used in the EU under the Medicinal Products Directive. The online sale of medicinal products is otherwise subject to the same principles as other sales of medicinal products.

According to subsection 2 of the section, access to online service activities would require prior notification to the Finnish Medicines Agency. The activity may be commenced unless, within 60 days of receipt of the notification, the Centre has requested further information on the matters referred to in this section or has prohibited the commencement of the activity. The Centre shall be notified of the start of operations, the cessation of operations and any substantial changes. Material changes would include, for example, new premises or changes related to the premises of the online service, a change of platform or platform provider of the online service, the introduction of a new distance sales channel or application, or the addition of own pick-up clubs.

The Centre could prohibit the start of operations or order the termination of an online service if the online service does not meet the conditions laid down in the Medicines Act or the provisions adopted pursuant to it. The retail licence holder is responsible for the operation and management of the online service. The online service shall be subject to annual inspection by the retail licensee.

According to paragraph 3 of the proposed section, the holder of a retail licence operating an online service must ensure that the medicinal product is lawfully marketed in the State to which it is sold. The holder of a retail licence shall also ensure appropriate storage and transport conditions for the medicinal products for self-care supplied through its online service. According to subsection 4, online service activities would comply with the provisions of Chapter 6 of the Consumer Protection Act (38/1978) on distance selling.

According to subsection 5 of the section, the Finnish Medicines Agency could issue regulations on online service activities.

ARTICLE 55. It is proposed that subsection 2 be amended to remove the obligation for pharmacists to inform the municipality where the pharmacy is located of their opening hours on the basis of changed responsibilities for the organisation of social and health care. The announcement of opening hours, for example to the wellbeing services county, could take place through the normal communication of the pharmacy without regulation.

Article 55a. The section defines the pharmacy's role as the competent authority within the meaning of Article 75 of the Schengen Convention, which may issue the certificate referred to in that Article for the carriage of medicinal products containing narcotic drugs or psychotropic substances when travelling from one Contracting State to another.

It is proposed to add a second paragraph to the section, which would allow the pharmacy to

charge a fee for issuing the certificate. This addition is necessary because the issue of the certificate is a matter of the public management of pharmacies, the pricing of which should be determined by the population on an equal basis. The fee would be based on a cost-value calculation.

It is proposed to add a paragraph 3 to the section, which would include a power to issue a decree, according to which more detailed provisions on the fee to be charged for the Schengen Certificate will be laid down by government decree.

Article 55b. Section 55b of the Medicines Act governs the pharmacy agreement. It is proposed to amend the regulation of the pharmacy contract in order to replace the pharmacy contract procedure with a new pharmaceutical contract procedure. It is proposed that Section 55b of the Medicines Act be repealed with effect from 1 October 2028. Instead of the Law on Medicinal Products, the provisions on the contract for medicinal products would be placed entirely in the Law on prescription. The provisions on the pharmaceutical contract would enter into force on 1 October 2028. However, it would be necessary to provide for a transitional period for pharmacy agreements concluded before the entry into force of the Act. More specifically, the Law on prescriptions would also provide for a transitional period for pharmacy contracts from 1 October 2028 to 30 September 2030.

Article 55c. The section would provide for the possibility for a pharmacy to organise, in cooperation with another trader, the supply of a medicinal product via an online service. As things stand at present, the dispensing of a medicinal product may be carried out exclusively by a particular pharmacy. According to the proposed section, the supply of a medicinal product could take place in two or more stages, by different persons and at different premises. A pharmacy providing an online service to a customer would be responsible for the entire process vis-à-vis the customer in the event of cooperation. In practice, cooperation could take place between traders who are entitled to carry out the steps involved in the supply of a medicinal product. Activities which are not connected with the supply of a medicinal product but with the supply or transport of a pre-packaged medicinal product, the production of which is not subject to a pharmacy licence, would be excluded from the scope of the section.

The purpose of subsection 1 would be to allow the pharmacy a wider possibility than at present to agree on the arrangements made for the supply of the medicinal product through its online service. A pharmacy could acquire activities or services from other traders in order to supply a medicinal product. This would be referred to in the Medicines Act as an agreement to cooperate. The pharmacy should ensure that, for example, medical advice and advice is provided by a pharmacist or pharmacist and that cooperation is agreed with the relevant authorisation holder, for example a pharmacist or a Soteri-registered trader.

Example

Pharmacy A could agree to cooperate with another trader B in relation to the supply of a medicinal product via an online service. Cooperation could be agreed with another pharmacy licence holder or with a health service provider registered in the Soteri register. Depending on the nature of the cooperation, trader B should fulfil the legal obligations relating to the supply of medicinal products and the provision of information and advice on medicinal treatment. Cooperation involving the storage or handling of a medicinal product could only be agreed between the holders of a pharmacy licence.

According to subsection 2, when agreeing to cooperate, the pharmacy should take into account the effects of the activity. The pharmacy should not make any arrangements for the supply of the medicinal product which may jeopardise the availability of medicinal products in the area, the safety of medication or patients, or increase the financial burden on the user of the

medicinal product or on society. As regards access to medicinal products, this would mean that the pharmacy should continue to manage its own stock of medicinal products, as required by Section 55 of the Medicines Act. Otherwise, the pharmacy should ensure that the dispensing of medicinal products complies with the Medicines Act and other regulations relating to the dispensing of medicinal products. For example, when dispensing a medicinal product, the pharmacy could provide advice and guidance on medicinal treatment in cooperation with an entity qualified to do so, but the pharmacy should take into account, inter alia, the implementation of Sections 56d and 57 of the Medicines Act. The pharmacy would be responsible for the provision and quality of the service. In order to ensure the safety of medication, the pharmacy should ensure that the cooperation is lawful throughout the term of the contract. The right to process medication data required for advice would be based on the processing of data in the service of, on behalf of or on behalf of a pharmacy, in accordance with Section 11 of the Medicines Act and Section 4 of the Customer Information Act.

Under subsection 3, before engaging in the cooperation referred to in subsection 1, the pharmacy should give prior notification of the cooperation to the Finnish Medicines Agency. The activity should be allowed to commence unless, within 60 days of receipt of the notification, the Centre has requested further information on the matters referred to in the section or has prohibited the start of the activity. The Centre should be notified of the start of operations, the cessation of operations and material changes. A material change in the activity would be, for example, a change in the notified approach to the supply of the partner or the collaborative medicine or to the guidance and advice on medical treatment.

According to subsection 4 of the section, the Finnish Medicines Agency could prohibit the commencement of activities or order their cessation if they are contrary to the Medicines Act or other regulations governing the supply of medicinal products. This could be, for example, shortcomings in the provision of guidance and advice on medication.

Article 56b. According to the proposed section, the pharmacy should offer to the purchaser of the medicinal product the medicinal product which is actually the most advantageous in terms of price. The proposed section would apply to both prescription-based and non-prescription medicines. The purchaser of the medicinal product should be provided with information on the prices of the medicinal products available. The pharmacy could organise the provision of information not only by means of personal advice, but also, for example, by means of IT solutions. The alternative medicinal product and the cheapest price are regulated in Section 57b of the Medicines Act.

Article 56c. The section would be new. According to the section, the pharmacy should have a mechanism in place to monitor the performance of the pharmacy's tasks and to report and handle any deviations therefrom. The pharmacy should monitor both quantitative and qualitative information on how the proposed Section 38b of the Medicines Act is implemented and how the services provided by the pharmacy are implemented. The purpose of monitoring would be to ensure that the pharmacy operates in accordance with the needs of its customers and that patient safety is achieved. Occurrence reporting would cover both actual and 'near misses'. This could include, for example, deviations in prescription or dispensing that endangered medication safety. According to paragraph 2 of the proposed section, the pharmacy should organise the handling of events to the extent required by their nature. For example, dealing with a single near miss would not require dealing with an incident to the same extent as an incident, damage or incident that has seriously compromised patient safety. There should be agreed procedures in the pharmacy for handling reported occurrences, corrective actions and operational development. The IT solution would not be further regulated as the development of incident reporting procedures at national level is ongoing.

Article 56d. Under the proposed Section 56d, a pharmacy should organise its activities in

such a way that it can perform the functions of a pharmacy of good quality. The proposed section would apply to a pharmacy and its various branches, including an online pharmacy.

According to the first paragraph of the proposed section, the pharmacy should ensure that its personnel have the necessary skills to perform the pharmacy's tasks and provide up-to-date tools to support the performance of the pharmacy's tasks in the pharmacy and its outlets. The pharmacy should provide the necessary training, access to up-to-date information sources, databases, decision support tools, etc. that support the identification and optimisation of the risks of medication. It would be appropriate for staff skills to take into account the therapeutic pathways and operating practices in the area, for example to support guidance and advice on medication, thus ensuring consistent and comprehensive information to the user on medication treatment and approaches to monitoring the effects of treatment.

According to the proposed paragraph 2, the pharmacy should ensure that its premises and systems are suitable for the processing of confidential personal data concerning health in the pharmacy and its branches, as well as for teleworking, if any. In doing so, the pharmacy should ensure, for example, that personalised advice on medicinal products is provided in a manner that respects the privacy of the pharmacy, in conditions that allow confidential discussion or, for example, that an adequate level of data protection and security is ensured when information containing advice on medicinal products, dosage instructions and ordering and delivery confirmations containing information on medicinal products is provided to the customer.

According to paragraph 3 of the proposed section, the pharmacy and its branches should have a policy on critical functions for the operation of the pharmacy. This would include, for example, stock management of medicinal products, dispensing of medicinal products, preparation of medicinal products in a pharmacy, provision of advice and guidance, receipt and handling of suspected product defects or falsified medicinal products, and a description of the procedure for reporting and learning about medication-related incidents.

According to the proposed subsection 4, the pharmacy should ensure that the operating instructions are up-to-date and regularly check that the activity actually complies with the instructions. On the basis of the observations made, the pharmacy should assess what measures it would need to take to remedy the deficiencies. Corrective measures may include, for example, the development of technical systems to support work processes, the updating of operational instructions or the training of staff.

According to paragraph 5 of the proposed section, the Finnish Medicines Agency could issue regulations on the development and revision of guidelines.

ARTICLE 57. The purpose of the proposed amendments to the section would be to provide a basis for the pharmacy's activity in supplying medicinal products and providing advice and guidance on medical treatment, and to harmonise the conditions for the provision of the various channels of communication. It is also proposed to change the legal situation by separating advice relating to the treatment of a medicinal product from advice on the price of a medicinal product. They would then be identified as their own, separate processes, allowing for a wider range of implementation methods for the provision of medical advice and price advice.

According to the proposed paragraph 1, the pharmacy should organise the dispensing of the medicinal product in such a way as to contribute to the success and continuity of the treatment and to ensure patient safety.

The dispensing of a medicinal product would refer to the steps in the process of releasing the medicinal product for consumption. In addition to the Medicines Act, the supply of a medicinal product is regulated by the Electronic Prescription Act (61/2007) and the Decree of the Ministry of Social Affairs and Health on prescribing a medicinal product (1088/2010), the Act

on the Processing of Customer Data in Social Welfare and Healthcare (703/2023). This includes verifying the right to purchase the medicinal product and the accuracy of the prescription, ensuring that the treatment is fit for purpose, advising and advising on the price and use of the medicinal product, carrying out the exchange of medicinal products, treating the direct reimbursement of the medicinal product under a contract between pharmacies and Kela, marking the packaging of the medicinal product to be supplied and verifying the authenticity of the medicinal product.

At the pharmacy, the dispensing of the medicinal product is subject to customer-specific verification of medication safety and the economy of the treatment. Pharmacy dispensing practices play a key role in the delivery of successful medication. Successful pharmacological treatment means, among other things, that pharmacological treatment is carried out correctly and safely, is effective and achieves its objectives. For a medicine to be successful, the user must be able to use it correctly. Successful treatment is sensible, necessary and well-dosed and does not cause avoidable problems.

Dispensing practices in a pharmacy can prevent errors, disadvantages and risks associated with the treatment of a medicinal product and prevent interruption of treatment. These practices include verifying the correctness of the prescription, checking the dosage, monitoring delivery intervals, calculating and limiting the quantity of medicinal product to be dispensed, making the medicinal product available for supply and ensuring documentation of delivery. Factors to be taken into account in order to verify the accuracy of a prescription include, inter alia, the prescriber’s right to prescribe medicinal products, compliance with prescribing regulations and the appropriateness of prescribing a medicinal product. When checking dosage, care should be taken to ensure that the dosage instruction given on the prescription does not exceed the authorised treatment practices, taking into account any SIC marking. In the pharmacy, the monitoring of delivery intervals makes it possible, in particular, to ensure that there are sufficient intervals for the supply of medicinal products suitable for misuse and that the intervals for the delivery of the iterated prescription are appropriate. For example, as regards the volume of medicinal products to be dispensed, it must be ensured that, subject to certain exceptions, the volume of medicinal products dispensed on prescription does not exceed the prescribed total volume of medicinal products. Exceptions include, for example, slightly different pack sizes of interchangeable products and situations of exemption from prescription under Section 57f of the Medicines Act. Making a medicinal product available for supply means, for example, taking into account the conditions governing the supply of the medicinal product to be supplied and the marketing authorisation, as well as the instruction flag affixed to the package of medicinal products. Making medicinal products dispensed mechanically available means, inter alia, checking that the dispensed medication corresponds to the medication prescribed for the customer.

According to subsection 2 of the section, the pharmacy should provide the user of the medicinal product with access to medication guidance and advice aimed at guiding the correct and safe use of the medicinal product and supporting the success of the medication. Guidance and counselling on medicinal products should be provided in such a way as to support the individual needs of the user of the medicinal product, taking into account the overall pharmacological treatment of the customer, the illnesses and age, and the categories of customers requiring special attention. Guidance and advice should also be provided on how to carry out medication, e.g. on the device needed to use the medicinal product. Advice and guidance on medication would apply to both prescription-only and non-prescription medicinal products. In the case of self-care, guidance and counselling would also include an assessment of the need for care. Guidance and counselling should be provided on issues affecting the choice of the medicinal product before dispensing.

A key change to the current status of the Medicines Act would be that guidance and advice on medicinal treatment would take into account the individual needs of the user of the medicinal product, which would mean that different issues should be addressed in the guidance and advice depending on the situation of the user of the medicinal product. At the start of the use of the medicinal product, advice and guidance should focus on guiding the correct use of the medicinal product compared to long-term treatment, emphasising the monitoring of treatment and the identification, resolution or communication of any problems with the treatment to other parties involved in the treatment process. The content of the medical advice and advice would be determined according to the needs of the client, allowing the pharmacy to focus the pharmaceutical expertise on activities that are as effective as possible. Specific customer groups for the success of pharmacotherapy would be those who use high-risk medicines, those who use high-risk medicines, those who start pharmacotherapy and those who identify potential problems in pharmacotherapy. The changes would strengthen the role of the pharmacy, in particular with regard to the start of new medication treatments and the success of and support for adherence to medication for long-term sick people.

Self-care advice would be a package that includes an assessment of the need for medication supported by a pharmacy professional and guidance on the use of the chosen product and, if necessary, guidance on healthcare. The pharmacy would provide guidance and advice on self-medication, but depending on the needs of the client, the pharmacy should also assess and advise on the use of non-medicated treatment options. If necessary, the pharmacy should refer the customer to healthcare, which may require regional cooperation with other social and healthcare actors in order to be effective.

The purpose of subsection 3 would be to ensure access to information and advice on medical treatment for the user of the medicinal product even in a situation where another person is present in the pharmacy on his or her behalf. The pharmacy should take into account the different roles and information needs when dealing on behalf of another person. This could be, for example, an application for a medicine on behalf of acquaintances, a caregiver who is responsible for the implementation of home-based medication, or an employee of a residential or home-based medication service who intervenes on behalf of dozens of medication users in one transaction. Depending on the transaction, the content of advice on the same treatment could be significantly different. Counselling and guidance can also be organised as separate sessions for counselling and guidance support for staff in home care or housing services. The pharmacy should provide advice and guidance on medical treatment to the user of the medicinal product or to anyone acting on his or her behalf, even after contacting the pharmacy by telephone. Again, the guidance and advice on medical treatment could be different depending on whether the customer can be reliably identified. In addition to telephone contact, the pharmacy could offer other service channels which could be considered by the pharmacy.

The current subsection 3 of the section would become subsection 4. Subsection 4, which includes the authority's power to issue orders, would become subsection 5. It is proposed to clarify the power of the Finnish Medicines Agency to issue orders for the supply of medicinal products in subsection 5 of the section. The Centre for the Safety and Development of Medicinal Products could lay down rules on the procedures for the supply of a safe medicinal product, concerning the preparation and delivery of the medicinal product to the customer, the verification of the correctness of the prescription, the verification of the dosage, the frequency and quantities of supply, and the provision of advice and advice on medicinal treatment. It is not proposed to amend the section in any other way.

Article 57e. It is proposed to amend subsection 1 so that in future the location of the pharmacy's pick-up box is not limited to the area in which the pharmacy is located. As the law currently stands, the pharmacy pick-up box is used only in the area in which the pharmacy is

located, which has contributed to limiting the operation of the pharmacy's online service. The rationale behind the rules was to ensure that pharmacists would then be in a position effectively to verify the proper functioning of the pick-up clubs. The purpose of the proposed amendment would be to allow the pharmacist himself to carry out an assessment of the location of the pick-up clubs. The pharmacist would continue to be responsible for the proper functioning of the collection club. For the rest, no changes are proposed to the section.

ARTICLE 58. It is proposed to amend subsection 4 so that the price of a self-care medicine would not have to be the same in all pharmacy outlets and online services in the future. The purpose of the amendment would be to allow greater price competition between pharmacies.

It is proposed to amend subsection 8 so that the Finnish Medicines Agency should provide the Ministry of Social Affairs and Health annually with information on the tasks and finances of pharmacies. The Finnish Medicines Agency should develop its reporting to describe not only quantitative but also qualitative information, e.g. how the proposed Section 38b of the Medicines Act will be implemented and how the services provided by the pharmacy will be implemented. The Finnish Medicines Agency's knowledge base on the performance of pharmacy tasks will be improved and the Finnish Medicines Agency's ability to evaluate the activities of pharmacies will improve as the knowledge base develops. Going forward, the annual provision of information should take greater account of the requirements and implementation of pharmacy activities in order to improve the regulation and financing of pharmacies on the basis of more accurate and up-to-date information. In addition, an up-to-date and broader knowledge base would support other guidance. The annual provision of information would also include information on pharmacy services and separate undertakings in the case of activities carried out in connection with a pharmacy.

ARTICLE 67. It is proposed that subsection 3 of the section be deleted because, under the proposed section 12b, bodies governed by public law would be eligible to apply for a licence for a dosage distribution unit.

ARTICLE 77. As the Medicines Act currently stands, the Finnish Medicines Agency has no explicit right of inspection over the dosage distribution unit. The proposed section would add the Dose Distribution Unit to the list of operators to which the Finnish Medicines Agency would have the right to inspect. As the legislation stands at present, the right to inspect the dosage distribution premises has been based on the right to inspect the pharmacy, even though the dosage distribution unit carrying out the dosage distribution is a separate operator operating in conjunction with the pharmacy. The proposed amendment would clarify the basis for the right of inspection, subject the right operator to official controls and thus improve the effectiveness of medication safety by allowing inspections to be planned and carried out more efficiently. From the point of view of the Dose Distribution Unit, a direct right of inspection would clarify its legal position and remove any ambiguity in relation to controls.

ARTICLE 89. It is proposed that subsection 1 of the section be amended so that the Finnish Medicines Agency is entitled to receive, free of charge, on request from a dosage-distributing unit and without prejudice to confidentiality provisions, information and explanations relating to the import, manufacture, inspection, distribution, sale or other release for consumption of medicinal products that are necessary for the Agency to carry out the tasks laid down in the Medicines Act, other legislation or an act of the European Union. The Centre would be entitled to receive from the aforementioned bodies the information necessary for the protection of patients and other persons and otherwise for the performance of its supervisory tasks, including medical records. For the rest, no changes are proposed to the section.

Article 101b. It is proposed to add a new paragraph 2 to the section and to allow the Finnish Medicines Agency to impose a conditional fine in order to enforce the prohibition referred to in

sections 52b, 54j and 55c of the Medicines Act. It is also proposed to include in the subsection, for the sake of clarity, an informative reference in the current Act to the fact that the penalty payment procedure is provided for in the Act on Penalty Fines. Section 52b of the Medicines Act and the proposed new Section 54j concern the online distance sale of medicinal products by a pharmacy and by the holder of a retail licence for non-prescription medicinal products, which requires notification to the Finnish Medicines Agency. The centre could prohibit the start of the activity or order the termination of the network service if the activity does not meet the conditions set for it. A similar provision is contained in the proposed Article 55c on cooperation in the provision of an online pharmacy service.

ARTICLE 102. The section provides for appeals against decisions under the Medicines Act. It is proposed that subsection 1 of the section be amended to take account of the decisions of the authorities concerning the authorisation of a mechanical dispensing unit, the prohibition and order to maintain the online service of the holder of a retail licence for non-prescription medicinal products and the prohibition on cooperation between pharmacies. The authority is proposed to have the right to inspect the dosage distribution unit to be added in Section 77(1) of the Medicines Act. Under Section 78 of the Medicines Act, the inspector may issue orders to remedy any deficiencies found. Any order made in the course of the inspection must be followed up without delay. An appeal against the order could be lodged with the Finnish Medicines Agency under Section 102(1) of the Medicines Act.

It is proposed to amend subsection 2 of the section in such a way that the appointment of a new person responsible for the dosage distribution unit referred to in section 12i may be appealed to the Supreme Administrative Court without permission to appeal. The rules would then be equivalent, in the case of a dispensing unit, inter alia, to an appeal against a decision withdrawing a pharmacist's authorisation. For the rest, no changes are proposed to the section.

7.2. Act amending the ePrescription Act

ARTICLE 3. It is proposed to amend Paragraph 3(4) of the Law on prescriptions concerning the definition of a prescription centre by proposing that information on the medicinal product contract referred to in Paragraph 3(12) be added to the information to be stored in the prescription centre, since the medicinal product contracts concluded from 1 October 2028 would be stored in the prescription centre. A definition of a pharmaceutical contract would be added to the definitions in Section 3 of the prescriptions act as a new paragraph 12 of the section. A 'medicinal product contract' would be understood to mean a contract concluded between the health care unit responsible for the patient's medical treatment and the patient in order to centralise the patient's medical treatment in a single health care unit. Linking the contract to a single doctor in the same way as under the legislation in force would not be justified, since the care relationship is usually in the care unit, where doctors may change. Despite its well-established nature, it is proposed to change the name of the pharmacy agreement to that of a medicinal product agreement, as it is a sufficiently common name and a reference to a medicinal product agreement within the meaning of the prescription law would serve as a more specific reference. The changed purpose of the agreement would also militate in favour of a change of name, since only one pharmacy would not normally be the pharmacy supplying the medicinal products covered by the agreement. In the definition, a healthcare service unit would mean a service unit within the meaning of Section 4(5) of the Act on the Supervision of Social Welfare and Healthcare (741/2023).

Article 12a. A new Section 12a would be added to the Act, which would be in force on a temporary basis. The new Paragraph 12a of the Law on prescription would govern pharmacy agreements concluded on the basis of the Law on medicinal products in force, with a maximum transitional period between 1 October 2028 and 30 September 2030. The proposed Article 12a(1) would define what is meant by a pharmacy contract. The definition would not be placed

in the definitions in Section 3 due to its temporary nature. Since the registration of pharmacy and pharmaceutical contracts would be transferred from the Finnish Pharmacy Association (brokering server) to Kela (Kanta services) when the Act entered into force on 1 October 2028, the pharmacy or branch pharmacy should then, when supplying prescription-only medicinal products, check with the prescription centre referred to in Section 65 of the Client Information Act whether the patient has a valid pharmacy contract. The pharmacy agreements would continue to apply in respect of all the elements referred to in the agreement, i.e. medicinal products covered by the pharmacy agreement could only be supplied by the pharmacy named in the pharmacy agreement. The pharmacy would be obliged to check the validity of the pharmacy agreement at the prescription centre after the transfer of the register, even though the information in the pharmacy agreement was originally in the system of the Association of Pharmacists. The pharmacy contracts would be transferred by operation of law to the data maintained by the prescription centre, without this altering the terms of the contract.

This section would specify more precisely what information a pharmacy or branch pharmacy would be allowed to communicate as essential information about the patient to the treating physician. The section would also provide for the possibility of concluding, during a transitional period, a pharmaceutical contract in place of a previously concluded pharmacy contract, in which case the pharmacy contract would cease to have effect. In the case of medicinal products covered by a pharmacy agreement, it should be assessed whether, at the latest after the expiry of the term of the agreement, they should, where appropriate, be marked as having been discontinued. Following the introduction of the Kanta list, the invalidation of the prescription will no longer be carried out in such a situation, but the medicinal product will be marked ‘withdrawn’ if necessary and, if the pharmacy agreement is ‘updated’ into a medicinal product agreement, the medicinal product will not have to be discontinued on its own.

Article 12b. A new Section 12b would be added to the Act. The section would provide for a contract for medicinal products. The provisions on the pharmaceutical contract would enter into force on 1 October 2028 and would then apply to contracts concluded in the healthcare sector.

It would provide that a pharmaceutical contract, like a pharmacy contract, would no longer be tied to only one pharmacy, so that medicinal products covered by the contract could be collected from any pharmacy. However, it must be possible to restrict the supply of a medicinal product to a single pharmacy or to a limited number of pharmacies at most, where this is necessary for the organisation of the treatment, without, however, preventing the prescription or dispensation of the medicinal product where this is necessary to ensure the safe treatment of the patient. Since a pharmaceutical contract could be concluded in the future without being tied to a particular pharmacy, it could create problems with regard to the distribution of medicinal products. A traditional feature of the pharmacy contract system is that the medicinal products covered by the contract are regularly supplied and distributed in the pharmacy in smaller portions of factory packs. If users of medicinal products were free to apply for their medicinal products at different pharmacies in the future, this could lead to a multiplication of workloads, increase pharmaceutical waste and reduce distribution management, in particular for so-called ‘distributable medicinal products’. Where, at the time of dispensation, the medicinal product contract involves the distribution of a complete package of medicinal products, the medicinal product contract should primarily indicate the pharmacy or branch pharmacy from which the patient undertakes to collect the medicinal products distributed, but there may also be situations in which, even in those situations, it should be possible to collect from more than one pharmacy or branch pharmacy.

The use of a medicinal product contract would not only be limited to follow-on and

substitution treatments, but could also be used to prevent drug addiction and, where appropriate, in other cases where the safety of the patient could be compromised or where it would otherwise be appropriate to restrict the use of the medicinal product and other means would not allow the necessary medical treatment or its implementation would be significantly impeded for the patient. The new pharmaceutical contracts could cover medicinal products other than ddmmyyyy and narcotic drugs.

By partially amending the existing provision, it would also be stipulated that the health care unit must inform the patient, before entering into a pharmaceutical contract, of the pharmacy's right to disclose the information referred to in section 12c to the health care unit that is a party to the contract. The change would concern the obligation of the service unit, and no longer of the doctor, to inform the pharmacy of the right to provide information about the patient, since the contracting party is the service unit.

The healthcare service must record the contract for medicinal products in the prescription centre referred to in Section 65 of the Client Information Act. The contract for medicinal products would therefore be concluded between the patient and a particular health care establishment treating him or her. That entity would be obliged to record the contract in the Kanta service recipe centre. The storage and termination of the contract would be technically limited to the contracting service. Any modification or termination of the contract would be done by the treating health institution. The patient himself would only see the contract for the citizen's interface (MyCanta service) and would not be able to make any changes to it. The contract could not be modified by other care units either. Section 15 of the Client Information Act and Section 46 of the Medicines Act regulate situations in which the registrar of a healthcare service unit may change its decision.

12 Article C. A new Section 12c would be added to the Act on prescriptions. The section would provide for a contract for medicinal products. Compared to the current provision on pharmacy agreements in the Medicines Act, the amendment would concern the obligation for a pharmacy and a branch pharmacy, when supplying prescription-only medicinal products, to check at the prescription centre referred to in Section 65 of the Customer Information Act that the patient has a valid pharmaceutical contract and no longer as an intermediary service of the Finnish Pharmacists' Association from the pharmacy system. The existing provision on the pharmacy's right of notification would be amended and clarified to include essential patient information related to the dispensing of the medicinal product and patient safety. For example, the right to report could apply if a patient requests too much medicinal products (prescribed by another organisation) or too little.

13 §. Section 13 of the Act on prescriptions provides for the patient's right to be prohibited from disclosing information. The patient could also, in principle, prohibit the disclosure of information relating to the pharmacy and pharmaceutical contract. However, if the patient were to exercise his right of prohibition in respect of those agreements, that would, by its very nature, lead to the termination of the agreement in a comparable situation, since the information in the agreement would not be available either to other prescribers or to the dispensing pharmacy. The purpose of the proposed amendment would be to exclude the patient's right to obtain an injunction from the information contained in the medicinal product contract in the following situations.

It is proposed that, notwithstanding the prohibition imposed by the patient, the details of the pharmacy and pharmaceutical contract could be handed over from the prescription centre to the prescriber when he prescribes medicinal products for ddmmyyyy or narcotic drugs and to the pharmacy when it supplies medicinal products for ddmmyy or narcotic drugs, whether or not the pharmacy is designated in the pharmaceutical contract as the only supplying pharmacy.

It is proposed to amend point 2 of Paragraph 13(3) of the Law on prescription in such a way that, notwithstanding the patient's prohibition, information may be provided to the person who prescribes the medicinal product ddmmyy and narcotic drugs on all the medicinal products ddmmyy and narcotic drugs prescribed to the patient, together with the particulars of the pharmacy and medicinal product agreement referred to in Paragraph 13, and to the pharmacy supplying the medicinal product ddmmyy and narcotic drugs, together with the particulars of the pharmacy and medicinal product agreement referred to in Paragraph 13(3).

The purpose of the pharmaceutical agreement is to centralise the prescription of the medicinal products or categories of medicinal products included in the pharmaceutical agreement to a single therapeutic entity. Therefore, medicinal products covered by a medicinal product contract should be prescribed to the patient only in the therapeutic units designated in the medicinal product contract (and, if agreed, by the doctors designated in the contract). According to the ruling on the pharmacy agreement procedure (THL12/2023), in practice, the existence of a pharmaceutical agreement during its term would always become a separate reminder to the prescriber when he or she is prescribing medicinal products for ddmmyyyy or narcotic drugs. Prescribers would always be shown the details of the pharmaceutical contract when prescribing medicinal products for ddmmyyyy or narcotic drugs, noting that, for the medicinal products named in the contract, treatment is centralised in the treatment unit named in the contract and that others should not prescribe these medicinal products without first consulting the treatment unit. However, even in exceptional situations, the prescription of a medicinal product would not be prevented in order to ensure the necessary treatment of the patient, and the doctor would always take the decision to prescribe or not to prescribe the medicinal product ddmmyyyy or narcotic drugs to the patient.

According to the description of the outcome of the pharmacy contract procedure, since the restrictions caused by the concentration of certain medicinal products in one unit of care are primarily taken into account when prescribing the medicinal products, it would not be necessary, as a general rule, to restrict the supply of the medicinal product, which could be collected at any pharmacy. In some cases, however, it would be in the interests of the patient to limit the supply of the medicinal product to a particular pharmacy. A restriction would be justified, for example, where a medicinal product is supplied in single deliveries below pack size. The pharmacy restriction would apply only to the supply of the medicinal products specified in the pharmaceutical contract. The pharmacy would be free to supply medicinal products not covered by the pharmaceutical contract. The use of a medicinal product contract would not only be limited to follow-on and substitution treatments, but could also be used to prevent drug addiction and, where appropriate, in other cases where the safety of the patient could be compromised or where it would otherwise be appropriate to restrict the use of the medicinal product and other means would not allow the necessary medical treatment or its implementation would be significantly impeded for the patient. The new pharmaceutical contracts could cover medicinal products other than ddmmyyyy and narcotic drugs.

The proposal also proposes the right for a pharmacy supplying ddmmyy and narcotic drugs to receive information on all prescribed ddmmyy and narcotic drugs, despite the patient's ban. That would correspond, in essence, to the prescribing right provided for in the same paragraph. The proposal would contribute to the safe use of ddmmyy and narcotic drugs, which carry a heightened risk of misuse, and wider access to information by the pharmacy can prevent misuse and harm from using those drugs.

7.3 Act amending the Act on the Processing of Customer Data in Social Welfare and Healthcare

ARTICLE 65. The section sets out what information system services are centrally managed at national level in relation to the electronic processing of customer data. The Social Insurance Institution should organise the information system services provided for in the section. It is

proposed to add the pharmaceutical contract management service as paragraph 1(11) to these services. In addition, it is proposed to make maintenance technical changes to the language with regard to paragraphs 9 and 10. A management service would mean a technical interface to store a contract for a medicinal product in a prescription centre and to maintain contract information as part of Kanta services. The interface enables the storage of a contract for a medicinal product in a healthcare setting at a prescription centre and, if necessary, the modification or termination of the contract.

8 Subordinate legislation

It is proposed that more detailed provisions on the fee for the Schengen Certificate issued by a pharmacy referred to in Section 55a of the Medicines Act may be laid down by Government decree. It is proposed to add the power to adopt regulations to Section 55a(3).

It is proposed that the Medicines Act provide for the possibility for the Finnish Medicines Agency to issue regulations on the content, form and annexes of the application for a licence for a dosage distribution unit (Section 12c(3)), on the requirements for industrial manufacturing activities (Section 12e). Paragraph 3), defects in the medicinal product, and the handling of suspected falsified medicinal products and the notification and handling of the recall of a medicinal product (Paragraph 30o(2)), the content and making of a prior notification by the holder of a retail licence, the packaging and checking of consignments of medicinal products, transport, outsourcing of activities, returns, the handling of product defects, the provision of information on a medicinal product by means of an online service, the storage of medicinal products, the supply of medicinal products by means of an online service, premises, technical implementation, the selection of medicinal products, the management of medicinal products and the carrying out of an inspection of online service activities (Paragraph 54j(4)) and the drawing up and revision of the pharmacy's policy (Paragraph 56d(5)). It is also proposed to clarify the existing power to issue orders under Section 57(4) of the Medicines Act.

Amendments are proposed to the Medicinal Products Decree (693/1987), which is annexed to the proposal, concerning the recipients to whom the inspection report drawn up by the Finnish Medicines Agency would be submitted, and amendments are proposed to the Council of State Decree on the price regulation of the Schengen Certificate and on the tariff for medicinal products (713/2013), which would remove the price equivalence requirement for non-prescription medicinal products in the various pharmacy branches. In addition, amendments are proposed to the Decree of the Ministry of Social Affairs and Health on treatment for opioid addiction and replacement with opioid medicines (642/2023), as it includes a reference to Section 55b of the Medicines Act, which is now proposed to be repealed.

The constitutionality of the proposed legislative and regulatory powers has been assessed in section 12.

9 Entry into force

It is proposed that the amendments to the Medicines Act enter into force on 1 January 2027. However, the repeal of Paragraph 55b of the Law on medicinal products would take effect on 1 October 2028. The amendments to the ePrescription Act are intended to enter into force on 1 October 2028. The amendments to the Act on the Processing of Customer Data in Social Welfare and Healthcare are intended to enter into force on 1 October 2028.

10 Implementation and monitoring

In accordance with Article 2(1) and (15) of the Law on the Finnish Medicines Agency, Fimea, the Finnish Medicines Agency, is responsible for carrying out the pre- and post-control of

medicinal products, directing and controlling the manufacture, import, distribution, marketing and release for consumption of medicinal products, providing scientific advice and improving the efficiency and safety of the pharmaceutical sector, pharmaceutical activities and other pharmaceutical services. FIMEA should provide guidance and advice to pharmacy and dispensing operators in relation to the proposed legislative amendment.

The Ministry of Social Affairs and Health provides information on the adoption and adoption of laws. The Ministry of Social Affairs and Health will monitor the impact of the legislative change together with Fimea.

11 Relationship to other proposals

11.1 Relationship of the proposal to other proposals

In the draft Government proposal to Parliament for an Act amending the ePrescription Act and Section 102 of the Act on the Processing of Customer Information in Social Welfare and Healthcare, it is proposed to amend the paragraphs of Section 18 of the Act on Prescriptions which, upon their entry into force, would compensate for the need to propose an amendment to those paragraphs in this Government proposal. This should be taken into account during parliamentary proceedings.

11.2 Relation to the draft budget

The development of the master medication list is part of the data management of the social services, so the related financing of the Kanta services is part of the budget article 4.23.33.01.25. Regarding the financing of budget article 4.23.33.01.25 of the Fiscal Plan 2026-2029, the development of the Kanta medication list requires EUR 6.7 million, of which this government proposal accounts for approximately EUR 0.4 million to change the data management solution of the pharmaceutical contract.

12 Relationship to the Constitution and order of enactment

Freedom to conduct a business and protection of property

The proposal proposes to amend the Medicines Act and contains a number of proposals relevant to the Constitution (731/1999). In particular, the proposed regulation affects the fundamental right of operators to conduct a business (section 18 of the LPE) and to the protection of property (section 15 of the LPE) by imposing restrictions and requirements on their activities. However, those restrictions and requirements are based on the public authority's task of promoting the health of the population (Article 19.3 of the LPE).

According to Article 15(1) of the Constitution, everyone's property is protected. The right to property includes, in principle, the right of the owner to use, exploit and dispose of his property. Freedom of contract is also protected by the right to property (PeVL 41/2006 vp, p. 2).

Pursuant to section 18(1) of the Constitution everyone has the right, as provided by an act, to earn his or her livelihood by the employment, occupation or commercial activity of his or her choice. This provision is fundamentally a right to liberty, the freedom to earn a living and the freedom to choose the form and method by which one wishes to earn a living. The possibilities and obligations of the trader should be compatible with the different constitutional provisions.

In the proposal, the freedom to conduct a business and the protection of property are examined, in particular, in the light of the role of the public authorities in promoting the health of the population (Article 19.3 of the LPE). According to the explanatory memorandum to that

provision, the public authority's obligation to promote the health of the population refers, on the one hand, to preventive action in the field of social and health care and, on the other, to the development of social conditions in the various areas of public authority in a general manner conducive to the health of the population (HE 309/1993 vp). The rationale behind the authorisation requirement for pharmaceutical activities is the public health objective of ensuring the safety of medicines and the availability of medicines throughout the country. The Constitutional Law Committee has considered authorisation procedures for pharmacy operations to be justified, provided that this is justified by a reason that is acceptable from the point of view of the fundamental rights system. The safety of medicines and the safeguarding of the availability of medicines are closely linked to the public authority's task of promoting the health of the population, as laid down in Article 19(3) of the Constitution (PeVL 46/2025 vp, paragraph 9 and its references to, inter alia, PeVL 69/2014 vp, pp. 2-3).

Permissible limitations to fundamental rights must be based on law and be specific and sufficiently defined. Any restriction of fundamental rights must be justified and justified by a pressing social need. Restrictions must comply with the principle of proportionality and be necessary so that the objectives cannot be achieved by less intrusive means. The restriction must not go beyond what is justified by the importance of the social interest underlying the restriction in relation to the limited legal interest. Adequate legal protection must also be provided (PeVM 25/1994 vp, pp. 4-6).

The Constitutional Law Committee has stressed that, under the Constitution, the freedom to conduct a business is the general rule, but that authorisation may exceptionally be required. The Constitutional Law Committee has stated that restrictions on the freedom to conduct a business laid down by law must not only be precise and precise, but the extent and conditions of the restriction must also be apparent from the law (PeVL 36/2021 vp, paragraph 4, and PeVL 69/2014, p. 2). With regard to the need for a licence for the freedom to conduct a business, the Constitutional Law Committee has considered it important that the provisions on the conditions and the permanence of the licence provide sufficient predictability as regards the activities of public authorities. In that regard, it is relevant, inter alia, to what extent the powers of the authorities are determined by 'tied and discretionary powers' (PeVL 33/2005 vp, p. 2, and PeVL 19/2002 vp, p. 2).

The proposed amendments to the Medicines Act, which are central to the fundamental right to freedom to conduct a business and to the protection of property, include provisions on the authorisation and operation of a dispensing unit (Paragraphs 12b to 12i), on the establishment of pharmacy functions (Paragraph 38b) and cooperation (Paragraph 55c), on changes to branch pharmacies that are subject to branch pharmacy regulation (Paragraph 52), on functional and qualitative requirements for pharmacy operations (Paragraphs 56c to 56d), on the abolition of the requirement for equal prices for non-prescription medicinal products between the various pharmacy service channels (Paragraph 58 and Paragraph 4 of the Decree on the fee for medicinal products) and on improving the operating conditions of the pharmacy's online service by removing the restriction on the location of pick-up clubs in the pharmacy area (Paragraph 57e) and on the declaration of the online service of the holder of a retail licence for non-prescription medicinal products (Paragraph 54j). The proposed regulation must meet the general conditions required for a law restricting a fundamental right, such as the requirements of admissibility, accuracy and precision.

The granting of a concession for a dose distribution unit would be based on the authority's obligation to grant the concession if the conditions laid down by law for the grant of the concession were met. The rationale for regulating the dispensing activity is the same as that underlying the pharmacy licensing system, i.e. the safeguarding of public health. The rules governing the withdrawal of authorisation would be based on the consent holder's own

initiative, which would require the consent holder to ensure that the patient safety of customers using its service would not be compromised. The obligation to appoint a new responsible person on the instructions of the authority would also be based on the risk to patient safety. The proposed regulation would be based on the reconciliation of the freedom to conduct a business with the public authority's task of promoting the health of the population. The size of the dosage distribution units is significant and there is a direct link between the dosage distribution activity and the safe use of medicinal products (Centre for Accident Investigation: Absence of dose dispenser in Satakunta in spring 2023, 13 February 2024, T2023-1). The ability of the customer base and the pharmacy which supplies the dosage distribution service to customers to control or influence the activities of the dosage distribution unit is limited.

In the context of restrictions of the freedom of economic activity, the Committee on Constitutional Law has established that cancelling a permit intervenes with the individual's legal status and has more severe consequences than the rejection of an application. The Constitutional Law Committee has consistently considered it necessary, from the point of view of proportionality, to link the possibility of withdrawal of the authorisation to serious or substantial infringements or omissions and to the fact that any comments or warnings addressed to the holder of the authorisation have not led to the correction of shortcomings in the operation (see, for example, PeVL 48/2005 vp, p. 2). The proposed regulation and withdrawal of the authorisation on the initiative of the authority would be based on a proportionality test and would be based on serious or repeated breaches or omissions and on the fact that the holder of the authorisation has been given the opportunity to rectify its actions within a reasonable period of time, provided that the deficiency or omission can be remedied, or on any written warnings issued. The issuing of a written warning would be similarly based on the conditions of proportionality. As required by the Constitutional Law Committee's opinion-making practice, the Authority's powers would be binding.

It is also proposed to add a rule of principle to the operation of the mechanical dispensing unit with regard to the composition of the range of medicinal products. The formulation of the range of medicinal products to be used in a dose distribution unit should take into account national treatment practices and economic efficiency. The selection should be made, in principle, of medicinal products covered by health insurance and authorised for marketing, which are covered by the exchange of medicinal products and the reference price system. The restriction of the freedom to conduct a business and the freedom of contract would be based on the protection of health and safety of medication and would not go beyond what is necessary. The provision would allow for an exception where it is justified and would not bind the trader to individual products or set a price for the activity, but would determine the basis of principle in an environment where the user of the medicinal product would not have effective control over the medicinal products distributed to him. The proposed selection principle would be consistent with the tasks of the pharmacy supplying the medicinal products to the customer, since, under Paragraph 55(1) of the Law on medicinal products, the pharmacy must also hold in stock the medicinal products which are most advantageous and, under Paragraph 57(1), it must offer to the purchaser of the medicinal product the medicinal product which is actually the most advantageous in terms of price.

The presentation proposes qualitative and functional requirements for both the dispensing unit and the pharmacy. These may have economic implications for traders, but have been estimated to be minor, as operators have already largely complied with the proposed regulation in the current state, as the requirements have previously been based on an order of the Finnish Medicines Agency. From the point of view of the user of the medicinal product, those requirements based on safety and privacy are assessed to be proportionate, precise and precise in relation to the traders' fundamental right to freedom to conduct a business and to the protection of property. The proposals for Sections 57(1) and (2) (guidance and advice on

medical treatment) and 56b (price advice) of the Medicines Act can enable the development of activities and the introduction of digital solutions, which can also improve the position of different language groups.

No changes are proposed to the basic principles of the pharmacy system, i.e. licensing, location and volume regulation of pharmacies. No new obligations would be proposed for the pharmacy. The core of the pharmacy's tasks would essentially remain unchanged, the proposed regulation would contain provisions of principle that would guide the pharmacy's activities vis-à-vis society, social and health care and the user of the medicinal product and would also strengthen in law the qualitative structures underlying the pharmacy's tasks. The proposals would aim to align the functional and qualitative requirements of the pharmacy with other regulations governing the provision of social and healthcare services, ensuring equal, high-quality and safe services to protect the health of the user of the medicine. The proposal does not contain any proposals for changes that would only affect the status of the pharmacy of the University of Helsinki or of the pharmacy of the University of Eastern Finland (Section 123 PEL).

It is proposed to add to Section 55c of the Medicines Act the possibility for a pharmacy to agree to cooperate with other traders in the supply of a medicinal product through the pharmacy's online service. The amendment would give the pharmacy greater freedom to organise its activities as it sees fit and to exercise contractual freedom. An agreement to cooperate would only be possible on the pharmacy's online service, which is remote and not in direct face-to-face contact. The limitation would be based on ensuring Article 19(3) of the Constitution and access to pharmacy services. Some of the pharmacy's customers are still only in a physical pharmacy, in which case the availability of their medicines or the related helpdesk should not be inferior to online users. Without restrictions, parts of the population could be disadvantaged, e.g. many elderly, drug-intensive or incapacitated customers will not be able to take advantage of multi-channel applications. Regulation would ensure that essential health-related services are equally available and that the service system is not made accessible to different groups in different ways.

In addition to the freedom to conduct a business and the protection of the property of pharmacists, an agreement to cooperate would be an additional change, also from the point of view of the professional activities of other pharmacists, which would improve their position. This change would allow them to exercise their profession more widely in new ways.

The changes to the regulation of branch pharmacies would aim to streamline the current authorisation practice and to ensure the territorial availability of medicinal products, which is linked to the obligation of the public authorities to promote the health of the population. It is proposed to amend the regulation of branch pharmacies (Section 52 of the Medicines Act) so that the authorisation of a pharmacy could be made conditional on the application of a branch pharmacy by public notice when deemed necessary by the Finnish Medicines Agency to ensure the continuation of pharmacy services in the region. It is also proposed that the section be amended to allow the Finnish Medicines Agency to convert a branch pharmacy entitled to operate as a pharmacist into a branch pharmacy on the initiative of the pharmacist, if this is justified by the need to ensure the continuity of pharmacy services in the region. The regulatory proposals would contribute to the realisation of both the freedom to conduct a business and the fundamental right to protection of property by being based on the trader's own activity and business decision.

In the light of the fundamental rights to freedom to conduct a business and the protection of property, the possibility for the holder of a retail licence for non-prescription medicinal products to sell non-prescription medicinal products in the limited range of non-prescription medicinal products referred to in Paragraph 23d of the Law on medicinal products via an

online service by means of the proposed Paragraph 54j of the Law on medicinal products is also positive. Starting an online service activity would require the operator of the online service to have a website offering medicinal products for sale at a distance and, prior to starting the activity, to notify the Finnish Medicines Agency in advance. Activities should be allowed to commence unless, within 60 days of receipt of the notification, the Centre has requested further information on the matters referred to in this section or has prohibited the commencement of activities. The retail licence holder would be responsible for the operation and management of the online service. As the Law on medicinal products currently stands, similar procedural provisions concern the opening of a pharmacy's online service and would be justified not only in order to ensure equality as a fundamental right (Paragraph 6 of the Law on medicinal products), but also in order to ensure the safety of medicinal products.

Protection of privacy

It is proposed that, despite the patient's ban, information on all drugs and drugs prescribed to the patient should be made available to the prescriber, along with the associated labelling and the pharmaceutical contract, as well as information on all drugs and drugs prescribed to the dispensing pharmacy.

The proposed provision is relevant to the protection of private life provided for in Article 10 of the Constitution. Everyone's private life, honour and inviolability are safeguarded. Further provisions on the protection of personal data are laid down by law.

The patient's right to obtain a prohibitory injunction, as provided for in Paragraph 13 of the Law on prescription, is a specific safeguard provided for at national level in order to protect the confidentiality of patients' data. The provision on the right to obtain a prohibitory injunction in the Law on prescription must be considered to have been based on Article 9(4) of the GDPR, which allows Member States to maintain or introduce further conditions, including limitations, with regard to the processing of genetic data, biometric data or health data. The right to obtain a prohibitory injunction is an additional condition laid down in national law for the processing of health data and their disclosure. The proposed new exception in Paragraph 13(3)(5a) is a provision which is subject to the same additional condition. Therefore, the proposed exception to the patient's right to injunction would not constitute a legislative measure of a Member State within the meaning of Article 23 limiting the scope of the obligations and rights provided for in Articles 12 to 22 and Article 34 and Article 5 of the EUDPR. Therefore, the limitation of the patient's right to obtain a prohibitory injunction is assessed only as a constitutional limitation.

As the information content of the prescription centre expands, the range of patient-related information under Paragraph 13 of the Law on prescription would be expanded accordingly. The patient's right under the section to prohibit the disclosure of information relating to a medicinal product prescribed to him to social welfare and healthcare providers, prescribers and pharmacies would, in principle, also apply to the information contained in the contract for medicinal products.

The Constitutional Law Committee has paid particular attention to the fact that restrictions on the right to privacy must be assessed in the specific regulatory context in the light of the general conditions for restricting fundamental rights (see PeVL 42/2016 vp, pp. 2-3 and the opinions referred to therein).

The Constitutional Law Committee has considered the right to informational self-determination to be central to the protection of personal data (see, for example, PeVL 23/2020 vp, p. 9, PeVL 2/2018 vp, p. 8). In practice, the Committee's autonomy has been considered to be linked to a number of fundamental rights, in particular Article 7 of the Constitution; the provisions on personal liberty laid down in Paragraph 21, and

immunity and the provisions of Article 10 of the Constitution on the protection of private life (see PeVL 48/2014 vp, p. 2/II).

According to the Constitutional Law Committee, the necessity of specific legislation must also be assessed in accordance with the risk-based approach required by the GDPR, taking into account the threats and risks posed by the processing of data. The higher the risk to the rights and freedoms of natural persons, the more justified is:

more detailed regulation. This is particularly relevant for the processing of sensitive data (see PeVL 14/2018 vp, p. 5). According to the Constitutional Law Committee, medical data are personal data that are considered to be constitutionally sensitive (see e.g. PeVL 15/2018 vp, pp. 35-43, PeVL 1/2018 vp). The Committee has consistently emphasised the threats posed by the processing of sensitive data. In the Committee's view, large-scale databases containing sensitive information present serious risks in terms of data security and data misuse, which may ultimately pose a threat to a person's identity (PeVL 13/2016 vp, p. 4, PeVL 14/2009 vp, p. 3/I). The committee has therefore paid particular attention to the need to limit the processing of sensitive data to what is strictly necessary by means of precise and precise provisions (see, for example, PeVL 3/2017 vp, p. 5). As regards the processing of those data, compliance with the conditions for restrictions of fundamental rights must be carefully assessed and justified, in particular from the point of view of the admissibility and proportionality of the restrictions (e.g. PeVL 29/2016 vp, pp. 4-5).

The Constitutional Law Committee has also paid particular attention to the fact that the national switchover to nationwide electronic information system services in the healthcare sector may result in a very significant violation of fundamental rights in the event of a breach, leak or misuse of such systems. The possible processing of data for a purpose other than that for which it was originally collected has also been relevant in this regard. In such a regulatory environment, the committee has also stressed the importance of an IT-assured care relationship or the proposed contextualisation (PeVL 4/2021 vp, paragraph 23, PeVL 71/2018 vp, p. 4).

The proposed regulation would meet the general requirements for restrictions of fundamental rights. The regulation would be based on the ePrescription Act and would be precise and precise. By national law, the restriction would apply to the processing purpose, operators and data that are limited by law; despite the prohibition, the processing of contract information for medicinal products would be possible only for the person who prescribes the medicinal product ddmmyy and narcotics and for the pharmacy supplying them.

The information contained in the contract would include the name of the patient, the patient's personal identification number, the responsible treatment unit, the responsible physician, any other treatment units and the medicinal products, medicinal products and categories of medicinal products specified in the contract, but the legislation is not intended to regulate in detail what the information contained in the contract is and the THL has the power to issue orders in that regard. However, the pharmaceutical contract would have been defined in the section on the definition of prescription law.

The purpose of the agreement is to centralise the prescription of medicinal products or categories of medicinal products included in the pharmaceutical contract to a single therapeutic entity. Therefore, medicinal products covered by a medicinal product contract should be prescribed to the patient only in the therapeutic units designated in the medicinal product contract (and, if agreed, by the doctors designated in the contract). However, if the patient were to exercise his right to obtain a prohibitory injunction in relation to the medicinal product agreement, that would, by its very nature, lead to the termination of the medicinal product agreement in a situation comparable to that in which the information in the medicinal product agreement would not be available to other prescribers or to the dispensing pharmacy.

In the light of the above, the proposal would consider that there is a legitimate reason in the proposal for restricting the right to prohibit extradition.

Paragraph 4.2 above. The technical and organisational safeguards set out in the Client Information Act and the Regulation, as explained in section, now also apply to data added to a prescription centre. Nor is it a new and ambiguous assessment. The patient's right to order the disclosure of the information contained in the prescription has already been restricted on statutory grounds (Section 13(3)(1) to (9) of the Medicines Regulation Act). As has also been stated above, the Kanta medication list is already governed by a comprehensive reform of the processing of customer data, including the Client Data Act and the Law on prescriptions. It is true that, in its opinion on the government proposal for the overall reform (HE 246/2022 vp) (PeVL 89/2022 vp), the Constitutional Law Committee did not specifically comment on the Kanta medication list.

Overall, the proposed restriction on the processing of personal data is acceptable and proportionate to the fundamental rights system, and the objective to be protected, namely the prevention of health and life-threatening risks for the patient, can be considered to outweigh the interference with the protection of private life.

Nor can the restrictions be considered incompatible with Finland's international human rights obligations (Article 8 of the European Convention on Human Rights, Articles 7 to 8 of the Charter of Fundamental Rights of the European Union and Article 17 of the UN International Covenant on Civil and Political Rights) where the processing is based on the law and the purpose of supporting the patient's medical treatment and ensuring medication safety.

In the proposal, the limitations of patients' rights to the processing of sensitive data must be regarded as precise and precise, limited to what is strictly necessary for the treatment of medicinal products and, moreover, as acceptable and proportionate.

Action by public authorities and judicial protection

The proposed licence for the dosage distribution unit would be independent of the current rules which link the mechanical distribution of the dosage to the operation of a pharmacy or a hospital pharmacy. It is proposed to amend Section 77(1) of the Medicines Act in order to provide the Finnish Medicines Agency with the right to inspect the dosage distribution unit as often as necessary for proper pharmacovigilance. Under Section 78 of the Medicines Act, the inspector may issue orders to remedy any deficiencies found. Any order made in the course of the inspection must be followed up without delay. The authority's right to inspect the activities of operators of dosage distribution services has been based on the pharmacy's right to inspect (Section 12a of the Medicines Act) and therefore the proposed amendment would have positive effects on the operator's legal certainty (Section 21 of the Medicines Act).

The Constitutional Law Committee has stated that, from the point of view of Article 21 of the Constitution, it is therefore essential to ensure that the appeal system as a whole ensures both the availability and adequacy of legal protection and that the case is dealt with as expeditiously as is possible in the light of the requirement for legal protection. The application of the system in all categories of cases should therefore be based on a coherent and consistent assessment of the legitimate interest in bringing proceedings (PeVL 39/2013 vp, pp. 2-3). It is also proposed that the Medicines Act provide for the right to appeal against a decision on an application for authorisation by a dosage distribution unit. The objection procedure is also proposed for decisions under Sections 54j and 55c. The rules would be similar to those in other similar categories of cases, such as the prescription referred to in Section 78 of the Medicines Act and the decision on the pharmacy's online service issued to entities other than the dosage distribution unit.

The proposal proposes to amend section 102(2) by adding the proposed new section 12i to the list of cases that may be appealed to the Supreme Administrative Court without permission. The reasons for the case are set out in the Government proposal to Parliament for an Act amending the Medicines Act (HE 107/2021 vp, p. 1114). In the same vein, the new proposal deals with a matter of particular importance for the legal certainty of the party concerned and for the conduct of the business, making it necessary to have a direct right of appeal.

It is proposed to add to Section 89 of the Medicines Act a right of access to information from the Dose Distribution Unit so that it must, on request, provide the Finnish Medicines Agency, free of charge and without prejudice to confidentiality provisions, with the information and explanations relating to the import, manufacture, inspection, distribution, sale or other release for consumption of medicinal products that are necessary for the fulfilment of its tasks under this Act, another Act or a legal act of the European Union. The Centre shall also have access to the medical records necessary for the protection of patients and other persons and otherwise for the performance of its supervisory tasks.

The Constitutional Law Committee has assessed the rules on access to information by public authorities in the light of the protection of private life and personal data provided for in Article 10(1) of the Constitution, drawing attention, inter alia, to what and to whom the right of access extends and how the right of access is linked to the necessity of the information (PeVL 15/2018 vp, p. 39). The Constitutional Law Committee has drawn attention, among other things, to what information and to whom the right of access extends and how the right of access is linked to the necessity of the information. In the Committee's view, the authority's right of access and its ability to disclose information may have been linked to 'necessary information' for a purpose if the law attempts to list the information content concerned exhaustively. If, on the other hand, the datasets are not listed in the same way, the regulation must have included the requirement of 'necessity of the data' for a purpose. On the other hand, the Constitutional Law Committee did not consider very broad and unidentified rights of access to information to be possible, even when they are linked to the criteria of necessity (PeVL 62/2010 vp, p. 3, and PeVL 15/2018 vp, p. 39).

The proposed right of access concerns several other actors. The data are limited in purpose, the provisions would include a necessity test and would be clearly based on the tasks of the authority as laid down by law.

Right to information and advice on medical treatment

It is proposed that Section 57 of the Medicines Act be amended so that the customer of a pharmacy would always have the right to receive medical advice and advice from a pharmacist or pharmacist. It would be up to the customer to assess whether he or she wishes to receive advice and advice on his or her treatment at the time of dispensing the medicine. According to the established practice of the Constitutional Law Committee, the right of self-determination and the right of a person to decide whether or not to receive services concerning him or her are essential to health and medical care activities (PeVL 77/2022 v and PeVL 15/2015 vp). It is proposed to amend the section in such a way that the customer would always have the right to advice and advice on medication when the pharmacy delivers the medicine to him.

In relation to the right to self-determination, account must be taken of the role of public authority under Article 19(3) of the Constitution, which promotes the health of the population. From a medication safety perspective, the lack of guidance and advice can increase the risk of incorrect medication uptake or other harm. According to Article 1(2) of the Constitution, the Constitution guarantees the inviolability of human dignity and the freedom and rights of the individual and promotes justice in society. The reference to the protection of the rights and freedoms of individuals also includes the individual's right to self-determination, which

underpins the exercise of many other rights, namely the freedom to determine one's own affairs and actions (HE 309/1993 vp, p. 42). The right to self-determination is also considered to relate to the freedom and integrity of the person, as guaranteed by Article 7 of the Constitution, and to the protection of privacy, as guaranteed by Article 10 of the Constitution (PeVL 77/2022 vp, point 2).

The proposal takes account of fundamental rights and the role of public authorities, so that advice is always available to the client, but the client may choose not to use it without detriment or limitation to access the service. The proposal makes it possible to respond to different needs.

The proposed regulation does not interfere negatively with the customer's autonomy, but strengthens it by providing access to medical support without being mandatory. At the same time, it safeguards the duty of public authorities to promote medication safety and prevent harm to health.

Relationship with the autonomy of the Åland Islands and the municipalities

It is proposed that Sections 41 and 52 of the Medicines Act amend the entity involved in the assessment of the organisation of pharmacy services. According to the amendment, the references to the municipality in the articles would be replaced by a body responsible for the organisation of the social and healthcare services in the area. Pharmaceutical services are an essential part of outpatient medication. Pharmacy services should be taken into account by the organisation of other social and health services in the region as part of the coordination of services for out-patients. The proposed amendment is a key consequence of the establishment of the wellbeing services counties and their statutory tasks. The main objective of the amendment would be to technically update the legislation to reflect the new structural landscape and organisational responsibility, without touching upon the substance of the legislation. The amendment would be in line with the changes introduced in the context of the so-called SOTE100 package. The impact of the proposal on the status of the municipality should be examined, taking into account the impact of the proposals on the Province of Åland.

According to Section 121(1) and (2) of the Constitution, Finland is divided into municipalities whose administration must be based on the self-governance of the inhabitants of the municipality. The general criteria for the administration of municipalities and the tasks entrusted to them are laid down by law.

Act on the Organisation of Social Welfare and Healthcare (612/2021; under Section 8 of the Social Security Act, the wellbeing services county is responsible for the organisation of social and healthcare services in its territory and is responsible for the social and healthcare services of its residents. According to Section 4 of the Social Security Act, the wellbeing services county must plan and deliver social welfare and healthcare with the content, scope and quality required to meet customers' needs. The wellbeing services county must ensure the accessibility of the social and healthcare services for which it is responsible. The wellbeing services county could base its assessment at the request of the Finnish Medicines Agency on, for example, a report under Section 29 of the Act on the Organisation of Social Services.

It would be possible for the organisation of social and health services in the region to seek the opinion of the relevant municipality in support of its assessment. Under Section 6(1) of the Act on the organisation of social services, one of the tasks of a municipality is to promote the well-being and health of its inhabitants. The municipality has the primary responsibility for promoting well-being and health insofar as this task is linked to other statutory tasks of the municipality. Local knowledge of the municipality can serve as a complementary source of information for the organisation of social and health services in the region. The aim of the

proposed amendment would not be to change the current territorial regulation of pharmacies in the Medicines Act. The Finnish Medicines Agency could still decide to open a new pharmacy in an area adjacent to a municipality, a part of a municipality or a social or healthcare institution.

According to Section 120 of the Constitution, the Province of Åland has autonomy in accordance with specific provisions in the Act on the Autonomy of Åland. According to Section 75 of the Constitution, the provisions of the Act on the Autonomy of Åland and the Act on Land Purchase in Åland specifically provide for this.

Under Section 27(30) of the Self-Government Act (1144/1991), the Finnish Government has legislative powers in matters relating to the qualifications of persons providing health care and medical care, the establishment of a pharmacy, medicinal products and pharmaceutical products, narcotics and the manufacture of poisons and the determination of their intended use. The proposed amendments to Articles 41 and 52 relating to the pharmacy licensing system fall within the national legislative competence. However, as regards the pharmacy licensing system, the proposal is also linked to the competence of the Åland Islands, where, according to Section 18(12) of the Self-Government Act, the Province has legislative competence in matters concerning health and medical care, with the exceptions provided for in Section 27(24), (29) and (30); burial and, under point 13, social assistance; a licence for the serving of alcoholic beverages.

Unlike the 21 wellbeing services counties in mainland Finland, Åland itself organises the social and healthcare and rescue services in its own area. In Åland, under the authority of the Provincial Government, Ålands hälso- och sjukvård ÅHS is responsible for health care. The 16 municipalities in the province are partly responsible for social services. The regulatory proposal takes into account the autonomy of the Åland Islands and the municipalities.

Enabling provisions for sub-statutory regulation

The draft law would include the Government’s power to issue decrees and orders. As regards the power to issue decrees and the power to issue decrees, the draft law must be examined in the light of Article 80 of the Constitution.

According to Article 80(1) of the Constitution, the President of the Republic, the Council of Ministers and the Ministry may issue decrees on the basis of powers laid down in the Constitution or in another law. However, the law must lay down the grounds for individual rights and obligations, as well as matters otherwise covered by the law under the Constitution. Where there is no provision specifying who is to issue a decree, it is issued by the government. The adoption of a regulation presupposes that the necessary basic provisions are laid down by law and that the law contains an appropriate enabling provision. The author of a regulation may be empowered by law to lay down more detailed rules on minor details relating to individual rights and obligations. However, such authorisation should meet the requirements of precision and precision (HE 1/1998 vp, pp. 131-132). The enabling law must meet the requirements of precision and precision laid down in the Constitutional Law Committee’s opinion practice.

Under Paragraph 55a of the Law on medicinal products, a pharmacy may act as the competent authority within the meaning of Article 75 of the CISA and issue the certificate referred to in that article for the carriage of medicinal products containing narcotic drugs or psychotropic substances when travelling from one Contracting State to another. It is proposed to add to Section 55a(2) of the Medicines Act the right for the pharmacy to charge a fee for the certificate. According to Article 81(2) of the Constitution, the general criteria for charging fees for official acts, services and other activities of state authorities, as well as the amount of the fees, are laid down by law. The issuing of the Schengen Certificate has been interpreted from

the point of view of Article 124 of the Constitution as a public administrative task, which is why, according to the opinion of the Constitutional Law Committee, the content of Article 81(2) of the Constitution should also be taken into account. It would be proposed to base the general contribution on the recovery of operating costs. Since there would be no intention to depart from those principles, it would not be necessary to lay down separate criteria for determining the amount of the charge (PeVL 2/2001 vp, pp. 2-3, and PeVL 14/1993 vp, p. 3).

It is proposed to add a new Section 55a(3) to the Medicines Act, according to which more detailed provisions on the fee for the Schengen Certificate issued by a pharmacy referred to in Section 55a of the Medicines Act will be laid down by Government decree. The proposed power to adopt regulations is precise and constitutionally acceptable and justified. According to Article 80(2) of the Constitution, another authority may also be empowered by law to issue legal rules on specific matters if there are specific reasons relating to the subject matter of the regulation and the substantive meaning of the regulation does not require that the matter be regulated by law or regulation. Such authorisation must be strictly limited in scope. According to the opinion practice of the Constitutional Law Committee, compared to the power to issue regulations, the power to issue regulations is subject to a more far-reaching requirement of general precision, according to which the matters covered by the power must be precisely defined by law (PeVL 34/2000 vp, pp. 3-4 and PeVL 19/2025 vp, pp. 5-6). The content of the authorisation must therefore be clearly defined by law and its scope clearly defined. The normative power of other authorities is exceptional from a constitutional point of view (PeVM 10/1998 vp, p. 23). In the context of the constitutional reform, the technical and minor detail regulation, which does not involve significant discretionary powers, was mentioned as an example of the authority's normative power (HE 1/1998 vp, p. 133).

It is proposed that the Medicines Act provide for the possibility for the Finnish Medicines Agency to issue regulations on the content, form and annexes of the application for a licence for a dosage distribution unit (Section 12c(3)), on the requirements for industrial manufacturing activities (Section 12e). Paragraph 3), defects in the medicinal product, and the handling of suspected falsified medicinal products and the notification and handling of the recall of a medicinal product (Paragraph 30o(2)), the content and making of a prior notification by the holder of a retail licence, the packaging and checking of consignments of medicinal products, transport, outsourcing of activities, returns, the handling of product defects, the provision of information on a medicinal product by means of an online service, the storage of medicinal products, the supply of medicinal products by means of an online service, premises, technical implementation, the range of medicinal products, the management of medicinal products and the carrying out of an inspection of online service activities (Paragraph 54j(4)), the drawing up and verification of the operating instructions of a pharmacy (Paragraph 56d(5)). It is also proposed to clarify the existing power to issue orders under Section 57(4) of the Medicines Act. The prescribing authority would concern the procedures for the safe supply of the medicinal product, relating to the preparation and delivery of the medicinal product to the customer, the verification of the correctness of the prescription, the verification of the dosage, the frequency and frequency of supply and the provision of information and advice on medical treatment (Article 57(5)).

The proposed prescribing powers would be of a relatively technical nature, mainly related to different procedural requirements or otherwise of a technical nature, e.g. to ensure safe handling of medicinal products. The adoption of orders would thus also be based on specific reasons relating to the subject-matter of the regulation and would, by its very nature, require special expertise. The proposal places the power to issue orders in the context of the relevant basic provision of the law (PeVL 49/2014 vp, pp. 5-6), with the power to issue orders being strictly circumscribed.

In the light of the above, the draft law may be subject to the ordinary legislative procedure.

Pontoon

Based on the foregoing, the following bill is submitted to be passed by Parliament:

1.

Law

amending the Medicines Act

By Decision of Parliament

sections 55b and 67(2) of the Medicines Act (395/1987), as amended, Section 55b of Act 208/2019 and Section 67(2) of Act 22/2006 are *repealed;*

sections 12a, 15, 30o, 31, 32(1), 41, 52, 55(2), 57, 57e, 58(4) and (8), 77(1), 89 and 102 are *amended* as set out in Sections 12a and 15 of Act 1112/2010, 30o of Act 1200/2013, 31, 58(4) and (8) and 77(1) of Act 1426/2025, Section 32(1) of Act 780/2025, Sections 41, 52 and 57e of Act 1258/2021, Section 55(2) of Act 248/1993, Section 57 of Acts 1233/2022, 339/2023 and 934/2024, Section 89 of Act 985/2021 and Section 102 of Act 1426/2025 and

new sections 12b-12i, 38b and 54j, new subsections 2 and 3 of section 55a as amended by Act 700/2002 and new sections 55c and 56b-56d and new subsection 2 of section 101b as amended by Act 553/2020 are added to the Act as follows:

12 section A

Contract manufacturing is subject to authorisation by the Finnish Medicines Agency. Authorisation shall be granted if the activity complies with the requirements laid down in section 15. The authorisation may be subject to conditions concerning the manufacture, supply and use of the medicinal product and other conditions necessary for the safety of medicinal products.

13 section B

The mechanical dispensing of medicinal products is subject to authorisation by the Finnish Medicines Agency (*licence of a dispensing* unit).

The authorisation of a dose distribution unit shall be granted if:

1) the applicant is a body governed by public law, 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 has designated a responsible person with sufficient knowledge of the mechanical dispensing service for medicinal products or the industrial manufacture of medicinal products; and

3) the premises, equipment and personnel of the dosage distribution unit comply with the requirements of this Act and the regulations issued under it.

Paragraph 12c

The licence of the Dose Distribution Unit must be applied for in writing from the Finnish Medicines Agency.

The application or the documents to be attached to it shall contain the following information:

1) the name or business name, business registration number and contact details of the applicant;

2) address and contact details of the facility;

3) the name and contact details of the responsible person; and

4) a description of the premises, equipment and personnel of the dosage distribution unit and an estimate of the extent of the operation.

The Finnish Medicines Agency may lay down rules on the content, form and annexes of the application.

Paragraph 12d

The Dose Distribution Unit's licence is valid indefinitely.

The holder of a Dose Distribution Unit licence must notify the Finnish Medicines Agency in writing of any changes to the licence holder and to the implementation of the mechanical dispensing system that have a material impact on the fulfilment of the conditions of the licence. The change may be implemented unless, within 60 days of receipt of the notification, the Centre has requested further information on the matters referred to in this section or has prohibited the change of activity.

Paragraph 12e

In order to ensure the quality of dosage distribution and patient safety, the Dose Distribution Unit shall comply with the good manufacturing practices for medicinal products laid down in section 11 in so far as they concern the general requirements for industrial manufacturing of medicinal products and the organisation of risk management.

The holder of a concession for a dose distribution unit shall be responsible for:

1) the suitability of the premises and equipment of the dosage distribution unit for the operation of the machine-based dosage distribution service;

2) the adequacy and skills of the personnel involved in the dosage service activities;

3) the fulfilment of operational quality standards;

4) the appropriate protection, integrity and other factors affecting the quality of the information systems used and the data contained therein; and

5) incident handling and corrective actions.

The Finnish Medicines Agency may issue further regulations on the requirements for industrial manufacturing operations.

Paragraph 12f

A Dose Distribution Unit may purchase medicinal products for its activities from a pharmaceutical factory or from a wholesale distribution of medicinal products and may agree on the terms of purchase of medicinal products.

National treatment practices and economy should be taken into account when establishing the range of medicinal products to be used in a dose distribution unit. In the case of out-patient mechanised dispensing, the range of medicinal products covered by health insurance and authorised for marketing must, in principle, be covered by the exchange of medicinal products and the reference price system.

In the event of a change in the range of medicinal products, the Dose Distribution Unit shall ensure continuity of medical treatment for users of the service.

A pharmacy or a hospital pharmacy may obtain medicinal products from a dispensing unit. The pharmacy or hospital pharmacy is responsible for supplying the dispensed medicinal product to the user.

Paragraph 12 g

The person responsible for the dosage distribution unit shall be responsible for ensuring that the medicinal products packaged by the dosage distribution unit comply with the requirements laid down by or pursuant to the law and that they are of sound quality and that the provisions of this Act and the provisions and regulations adopted pursuant thereto are complied with in the dosage distribution activity.

The responsible person in the Dose Distribution Unit must be an authorised pharmacist. In addition, the responsible person shall have at least one year's practical experience in the packaging or quality assurance of medicinal products or in the industrial manufacture of medicinal products related to dosage distribution activities.

The responsible person may not, in the exercise of that function, be a responsible manager in the wholesale distribution of medicinal products or in a pharmaceutical factory of another company, a pharmacist, a manager of a hospital pharmacy or a pharmaceutical centre, a manager of a military pharmacy, a manager of a pharmacy or a branch pharmacy, or the holder of a retail licence for non-prescription medicinal products, a member of its management or the responsible person for the sale of non-prescription medicinal products.

The holder of the concession for the Dose Distribution Unit must immediately notify the Finnish Medicines Agency in writing of any change in the person responsible.

Paragraph 12h

If the Finnish Medicines Agency finds that the responsible person referred to in section 12 g is performing his duties inadequately in such a way as to pose a risk to patient safety, the Finnish Medicines Agency may instruct the Dose Distribution Unit to appoint a new qualified responsible person.

Article 12i

The Finnish Medicines Agency shall withdraw the authorisation of a dosage distribution unit if the holder of the authorisation so requests, provided that the unit has ensured that the patient safety of the customers using its service is not compromised.

The Finnish Medicines Agency may withdraw the authorisation of a dosage distribution unit if:

1) the conditions for granting the authorisation are no longer fulfilled; or

2) the permit holder has repeatedly or seriously infringed the provisions laid down in or pursuant to this Act.

If the deficiency or omission referred to in subsection 2(1) and (2) can be remedied, the Finnish Medicines Agency shall set a reasonable deadline for the permit holder to remedy the deficiency or omission. The permit authority may revoke the permit if the permit holder has not remedied the deficiency or omission within the deadline.

In the situation referred to in paragraph 2, the Finnish Medicines Agency may issue a written warning to the holder of the authorisation instead of withdrawing the authorisation if withdrawal of the authorisation would be disproportionate in the circumstances.

ARTICLE 15

The preparation of medicinal products by pharmacies, branch pharmacies, hospital pharmacies and pharmaceutical centres is subject to the condition that the personnel are sufficiently familiar with the preparation of medicinal products and that the necessary production facilities and equipment are appropriate. The activity shall also comply, where applicable, with good manufacturing practice for medicinal products in accordance with section 11.

Further provisions on permit conditions may be issued by government decree. The Finnish Medicines Agency may issue orders to apply for a licence under Section 12a(1).

Article 30o

The holder of the marketing authorisation, parallel import marketing authorisation and registration shall immediately notify the Finnish Medicines Agency of any withdrawal or

suspension of the product from sale or distribution on its own initiative relating to the efficacy or safety of the medicinal product and of any suspected defects in the manufacture of the medicinal product dispensed from a pharmaceutical factory. In addition, the holder of the marketing authorisation, parallel import marketing authorisation and registration shall inform the Centre of detected or suspected falsified medicinal products.

The Finnish Medicines Agency may issue further regulations on the reporting and handling of recalls, product defects and suspected falsified medicinal products.

ARTICLE 31

A pharmaceutical company may sell or otherwise dispose of pharmaceuticals and its own pharmaceutical products only to another pharmaceutical company, to a wholesaler, to a dispensing unit, to a pharmacy, to a branch pharmacy, to a military pharmacy, to a hospital pharmacy and to a pharmaceutical centre. In addition, medicinal products which are not prescribed or prescribed for sale only in pharmacies may be sold and otherwise disposed of to retailers of those products. In addition, non-prescription medicinal products for human use which have been granted an extension of the sales channel within the meaning of Paragraph 23e(2) may be sold to holders of retail licences for non-prescription medicinal products.

The pharmaceutical factory may also sell or otherwise hand over pharmaceuticals and its own pharmaceutical products to a university, university or scientific research institute for research purposes. The pharmaceutical company must notify the Finnish Medicines Agency.

Outside Finland, medicinal products may only be supplied from a pharmaceutical factory to an operator who is legally entitled in that country to procure medicinal products from a pharmaceutical factory.

ARTICLE 32

Wholesale distribution of medicinal products shall mean any activity carried out for consideration and on a professional basis for the purpose of:

1) receipt of orders for medicinal products and delivery other than that referred to in subsection 2;

2) the acquisition and possession of medicinal products with a view to their further supply to pharmacies, dispensing units, retail licence holders within the meaning of Paragraph 54f and entities authorised to sell nicotine preparations, social and healthcare institutions and other entities within the meaning of Paragraphs 34 and 35 of this Law; or

3) export of medicines.

Article 38b

The pharmacy’s tasks are:

1) the supply of medicinal products and the provision of information and advice to the general public on medical treatment;

2) the supply of medicinal products to health and social care institutions;

3) activities to promote health and well-being in support of self-care by the customer and planned self-care by a healthcare professional;

4) ensuring the storage and accessibility of equipment, consumables and bandages necessary for the use of medicinal products and medicinal products, as provided for in Article 55; and

5) other tasks specifically provided for.

In carrying out the tasks referred to in subsection 1, the pharmacy shall seek to ensure that its activities constitute a safe, high-quality, effective and economic entity for the user of the medicinal product and for the health and social care system and society.

In performing the tasks referred to in subsection 1, the operation of the pharmacy shall be based on evidence and good management and operational practices.

Where a pharmacy provides dosage distribution services, contract manufacture or other similar services on a cooperative basis, it shall be responsible for the adequacy of the overall service and shall satisfy itself that the arrangements meet the conditions laid down for them throughout the term of the agreement.

ARTICLE 41

At the request of the Finnish Medicines Agency, the organisation of health and social services in the region must, if necessary, assess the functioning, location and adequacy of pharmacy services in the region. The entity responsible for organising the social and health services in the area may submit a proposal to the Centre to open a pharmacy and branch pharmacy, to change the area in which the pharmacy and branch pharmacy are located, or to transfer the pharmacy and branch pharmacy.

The Finnish Medicines Agency may decide to open a new pharmacy in an area adjacent to a municipality, a part of a municipality or a social or healthcare institution (area in *which the pharmacy* is located), to change the area in which the pharmacy is located and to transfer the pharmacy from one part of the municipality to another if the availability of medicinal products so requires or is necessary to ensure adequate pharmacy services. In assessing the availability of medicinal products and the adequacy of pharmaceutical services, account shall be taken at least of the number of inhabitants and the population served, the pharmaceutical services already existing in the area and other social and healthcare services. The Centre for the Safety and Development of the Pharmaceutical Sector may take a decision on its own initiative or on the initiative of the body responsible for the organisation of social and health services in the region.

The Finnish Medicines Agency may decide to dissolve a pharmacy if the availability of medicinal products or the adequacy of pharmacy services no longer requires the maintenance of the pharmacy, taking into account the population living or serving the area, the pharmacy services already in the area and other social and healthcare services. The termination decision may not be enforced until the pharmacy licence in question has become open, unless the pharmacist holding the pharmacy licence has expressed his agreement to the decision.

Before taking the decision referred to in subsection 2 or 3, the Finnish Medicines Agency shall consult the entity responsible for the organisation of social and health services in the region.

ARTICLE 52

The Finnish Medicines Agency may establish a branch pharmacy on the initiative of the entity responsible for the organisation of social and health services in the area or of a pharmacist or on its own initiative. The establishment of a branch pharmacy is subject to the condition that pharmacy services are required in the area in order to ensure the availability of medicinal products and that there is insufficient capacity for an independent pharmacy. However, the establishment of a branch pharmacy within a health or social care institution is subject to the condition that the establishment requires the provision of pharmacy services and that there is insufficient capacity for an independent pharmacy. A pharmacist may be authorised to operate up to three branch pharmacies.

The Finnish Medicines Agency shall publish the application for a new or newly opened branch pharmacy licence on the Agency’s website by means of a notice indicating the location of the branch pharmacy. An applicant for a branch pharmacy licence shall attach to his application the documents on which he wishes to rely in the assessment referred to in paragraph 3. This paragraph shall not apply to a branch pharmacy licence which is a condition

of authorisation to operate a pharmacy and which is published and applied for as part of the authorisation to operate a pharmacy, unless, on the basis of an assessment by the Finnish Medicines Agency, the application of this paragraph is unavoidable in order to ensure the continuity of pharmacy services in the area.

The Finnish Medicines Agency grants a branch pharmacy licence from more than one applicant to the pharmacist who is best placed to operate the branch pharmacy, taking into account the location of the pharmacy, the other operating conditions and, in the case of a new branch pharmacy licence, the plans for organising the branch pharmacy business. This paragraph shall not apply to a branch pharmacy licence which is a condition of authorisation to operate a pharmacy and which is determined as part of the authorisation to operate a pharmacy, unless the application of this paragraph is necessary in order to ensure the continuity of pharmacy services in the situation referred to in paragraph 2.

By way of derogation from paragraph 1, the University of Helsinki may, with the authorisation of the Finnish Medicines Agency in each case, operate up to 16 branch pharmacies.

The Finnish Medicines Agency decides on the location of the branch pharmacy. The centre may, on its own initiative or on the initiative of the entity responsible for the organisation of social and health services in the area or of the holder of a branch pharmacy licence, modify the area designated for the branch pharmacy in order to ensure the availability of medicinal products.

If justified by the need to ensure the continuity of pharmacy services in the region, the Finnish Medicines Agency may, on the initiative of the pharmacist, convert a branch pharmacy holding a licence to operate a pharmacy into a branch pharmacy on which a licence to operate as a pharmacy is conditional.

The pharmacist must inform the Finnish Medicines Agency in advance of the opening of a branch pharmacy. Further provisions may be issued by government decree on the reports required when applying for a branch pharmacy licence, the information to be provided in the application for a licence and the notice of commencement of the branch pharmacy’s activity.

Paragraph 54j

The holder of a retail licence for non-prescription medicinal products may sell non-prescription medicinal products from a limited range of non-prescription medicinal products via an online service. The operator of the online service shall have a website offering medicinal products for sale at a distance. This website shall contain a link to the list of lawful online services of holders of retail licences for non-prescription medicinal products maintained by the Finnish Medicines Agency and a clearly visible common logo in the European Union in accordance with Article 85c of the Medicinal Products Directive.

The maintenance of the online service of the holder of a retail licence for self-care medicinal products shall be subject to prior notification to the Finnish Medicines Agency. The activity may be commenced unless, within 60 days of receipt of the notification, the Centre has requested further information on the matters referred to in this section or has prohibited the commencement of the activity. The Centre shall be notified of the start of operations, the cessation of operations and any substantial changes. The Centre may prohibit the start of operations or order the termination of an online service if the online service does not meet the conditions laid down in the Medicines Act or in the provisions adopted on the basis thereof.

The retail licence holder is responsible for the operation and management of the online service. The online service shall be subject to annual inspection by the retail licensee. The holder of a retail licence shall ensure appropriate storage and transport conditions for the medicinal products supplied through its online service. The holder of a retail marketing authorisation shall ensure that the medicinal product is lawfully marketed in the State to which it is sold.

Otherwise, the provisions of Chapter 6 of the Consumer Protection Act (38/1978) on distance selling shall apply to online service activities. The provisions on the online service shall also apply to the sale of non-prescription medicinal products by other means of distance communication.

The Finnish Medicines Agency may issue regulations on the content and making of the prior notification by the retail licence holder and on the packaging and checking of consignments of medicinal products, transport, outsourcing of activities, returns, handling of product defects, information on the medicinal product provided on the web service, the storage of medicinal products, the supply of medicinal products via the web service, facilities, technical implementation, the range of medicinal products, management and the performance of the inspection of the web service activities.

ARTICLE 55

The pharmacy and branch pharmacy shall be kept open in such a way as to ensure the availability of medicinal products.

Section 55a

The pharmacy may charge a fee for the issue of the certificate referred to in paragraph 1. Further provisions on the fee shall be laid down by government decree.

Paragraph 55c

The pharmacy is responsible for the arrangements made for the supply of the medicinal product in the pharmacy's online service, under which another trader provides the pharmacy with a function or service that the pharmacy would otherwise have provided for the supply of the medicinal product *(agreement to* cooperate). The pharmacy must satisfy itself that the arrangements meet the conditions laid down for them throughout the term of the agreement.

The pharmacy shall not make any arrangements for dispensing the medicinal product which may jeopardise the availability of medicinal products in the area, the safety of medication or patients, or increase the financial burden on the user of the medicinal product or on society.

The pharmacy must give prior notification of the arrangement referred to in subsection 1 to the Finnish Medicines Agency. The arrangement may be commenced unless, within 60 days of receipt of the notification, the Centre has requested further information on the matters referred to in the section or has prohibited the commencement of operations. The Centre shall be notified of the commencement, termination and material changes to the arrangement.

The Finnish Medicines Agency may prohibit or order the termination of the arrangement referred to in the section if it is contrary to the Medicines Act or other regulations governing the supply of medicinal products.

Article 56b

When supplying a medicinal product, the pharmacy must offer to the purchaser of the medicinal product the medicinal product which is actually the most advantageous in terms of price. The purchaser of the medicinal product should be provided with information on the prices of the medicinal products available.

Paragraph 56c

The pharmacy must have a mechanism in place to monitor the performance of the pharmacy's tasks and to report and handle any deviations therefrom.

The pharmacy must organise the handling of anomalies to the extent required by their nature.

Paragraph 56d

The pharmacy must ensure that its staff are sufficiently skilled to carry out its tasks and provide up-to-date tools to support the performance of those tasks in the pharmacy and its outlets.

The pharmacy must ensure that its premises and systems are suitable for the processing of confidential personal data concerning health in the pharmacy and its outlets.

The pharmacy and its branches must have a policy on critical functions for the operation of the pharmacy.

The pharmacy should ensure that the policy is up-to-date and that compliance with the policy is checked regularly and, if necessary, that the pharmacy takes steps to remedy the shortcomings.

The Finnish Medicines Agency may issue guidelines and revisions.

ARTICLE 57

The pharmacy must organise the dispensing of the medicinal product in such a way that it supports the success and continuity of the treatment and ensures patient safety.

When dispensing a medicinal product, the pharmacy shall offer the user of the medicinal product the opportunity to receive medical advice and advice from a pharmacist or a pharmacist in order to direct the medicinal product to its correct and safe use and to support the success of medical treatment. Medical advice and advice shall be provided in such a way as to support the individual needs of the user of the medicinal product, taking into account, in particular, the overall medication provided by the customer, his illnesses and age, and his membership of a group of customers requiring special attention. Advice includes advice on how to use a device to administer a medicinal product. Guidance and counselling should be given on issues affecting the choice of the medicinal product before dispensing. In the case of self-care, guidance and counselling also include an assessment of the need for care supported by a pharmacy professional.

The pharmacy must also provide advice and advice on medical treatment to persons acting on behalf of the user of the medicinal product. The user of the medicinal product, or anyone acting on his behalf, should be able to receive advice and advice on medical treatment by telephone from the pharmacy in which he has been present.

When a pharmacy changes an inhaled medicinal product, a biological medicinal product or a biosimilar used for the treatment of asthma or chronic obstructive pulmonary disease, the pharmacists of the pharmacy shall provide the necessary medical advice and equipment for the correct and safe use of the medicinal product to be supplied to the purchaser of the medicinal product.

The Centre for the Safety and Development of Medicinal Products may lay down rules on the procedures for the supply of a safe medicinal product, with regard to the preparation and delivery of the medicinal product to the customer, the verification of the correctness of the prescription, the verification of the dosage, the intervals and quantities of supply, and the provision of advice and advice on medicinal treatment.

Paragraph 57e

A pharmacy may have a collection club to which the pharmacy can deliver and deliver medicinal products to customers for collection. The swab must be suitable for the proper and safe storage and warehousing of medicinal products.

The pharmacist is responsible for the proper functioning of the collection club. The pharmacist is responsible for the proper transport conditions and storage of the medicinal products in the collection club until the customer collects the medicinal product from the collection club.

Further provisions may be issued by government decree on the location, operation, storage of medicinal products in the collection club, transport of medicinal products and supply of medicinal products to the collection club.

ARTICLE 58

The price of a medicinal product for self-care at the pharmaceutical tariff consists of the retail price of the medicinal product plus VAT. If the medicinal product referred to in this paragraph is supplied on the basis of a medical prescription, a delivery charge and VAT shall be added to the retail price per delivery item. The retail price of a non-prescription medicinal product shall not exceed the retail price according to the pharmaceutical tariff and shall not be less than the national wholesale price for the medicinal product in accordance with Paragraph 37a. However, the retail price of a non-prescription medicinal product shall be the retail price according to the medicinal product tariff if it is a non-prescription medicinal product or if a uniform price at national level is justified in terms of the advice required for the use of the medicinal product, the possible adverse effects of the medicinal product or public health. By way of derogation from paragraph 1 and from this paragraph, the maximum retail selling price of a medicinal product included in the restricted range of non-prescription medicinal products referred to in Paragraph 23d shall be the sum of the national wholesale price declared by the marketing authorisation holder in accordance with Paragraph 37a and the profit margin calculated on that basis, and the maximum price in the pharmaceutical tariff shall be the maximum retail selling price plus VAT. VAT must always be added to the retail price of a medicinal product in the restricted range. If the product in the range is supplied on prescription, a delivery fee per lot is also added to the price.

The Finnish Medicines Agency must provide the Ministry of Social Affairs and Health annually with information on the pharmacy network, the performance of pharmacy tasks and the financial situation.

ARTICLE 77

The Finnish Medicines Agency shall ensure that manufacturers of medicinal products and pharmaceutical substances and importing entities manufacturing advanced therapy medicinal products for the use of an individual patient, contract manufacturers and analysts, laboratories conducting pre-clinical safety tests on medicinal products, the system for recording the safety features of medicinal products and the operator of the repositories system, wholesale distributors, brokers, dose dispensers, pharmacies, branch pharmacies, hospital pharmacies and pharmaceutical centres, and the military pharmacy are inspected as frequently as necessary for the purposes of appropriate pharmacovigilance. In addition, the centre may inspect the pharmacy counter, the pharmacy’s online service, the holder of a retail licence for non-prescription medicinal products, the holder of a marketing authorisation for a medicinal product and a registration for a traditional herbal medicinal product for pharmacovigilance activities and premises, as well as manufacturers of excipients used in the manufacture of medicinal products. The Finnish Medicines Agency may carry out inspections in cooperation with the European Medicines Agency as agreed.

ARTICLE 89

The pharmaceutical company, the authorisation holder manufacturing or importing medicinal products for clinical trials, the laboratory conducting pre-clinical safety studies on medicinal products, the entity and laboratory performing contract analysis or manufacturing for the pharmaceutical manufacturer, the wholesale distribution of medicinal products, the holder of a marketing authorisation or registration, the pharmacist, the University of Helsinki pharmacy, the University of Eastern Finland pharmacy, the hospital pharmacy and the pharmaceutical centre, the entity manufacturing advanced therapy medicinal products for an individual patient, the holder of a retail licence for self-treatment medicinal products, the dosage distribution entity and the military pharmacy shall, upon request, provide the Finnish Medicines Agency, free of charge and without prejudice to confidentiality provisions, with the information and explanations relating to the import, manufacture, inspection, distribution, sale or other release for consumption of medicinal products necessary for the performance of the Centre's tasks laid down in this Act, in another Act or in an act of the European Union. The Centre shall have the right to obtain from the aforementioned bodies the information necessary for the protection of patients and other persons and otherwise for the performance of its supervisory tasks, including medical records.

Notwithstanding the provisions on confidentiality, the pharmacist, the University of Helsinki's pharmacy and the University of Eastern Finland's pharmacy must provide the Finnish Medicines Agency with the information on pharmacy activities and other business activities carried out in the same premises as the pharmacy, which is necessary for the development, planning and supervision of the pharmacy, the imposition of a quality control fee and the compilation of statistics. Notwithstanding confidentiality provisions, the holder of a retail licence for para-pharmaceuticals must provide the Finnish Medicines Agency with the information on the sale of para-pharmaceuticals necessary for its development, planning and monitoring tasks and for the imposition of a quality control fee. Further provisions on the information to be disclosed may be issued by government decree. The Finnish Medicines Agency may lay down more detailed rules on the procedure for the provision of information.

Section 101b

The Finnish Medicines Agency may impose a conditional fine in order to enforce the prohibition or order referred to in Sections 52b, 54j and 55c. The procedure for periodic penalty payments is laid down in the Act on Conditional Fines.

ARTICLE 102

The inspector may request rectification of the order referred to in section 78 from the Finnish Medicines Agency. An appeal may also be lodged against a decision of the Finnish Medicines Agency in the cases referred to in Sections 2, 6, 8, 12a, 12b, 15a, 15c, 17a, 30e, 30 l, 30n, 32, 48, 51, 52a, 52b, 53, 54f, 54j, 55c, 57c, 61, 62, 67, 76a and 84b. The request for rectification is governed by the Administrative Procedure Act (434/2003).

An appeal against a decision of an administrative court in a case referred to in Sections 12i, 29(2), 49, 50, 66, 80, 80a, 80b, 88a, 93, 101 and 101a may be lodged with the Supreme Administrative Court without permission.

Decisions referred to in Section 2(4), Sections 6 and 23c, Section 23e(4), Sections 30 l, 30n, 59 and 66, Section 79(3), Sections 80, 80a, 80b, 88a, 93 and 101 of the Finnish Medicines Agency, decisions referred to in Sections 68 and 71 of the Finnish Medicines Agency and orders of the inspector shall be complied with regardless of the appeal, unless the appeal authority orders otherwise. Decisions on the marketing authorisation of a medicinal product pursuant to Sections 21, 21a, 21c and 23e(2) of the Finnish Medicines Agency may be

enforced before they have become final, unless the appeal authority orders otherwise. Decisions under sections 40, 41, 52, 53, 54 and 54f of the Finnish Medicines Agency may not be enforced until they have become final.

A decision issued under Section 19a of the Ministry of Social Affairs and Health and the Finnish Medicines Agency may be enforced notwithstanding an appeal, unless the appeal authority orders otherwise.

Save as otherwise provided in this section, the provisions of the Administrative Judicial Procedure Act (808/2019) shall apply to appeals to the Administrative Court.

This Act shall enter into force on 1 January 2027.

However, the repeal of Section 55b shall take effect on 1 October 2028.

2.

Law

amending and temporarily amending the Law on electronic prescription

By Decision of Parliament

section 3(4) and Section 13(3)(2) of the ePrescription Act (61/2007), as amended, Section 3(4) and Section 13(3)(2) are amended by Act 706/2023;

in Section 3, as partly amended by Acts 436/2010, 251/2014, 786/2021, 1232/2022 and 706/2023, a new paragraph 12 is *added*, as well as a temporarily new Section 12a and a new Sections 12b to 12c, as follows*:*

ARTICLE 3

Definitions

In this Act:

4) ‘ *prescription* centre’ means a repository of information, consisting of prescriptions stored by prescribers, prescriptions stored by pharmacies on the basis of the criteria laid down in Article 12, information on medicinal products dispensed to patients on the basis of the criteria laid down in Article 23 by social and healthcare providers, information on delivery attached to prescriptions, information on the self-care products available to patients, the contract for medicinal products and information on the implementation and evaluation of medical treatment; — – — – — – — – — – — – — – — – — – — – — – — – — – — – — – — – — – — – — —

12) ‘ *medicinal product* contract’ means a contract concluded between the health care unit responsible for the patient's medical treatment and the patient in order to centralise the patient's medical treatment in a single health care unit.

Paragraph 12a

Pharmacy agreement

The pharmacy contracts concluded on the basis of Section 55b of the Medicines Act and stored on the intermediary server of the Finnish Pharmacists' Association have been stored in the prescription centre since 1 October 2028, when the responsibility of the Finnish Pharmacists' Association for keeping a register of pharmacy contracts ends. A pharmacy contract is an agreement between a patient and his or her treating physician by which the patient undertakes to collect the agreed medication from only one pharmacy or branch pharmacy.

When dispensing prescription-only medicinal products, a pharmacy or a branch pharmacy must check with the prescription centre referred to in Section 65 of the Customer Information Act that the patient has a valid pharmacy contract. If the patient has a valid pharmacy contract, only the pharmacy or branch pharmacy indicated therein may supply the medicinal product specified in the pharmacy contract.

The pharmacy or branch pharmacy may communicate to the treating physician the necessary patient information related to the dispensing of the patient and patient safety.

If the patient's need for care so requires, the health service may conclude a pharmaceutical

contract with the patient, in which case the pharmacy contract shall be terminated.

Article 12b

Pharmaceutical contract

Where appropriate, the contract may provide that the patient undertakes to collect the medicinal products provided for in the contract only from the pharmacy or branch pharmacy indicated in the contract or from the registered pharmacies or branch pharmacies.

The healthcare service shall record the contract for medicinal products in the prescription centre referred to in Section 65 of the Client Information Act by means of the contractual service referred to in that Section.

The health care unit shall inform the patient, before entering into a pharmaceutical contract, of the right of the pharmacy or branch pharmacy to disclose the information referred to in Section 12c(2) of this Act to the health care unit.

Paragraph 12c

Supply of medicinal products included in a medicinal product agreement and pharmacy's right of notification

When dispensing prescription-only medicinal products, the pharmacy or branch pharmacy must check with the prescription centre referred to in Section 65 of the Customer Information Act that the patient has a valid pharmaceutical contract. Where a medicinal product contract restricts the supply of medicinal products to a specific pharmacy or branch pharmacy or to specific pharmacies or branch pharmacies, only that pharmacy or branch pharmacy or those pharmacies or branch pharmacies may supply medicinal products included in the medicinal product contract.

Notwithstanding confidentiality provisions, the pharmacy or branch pharmacy may communicate the necessary patient information related to the dispensing of the medicinal product and patient safety to the health institution with which the medicinal product contract has been concluded.

ARTICLE 13

Patient's right to order disclosure of data

Notwithstanding the provisions of subsection 1, the following may be disposed of:

2) information to the person prescribing the medicinal product ddmmyyyy and narcotic drugs about all medicinal products prescribed to the patient ddmmyyyy and narcotic drugs, their labelling and the pharmacy contract and to the pharmacy supplying the medicinal product ddmmyyyy and narcotic drugs about all medicinal products prescribed to the patient ddmmyyyy and narcotic drugs and the pharmacy contract and pharmaceutical contract;

This Act shall enter into force on 1 October 2028.

Section 12a in force at the time of entry into force of this Act shall apply to pharmacy agreements concluded before the entry into force of this Act until 30 September 2030 at the latest.

3.

Law

amending Section 65 of the Act on the Processing of Customer Data in Social Welfare and Healthcare

By Decision of Parliament

section 65 of the Act on the Processing of Customer Data in Social Welfare and Healthcare (703/2023) is *amended* as follows: Subparagraph 1, points 9 and 10, in the version resulting from Law 703/2023,

in section 65, subsection 1, as amended by Act 703/2023, a new paragraph 11 is added as follows:

ARTICLE 65

National information system services for social welfare and health care

The Social Insurance Institution shall provide the following nationwide information system services for the storage and processing of customer data:

9) the database on medicinal products;
10) interrogation and relay services; and
11) pharmaceutical contract management service.

This Act shall enter into force on 1 October 2028.

Helsinki, x.x.20xx

Premier

Given name Surname

Minister of State Name Surname

1.

Law

amending the Medicines Act

In accordance with a decision of Parliament, the following provisions are laid down:

sections 55b and 67(2) of the Medicines Act (395/1987), as amended by Sections 55b of Act 208/2019 and 67(2) of Act 22/2006, are *repealed*;

sections 12a, 15, 30o, 31, 32(1), 41, 52, 55(2), 57, 57e, 58(4) and (8), 77(1), 89 and 102 are *amended* as set out in Sections 12a and 15 of Act 1112/2010, 30o of Act 1200/2013, 31, 58(4) and (8) and 77(1) of Act 1426/2025, Section 32(1) of Act 780/2025, Sections 41, 52 and 57e of Act 1258/2021, Section 55(2) of Act 248/1993, Section 57 of Acts 1233/2022, 339/2023 and 934/2024, Section 89 of Act 985/2021 and Section 102 of Act 1426/2025 and

new sections 12b-12i, 38b and 54j, new subsections 2 and 3 of section 55a as amended by Act 700/2002 and new sections 55c and 56b-56d and new subsection 2 of section 101b as amended by Act 553/2020 are added to the Act as follows:

The Act in force	*Proposal*
(New article) Paragraph 12a	Article 12b *The mechanical dispensing of medicinal products is subject to the condition that the Finnish Medicines Agency: promise (dose Distribution Unit licence).*
Mechanical *dispensing in a pharmacy and in a hospital pharmacy and* contract preparation are *subject* to authorisation by the Finnish Medicines Agency. Authorisation shall be granted if the activity complies with the requirements laid down in section 15. The authorisation may be subject to conditions concerning the manufacture, supply and use of the medicinal product and other conditions necessary for the safety of medicinal products. *A pharmacist may arrange for the automatic dispensing to be carried out on the*	Paragraph 12a *The licence of the Dose Distribution Unit shall be:* Contract manufacturing is subject to authorisation by the Finnish Medicines Agency. Authorisation shall be granted if the activity complies with the requirements laid down in section 15. The authorisation may be subject to conditions concerning the manufacture, supply and use of the medicinal product and other conditions necessary for the

The Act in force	*Proposal*
	to be issued if: *1) applicant is a public law body, private the trader: or legal person registered in the Trade Register commercial Register Act (564/2023) pursuant to section 3;* *2) the applicant has designated a responsible person with sufficient knowledge of the mechanical dispensing service for medicinal products or the industrial manufacture of medicinal products; and* *3) the premises, equipment and personnel of the dosage distribution unit comply with the requirements of this Act and the regulations issued under it.*
(New article)	*The licence of the Dose Distribution Unit must be applied for in writing from the Finnish Medicines Agency.* *The application or the documents to be attached to it shall contain the following information:* *1) the name or business name, business registration number and contact details of the applicant;* *2) address and contact details of the facility;* *3) the name and contact details of the responsible person; and* *4) a description of the premises, equipment and personnel of the dosage distribution unit and an estimate of the extent of the operation.* *The Finnish Medicines Agency may lay down rules on the content, form and*
(New article)	*The Dose Distribution Unit's licence is valid indefinitely.* *The concession holder of a dose distribution unit shall declare: writing Pharmaceutical security and to the Centre for Development to the holder of the authorisation and to mechanised dispensing implementation-related changes that have a material impact on the fulfilment of the conditions for authorisation. The change may be implemented unless, within 60 days of receipt of the notification, the Centre has*

The Act in force	*Proposal*
	Paragraph 12e
(New article)	*The dose distribution unit shall comply with the requirements of the dosage distribution activity: quality and in order to ensure patient safety, the good manufacturing practices for medicinal products provided for in Article 11, in so far as they concern the general requirements for industrial manufacturing of medicinal products and the organisation of risk management.* *The holder of a concession for a dose distribution unit shall be responsible for:* *1) on the suitability of the premises and equipment of the dosage distribution unit mechanised dosage distribution services;* *2) the adequacy and skills of the personnel involved in the dispensing services;* *3) operational quality standards implementation;* *4) the information systems used, including: the correctness of the information; on data protection, integrity and other aspects of data quality effective authors appropriateness; and* *5) incident handling and corrective*
(New article)	*A Dose Distribution Unit may purchase medicinal products for its activities from a pharmaceutical factory or from a wholesale distribution of medicinal products and may agree on the terms of purchase of medicinal products.* *Dose Distribution Unit to be used national treatment practices and cost-effectiveness should be taken into account when formulating the range of medicines. The choice of outpatient mechanised dosage distribution should in principle be made up of: health insurance reimbursable from marketing*

The Act in force	*Proposal*
	covered. *In the event of a change in the range of medicinal products, the Dose Distribution Unit shall ensure continuity of medical treatment for users of the service.* *A pharmacy or a hospital pharmacy may obtain medicinal products from a dispensing unit. The pharmacy or hospital pharmacy is responsible for the dispensed medicinal product submission medication*
(New article)	*The person responsible for the dosage distribution unit shall be responsible for ensuring that the medicinal products packaged by the dosage distribution unit comply with the requirements laid down by or pursuant to the law and that they are of sound quality and that the provisions of this Act and the provisions and regulations adopted pursuant thereto are complied with in the dosage distribution activity.* *The responsible person in the Dose Distribution Unit must be an authorised pharmacist. In addition, the responsible person shall have at least one year's practical experience in the packaging or quality assurance of medicinal products or in the industrial manufacture of medicinal products related to dosage distribution activities.* *The responsible person may not, in the exercise of that function, be a responsible manager in the wholesale distribution of medicinal products or in a pharmaceutical factory of another company, or be a pharmacist, a manager of a hospital or pharmaceutical centre, a manager of a military pharmacy, a manager of a pharmacy or a branch pharmacy, or the holder of a retail licence for non-prescription medicinal products, a member of its management or the responsible person for the sale of non-prescription medicinal products.*
(New article)	*If the Finnish Medicines Agency finds that the responsible person referred to in section 12 g is performing his duties inadequately in order to:*

The Act in force	*Proposal*
	poses a risk to patient safety, the Finnish Medicines Agency may instruct the Dose Distribution Unit to appoint a new qualified person.
	Article 12i
(New article)	*The Finnish Medicines Agency shall withdraw the authorisation of a dosage distribution unit if the holder of the authorisation so requests, provided that the unit has ensured that the patient safety of the customers using its service is not compromised.* *The Finnish Medicines Agency may withdraw the authorisation of a dosage distribution unit if:* *1) the conditions for granting the authorisation are no longer fulfilled; or* *2) the permit holder has repeatedly or seriously infringed the provisions laid down in or pursuant to this Act.* *If the deficiency or omission referred to in subsection 2(1) and (2) can be remedied, the Medicines Sector shall: security and* *the Centre shall set a reasonable period of time for the holder of the authorisation to remedy the deficiency or omission. The permit authority may revoke the permit if the permit holder has not remedied the deficiency or omission within the deadline.* *In the situation referred to in paragraph 2, the Finnish Medicines Agency may issue a written warning to the holder of the authorisation instead of withdrawing the authorisation if withdrawal of the authorisation would be disproportionate in the circumstances.*
ARTICLE 15	ARTICLE 15
The preparation and *mechanical dispensing of medicinal products by pharmacies, branch pharmacies, hospital pharmacies and pharmaceutical centres is subject to the condition* that the personnel are sufficiently familiar with the	preparation of medicinal products and that the necessary production facilities and equipment are appropriate. The activity must also comply, where applicable, with the provisions of section 11; The preparation of medicinal products by pharmacies, branch

The Act in force	*Proposal*
pharmacies, hospital pharmacies and pharmaceutical centres is subject to the condition that the personnel are sufficiently familiar with the preparation of medicinal products and that the necessary production facilities and equipment are appropriate. The activity shall also comply, where applicable, with good manufacturing practices for medicinal products in accordance with section 11. Further provisions on permit conditions may be issued by government decree. The Finnish Medicines Agency may issue orders to apply for a licence under Section 12a(1).	A pharmaceutical company may sell or otherwise dispose of pharmaceuticals and its own pharmaceutical products only to another pharmaceutical company, to a wholesaler, to a dispensing unit, to a pharmacy, to a branch pharmacy, to a military pharmacy, to a hospital pharmacy and to a pharmaceutical centre. In addition, medicinal products which are not prescribed or prescribed for sale only in pharmacies may be sold and otherwise disposed of to retailers of those products. In addition, non-prescription medicinal products for human use which have been granted an extension of the sales channel within the meaning of Paragraph 23e(2) may be sold to holders of retail licences for non-prescription medicinal products. You can sell or otherwise dispose of pharmaceuticals and your own Further provisions on permit conditions may be issued by government decree. The Finnish Medicines Agency may issue orders to apply for a licence under Section 12a(1).
Article 30o	Article 30o
The holder of the marketing authorisation, parallel import marketing authorisation and registration shall immediately notify the Finnish Medicines Agency of any initiative concerning the efficacy or safety of a medicinal product.	The holder of the marketing authorisation, parallel import marketing authorisation and registration shall immediately notify the Finnish Medicines Agency of any initiative concerning the efficacy or safety of a medicinal product.
related to	related to
withdrawal from sale or suspension of distribution; and	withdrawal from sale or suspension of distribution; and
pharmaceutical factory	pharmaceutical factory
suspected product defects in the manufacturing of the donated medicinal product. In addition, the holder of the marketing authorisation, parallel import marketing authorisation and registration shall inform the Centre of detected or suspected falsified medicinal products. The Finnish Medicines Agency may issue further regulations on the reporting of recalls, product defects and suspected falsified medicinal products.	suspected product defects in the manufacturing of the donated medicinal product. In addition, the holder of the marketing authorisation,
ARTICLE 31	

parallel import marketing authorisation and registration shall inform the Centre of detected or suspected falsified medicinal products.

The Finnish Medicines Agency may issue further regulations on the reporting and handling of *recalls*, product defects and suspected falsified medicinal products.

ARTICLE 31

A pharmaceutical company may sell or otherwise dispose of pharmaceutical substances and its own pharmaceutical products only to another pharmaceutical company, to a wholesaler, to a dispensing unit, *to* a pharmacy, to a branch pharmacy, to a military pharmacy, to a hospital pharmacy and to a pharmaceutical centre. In addition, medicinal products which are not prescribed or prescribed for sale only in pharmacies may be sold or otherwise disposed of:

preparations

retailers. In addition, non-prescription medicinal products for human use which have been granted an extension of the sales channel within the meaning of Paragraph 23e(2) may be sold to holders of retail licences for non-prescription medicinal products.

You can sell or otherwise dispose of pharmaceuticals and your own

The Act in force	*Proposal*
pharmaceuticals also a university; higher education institution and institution and scientific a research institute for research activities. A pharmaceutical factory must: do notification of this fact Pharmaceutical security and security and the Centre.	pharmaceuticals also a university; scientific higher education research institute for research activities. The pharmaceutical factory must: donotification of this fact Pharmaceutical Sector the Centre.
Outside Finland, medicinal products may be supplied from a pharmaceutical factory outside Finland only to an operator in that country who is legally entitled in that country to acquire medicinal products from a pharmaceutical factory.	a pharmaceutical factory.
ARTICLE 32	ARTICLE 32
Wholesale distribution of medicinal products shall mean any activity carried out for consideration and on a professional basis for the purpose of:	be subject to the condition that the applicant has at his disposal appropriate facilities for the storage of medicinal products; and
1) receipt of orders for medicinal products and delivery other than that referred to in subsection 2;	Wholesale distribution of medicinal products shall mean any activity carried out for consideration and on a professional basis for the purpose of:
2) the acquisition and possession of medicinal products with a view to their supply to pharmacies, social and healthcare institutions and other entities referred to in Articles 34 and 35 of this Law; or	1) receipt of orders for medicinal products and delivery other than that referred to in subsection 2;
	2) the acquisition and possession of medicinal products with a view to their further supply *to pharmacies, dispensing units, retail licence holders within the meaning of Paragraph 54f and nicotine* formulations, social and healthcare institutions and other entities within the meaning of Paragraphs 34 and 35 of this Law; or
3) export of medicines.	3) export of medicines.
However, the wholesale distribution of medicinal products does not include the sale of medicinal products and medicinal products to the general public in accordance with Paragraph 38a, the supply of medicinal products and medicinal products from a pharmacy to another pharmacy or a social and health care 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 marketing authorisation holder or his representative, without holding, distributing or storing the products.	However, the wholesale distribution of medicinal products does not include the sale of medicinal products and medicinal products to the general public in accordance with Paragraph 38a, the supply of medicinal products and medicinal products from a pharmacy to another pharmacy or a social and health care 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 marketing authorisation holder or his representative, without holding, distributing or storing the products.
Wholesale distribution of medicinal products may only take place with the authorisation of the Finnish Medicines Agency. The granting of an authorisation shall	Wholesale distribution of medicinal

The Act in force	*Proposal*
products may only take place with the authorisation of the Finnish Medicines Agency. The granting of an authorisation shall be subject to the condition that the applicant has at its disposal appropriate facilities, equipment and facilities to preserve and ensure the	

The Act in force	*Proposal*
functioning of the medicinal products and that the applicant has the staff necessary for that purpose. The authorisation may be made subject to conditions relating to the exercise of the activity. The Finnish Medicines Agency shall be responsible for entering the information relating to the authorisation in a database maintained by the European Medicines Agency. The recognition of a wholesale distribution authorisation granted in a State belonging to the European Economic Area in accordance with European Community provisions and the period within which the application for authorisation must be decided shall be laid down by Government decree in order to	ensure that the activity is carried out and that the applicant has the necessary staff. The authorisation may be made subject to conditions relating to the exercise of the activity. The Finnish Medicines Agency shall be responsible for entering the information relating to the authorisation in a database maintained by the European Medicines Agency. The recognition of a wholesale distribution authorisation granted in a State belonging to the European Economic Area in accordance with the provisions of the European Communities and the period within which the application for authorisation must be decided shall be laid down by Government decree.
Article 38b	Article 38b
(New article)	The pharmacy's tasks are: 1) the supply of medicinal products and the provision of information and advice to the general public on medical treatment; 2) the supply of medicinal products to health and social care institutions; 3) activities to promote health and well-being in support of self-care by the customer and planned self-care by a healthcare professional; 4) ensuring the storage and accessibility of equipment, consumables and bandages necessary for the use of medicinal products and medicinal products, as provided for in Article 55; and 5) other tasks specifically provided for. In carrying out the tasks referred to in subsection 1, the pharmacy shall seek to ensure that its activities constitute the user of the medicinal product and the health and social care and society: safe for you; a high-quality, effective and economic entity. In performing the tasks referred to in subsection 1, the operation of the pharmacy shall be based on evidence and good management and operational practices. A pharmacy; when offering: dosage delivery services, contract manufacturing or similar services on a cooperative basis, shall be responsible for the adequacy of the service portfolio and shall ensure:

The Act in force	*Proposal*
ARTICLE 41	
At the request of the Finnish Medicines Agency, the municipality must, if necessary, assess the functioning, location and adequacy of the pharmacy services in the area. The municipality may submit a proposal to the centre to open a pharmacy and branch pharmacy, to change the location of the pharmacy and branch pharmacy or to transfer the pharmacy and branch pharmacy.	the pharmacy licence is in a position to satisfy the conditions laid down for them throughout the term of the agreement.
	ARTICLE 41
	The organisation of health and social services in the region must: security and at the request of the Centre, assess, if necessary, the functioning, location and adequacy of the pharmacy services in the region. *The entity responsible for organising the social and health services* in the area may submit a proposal to the Centre to open a pharmacy and branch pharmacy, to change the area in which the pharmacy and branch pharmacy are located, or to transfer the pharmacy and branch pharmacy.
The Finnish Medicines Agency may decide to open a new pharmacy in an area adjacent to a municipality, a part of a municipality or a social or healthcare institution (area in *which the pharmacy* is located), to change the area in which the pharmacy is located and to transfer the pharmacy from one part of the municipality to another if the availability of medicinal products so requires or is necessary to ensure adequate pharmacy services. In assessing the availability of medicinal products and the adequacy of pharmaceutical services, account shall be taken at least of the number of inhabitants and the population served, the pharmaceutical services already existing in the area and other social and healthcare services. Pharmaceutical security and the Centre may take a decision on its own initiative or on the initiative of the municipality concerned.	The Finnish Medicines Agency may decide to open a new pharmacy in an area adjacent to a municipality, a part of a municipality or a social or healthcare institution (area in *which the pharmacy* is located), to change the area in which the pharmacy is located and to transfer the pharmacy from one part of the municipality to another if the availability of medicinal products so requires or is necessary to ensure adequate pharmacy services. In assessing the availability of medicinal products and the adequacy of pharmaceutical services, account shall be taken at least of the number of inhabitants and the population served, the pharmaceutical services already existing in the area and other social and healthcare services. Pharmaceutical security and the Centre may take a decision on its own initiative or on the initiative of *the body responsible for the organisation of social and health services in the region*.
The Finnish Medicines Agency may decide to dissolve a pharmacy if the availability of medicinal products or the adequacy of pharmacy services no longer requires the maintenance of the pharmacy, taking into account the population living or serving the area, the pharmacy services already in the area and other social and healthcare services. The termination decision may not be enforced until the pharmacy licence in question has become open, unless the pharmacist holding	The Finnish Medicines Agency may decide to dissolve a pharmacy if the availability of medicinal products or the adequacy of pharmacy services no longer requires the maintenance of the pharmacy, taking into account the population living or serving the area, the pharmacy services already in the

The Act in force	*Proposal*
area and other social and healthcare services. The termination decision may not be enforced until the pharmacy licence in question has become open, unless the pharmacist holding the pharmacy licence has expressed his agreement to the decision.	branch pharmacy licence from more than one applicant to the pharmacist who is best placed to operate the branch pharmacy, taking into account the location of the pharmacy, the other operating conditions and, in the case of a new branch pharmacy licence, the plans for organising the branch pharmacy business. This paragraph shall not apply to a branch pharmacy licence which is a condition of authorisation to operate a pharmacy and which is determined as part of the authorisation to operate a pharmacy.
stated that he consented to the decision. The Finnish Medicines Agency shall consult the municipality concerned before taking the decision referred to in subsection 2 or 3.	Before taking the decision referred to in subsection 2 or 3, *the Finnish Medicines Agency shall consult the entity responsible for the organisation of social and health services in the region*.
ARTICLE 52	ARTICLE 52
The Finnish Medicines Agency may establish a branch pharmacy on the initiative of a municipality, an association of municipalities or a pharmacist or on its own initiative. The establishment of a branch pharmacy is subject to the condition that pharmacy services are required in the area in order to ensure the availability of medicinal products and that there is insufficient capacity for an independent pharmacy. However, the establishment of a branch pharmacy within a health or social care institution is subject to the condition that the establishment requires the provision of pharmacy services and that there is insufficient capacity for an independent pharmacy. A pharmacist may be authorised to operate up to three branch pharmacies.	The Finnish Medicines Agency may establish a branch pharmacy on the initiative of the *entity responsible for the organisation of social and health services in the area* or of a pharmacist or on its own initiative. The establishment of a branch pharmacy is subject to the condition that pharmacy services are required in the area in order to ensure the availability of medicinal products and that there is insufficient capacity for an independent pharmacy. However, the establishment of a branch pharmacy within a health or social care institution is subject to the condition that the establishment requires the provision of pharmacy services and that there is insufficient capacity for an independent pharmacy. A pharmacist may be authorised to operate up to three branch pharmacies.
The Finnish Medicines Agency shall publish the application for a new or newly opened branch pharmacy licence on the Agency’s website by means of a notice indicating the location of the branch pharmacy. An applicant for a branch pharmacy licence shall attach to his application the documents on which he wishes to rely in the assessment referred to in paragraph 3. This paragraph shall not apply to a branch pharmacy licence which is a condition of authorisation to operate a pharmacy and which is published and applied for as part of the authorisation to operate a pharmacy. The Finnish Medicines Agency grants a	The Finnish Medicines Agency shall publish the application for a new or newly opened branch pharmacy licence on the Agency’s website by means of a notice indicating the location of the branch pharmacy. An applicant for a branch pharmacy licence shall attach to his application the documents on which he wishes to rely in the assessment referred to in paragraph 3. This subsection does not apply to

The Act in force	*Proposal*
a branch pharmacy licence which is a condition of authorisation to operate a pharmacy and which is published and applied for as part of the authorisation to operate a pharmacy, *unless the application of this subsection is, on the basis of an assessment by the Finnish Medicines Agency: inevitable pharmacy services continuity secure in the area.*	
The Finnish Medicines Agency grants a branch pharmacy licence from several applicants to the pharmacist who is best placed to operate the branch pharmacy, taking into account the location of the pharmacy, other operating conditions and, in the case of a new branch pharmacy licence,	

The Act in force	*Proposal*
By way of derogation from paragraph 1, the University of Helsinki may, with the authorisation of the Finnish Medicines Agency in each case, operate up to 16 branch pharmacies. The Finnish Medicines Agency decides on the location of the branch pharmacy. The centre may, on its own initiative or on the initiative of the municipality, the association of municipalities or the holder of a branch pharmacy licence, modify the area designated for the branch pharmacy in order to ensure the availability of medicinal products. The pharmacist must inform the Finnish Medicines Agency in advance of the opening of a branch pharmacy. Further provisions may be issued by government decree on the reports required when applying for a branch pharmacy licence, the information to be provided in the application for a licence and the notice of commencement of the branch pharmacy's activity.	plans for the organisation of branch pharmacy operations. This paragraph shall not apply *to a branch pharmacy licence which* is a condition of authorisation to operate a pharmacy and which is determined as part of the authorisation to operate a pharmacy, *unless the application of this paragraph is necessary in order to ensure the continuity of pharmacy services in the situation referred to in paragraph 2.* By way of derogation from paragraph 1, the University of Helsinki may, with the authorisation of the Finnish Medicines Agency in each case, operate up to 16 branch pharmacies. The location of a branch pharmacy shall be determined by the Finnish Medicines Agency.The Centre may, on its own initiative or at the initiative of the *entity responsible for the organisation of social and health services in the area* or of the holder of a licence to operate a branch pharmacy, modify the location of a branch pharmacy in order to ensure the availability of medicinal products. *If justified by the need to ensure the continuity of pharmacy services in the region, the Finnish Medicines Agency may, on the initiative of the pharmacist, convert a branch pharmacy holding a licence to operate a pharmacy into a branch pharmacy on which a licence to operate as a pharmacy is conditional.* The pharmacist must inform the Finnish Medicines Agency in advance of the opening of a branch pharmacy. Further provisions may be issued by government decree on the reports required when applying for a branch pharmacy licence, the information to be provided in the application for a licence and the notice of commencement of the branch pharmacy's activity.
(New article)	Paragraph 54j *The holder of a retail licence for over-the-counter medicinal products may sell to a limited range of over-the-counter medicinal products: of which: self-medication web service*

The Act in force	*Proposal*
	through an intermediary. The operator of the online service shall have a website offering medicinal products for sale at a distance. This website shall contain a link to the list maintained by the Finnish Medicines Agency.

The Act in force *Proposal*

legal of auto-medicines retail licence holders online services with a clearly visible common logo in the European Union in accordance with Article 85c of the Medicinal Products Directive.

The maintenance of the online service of the holder of a retail licence for self-care medicinal products shall be subject to prior notification to the Finnish Medicines Agency. The activity may be commenced unless, within 60 days of receipt of the notification, the Centre has requested further information on the matters referred to in this section or has prohibited the commencement of the activity. The Centre shall be notified of the start of operations, the cessation of operations and any substantial changes. The Centre may prohibit the start of operations or order the termination of an online service if the online service does not meet the conditions laid down in the Medicines Act or in the provisions adopted on the basis thereof.

The retail licence holder is responsible for the operation and management of the online service. The online service shall be subject to annual inspection by the retail licensee. The holder of a retail licence shall ensure that the following are supplied through its online service: of auto-medicines appropriate storage and transport conditions. The holder of a retail marketing authorisation shall ensure that the medicinal product is lawfully marketed in the State to which it is sold.

Otherwise online service activities; the provisions of Chapter 6 of the Consumer Protection Act (38/1978) concerning distance selling shall apply. The provisions on the online service shall also apply to the sale of non-prescription medicinal products by other means of distance communication.

The Finnish Medicines Agency may lay down rules on the content and making of prior notification by the holder of a retail licence. and in the case of consignments of medicinal products: packaging, and revision, transport, outsourcing of activities, returns,

The Act in force	*Proposal*
	handling of product defects,

The Act in force	*Proposal*
ARTICLE 55	ARTICLE 55
A pharmacy and a branch pharmacy must store a quantity of medicinal products corresponding to the average need of its usual customer population of at least two weeks, together with the equipment, supplies and bandages necessary for the use of the medicinal products. The pharmacy and the branch pharmacy must also stock the cheapest medicines. The obligation to stock a pharmacy and a branch pharmacy does not apply to medicinal products for which the retail price, including VAT, of one package is higher than EUR 1000 at the time of supply, or to very rare medicinal products intended for the treatment of a small group of patients for which there is no regular demand or which are not regularly supplied by that pharmacy to patients. However, the pharmacy and the branch pharmacy are also obliged to ensure the availability of such medicinal products on their territory.	A pharmacy and a branch pharmacy must store a quantity of medicinal products corresponding to the average need of its usual customer population of at least two weeks, together with the equipment, supplies and bandages necessary for the use of the medicinal products. The pharmacy and the branch pharmacy must also stock the cheapest medicines. The obligation to stock a pharmacy and a branch pharmacy does not apply to medicinal products for which the retail price, including VAT, of one package is higher than EUR 1000 at the time of supply, or to very rare medicinal products intended for the treatment of a small group of patients for which there is no regular demand or which are not regularly supplied by that pharmacy to patients. However, the pharmacy and the branch pharmacy are also obliged to ensure the availability of such medicinal products on their territory.
The pharmacy and branch pharmacy shall be kept open in such a way as to ensure the availability of medicinal products. *The pharmacist must inform the municipality in which the pharmacy is located of the opening hours.*	The pharmacy and branch pharmacy shall be kept open in such a way as to ensure the availability of medicinal products.
For his part, the pharmacist must ensure that the medicinal products supplied from the pharmacy, the branch pharmacy, the pharmacy's outlet and the pharmacy's online service are of sound quality and that the sale or release for consumption of the medicinal product is duly authorised.	For his part, the pharmacist must ensure that the medicinal products supplied from the pharmacy, the branch pharmacy, the pharmacy's outlet and the pharmacy's online service are of sound quality and that the sale or release for consumption of the medicinal product is duly authorised.
Section 55a	Section 55a
Pharmacies may act as competent authorities within the meaning of Article 75 of the Schengen Convention, which may provide on the *web service referred to in that Article information on medicinal products, storage of medicinal products, supply of medicinal products through the web service, premises, technical implementation, the range of medicines;* *the management and the performance of the audit of the web service activities.*	Pharmacies may act as competent authorities within the meaning of Article 75 of the Schengen Convention, which may issue the certificate referred to in that Article to accompany medicinal products containing narcotic drugs or psychotropic substances when travelling from one Contracting State to another.

The Act in force	*Proposal*
Section 55b	
A pharmacy and a branch pharmacy, when supplying ddmmv medicinal products or medicinal products containing substances classified as narcotics, as defined in Paragraph 3(8) of the Law on electronic prescription, must check, through the pharmacy system, whether the patient has a valid pharmacy contract. If the patient has a valid pharmacy contract, only the indicated pharmacy or branch pharmacy may supply such a medicinal product. *A pharmacy agreement is an agreement between a patient and his or her treating physician whereby the patient undertakes to collect the medicinal products provided for in the agreement from only one pharmacy. Physician shall be subject to the provisions on confidentiality:* *without hindrance arrange for the contract to:* *the supply of the information necessary for implementation to a pharmacy of the patient's choice, which stores the contractual information in the pharmacy system.* *Personal data concerning the health of a person processed in connection with the management of a pharmacy contract system shall be covered by the obligation of professional secrecy, unless otherwise provided by law. Notwithstanding confidentiality provisions, a pharmacy may disclose to other pharmacies the information necessary to check the existence of a pharmacy agreement and communicate to the treating physician the information concerning the patient which is necessary to assess whether the treatment has been provided. Before entering into a pharmacy agreement, the doctor must inform the patient of the pharmacy's right to disclose the information in question.* a certificate to accompany medicinal products containing narcotic drugs or psychotropic substances when travelling from one country to another. *The pharmacy may collect: certificate of the European Parliament and of payment.* *Further provisions on the fee shall be laid down by government decree.*	Section 55b (repeal)

The Act in force	*Proposal*
	Paragraph 55c
(New article)	*The pharmacy answers the following via the pharmacy's online service: from submission* *arrangements whereby another trader provides a pharmacy with a function or service that the pharmacy would otherwise have provided for the supply of the medicinal product (agreement to cooperate). The pharmacy must satisfy itself that the arrangements are suitable for them; legislated conditions size during the contract period.* *The pharmacy must not make any arrangements for dispensing the medicinal product which could jeopardise the availability of medicinal products in the region;* *medication or patient safety or increase the financial burden on the user of the medicinal product or on society.* *The pharmacy must give prior notification of the arrangement referred to in subsection 1 security* *and* *the Centre. The arrangement may be commenced unless, within 60 days of receipt of the notification, the Centre has requested further information on the matters referred to in the section or has prohibited the commencement of operations. The Centre shall be notified of the commencement, termination and material changes to the arrangement.* *The Finnish Medicines Agency may prohibit or order the termination of the arrangement referred to in the section if it*
(New article)	*When supplying a medicinal product, the pharmacy must offer to the purchaser of the medicinal product the medicinal product which is actually the most advantageous in terms of price. The purchaser of the medicinal product should be provided with information on the prices of the medicinal products available.*
(New article)	*The pharmacy must have a procedure in place for: tasks gap between* *monitoring and there on-going*

The Act in force	*Proposal*
	reporting and handling incidents. *The pharmacy must arrange for a different treatment to the extent required by the nature of the treatment.*
	Paragraph 56d
(New article)	The pharmacy must ensure that its staff are sufficiently skilled to carry out its tasks and provide up-to-date tools to support the performance of those tasks in the pharmacy and its outlets. The pharmacy must ensure that its premises and systems are suitable for the processing of confidential personal data concerning health in the pharmacy and its outlets; The pharmacy and its branches must have a policy on critical functions for the operation of the pharmacy. The pharmacy should ensure that the policy is up-to-date and that compliance with the policy is checked regularly and, if necessary, that the pharmacy takes steps to remedy the shortcomings. The Finnish Medicines Agency may issue guidelines and revisions.
ARTICLE 57	ARTICLE 57
When dispensing medicinal products from a pharmacy and from a branch pharmacy, the advice and guidance of the pharmacist's personnel shall be aimed at ensuring that the user of the medicinal product is aware of the correct and safe use of the medicinal product for the successful treatment of the medicinal product. for verification purposes. When submitting: prescription the pharmaceutical staff of the pharmacy and of the branch pharmacy shall offer to the purchaser of the medicinal product the medicinal product which is actually the most advantageous in terms of price. In addition, the purchaser of the medicinal product should be informed of the prices of the cheapest medicinal products available and of other factors affecting the choice of medicinal products.	*The pharmacy shall organise the dispensing of the medicinal product in such a way as to support the success and continuity of the treatment and to ensure: patient safety implementation.* *When dispensing the medicine, the pharmacy must offer: medication possibility for the user such as: advice on medication provided by a pharmacist or pharmacist to guide them towards the correct and safe use of the medicine and support their success in medication. Medical advice and counselling shall be provided in such a way as to support: medication individual needs of users taking*

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take into account, in particular, the customer's medical treatment;	
The pharmacist, the University of Helsinki's pharmacy and the University of Eastern Finland's pharmacy must ensure that the purchaser of the medicinal product has access to advice and advice from pharmacists on the correct and safe use of the medicinal products, information on the prices of the cheapest medicinal products available and other information affecting the choice of medicinal products, when supplying medicinal products via the pharmacy's online service. When dispensing a prescription-only medicinal product, the pharmacists of the pharmacy's online service must offer to the purchaser of the medicinal product the medicinal product which is actually the most advantageous in terms of price. Medicinal products supplied from the pharmacy's outlet on the basis of a medical prescription may only be supplied by a pharmacist or pharmacist.	Paragraph 57e A pharmacy may have a collection club to which the pharmacy can deliver and deliver medicinal products to customers for collection. The *Noutoloker must be located in the area where the pharmacy is located. The* swab must be suitable for the proper and safe storage and warehousing of medicinal products. The pharmacist is responsible for the proper functioning of the collection club. The pharmacist is responsible for the appropriate range *of medicines, illnesses and age, and for belonging to a group of clients requiring special attention. Advice includes advice on how to use a device to administer a medicinal product. Guidance and counselling should be given on issues affecting the choice of the medicinal product before dispensing. In the case of self-care, guidance and counselling also include an assessment of the need for care supported by a pharmacy professional.* *The pharmacy must also provide non-pharmaceutical advice and counselling to persons acting on behalf of the user of the medicinal product. The user of the medicinal product, or anyone acting on his behalf, should be able to receive advice and advice on medical treatment by telephone from the pharmacy in which he has been involved.*
When a pharmacy changes an inhaled medicinal product, a biological medicinal product or a biosimilar used for the treatment of asthma or chronic obstructive pulmonary disease, the pharmacists of the pharmacy shall provide the necessary medical advice and equipment for the correct and safe use of the medicinal product to be supplied to the purchaser of the medicinal product.	When a pharmacy changes an inhaled medicinal product, a biological medicinal product or a biosimilar used for the treatment of asthma or chronic obstructive pulmonary disease, the pharmacists of the pharmacy shall provide the necessary medical advice and equipment for the correct and safe use of the medicinal product to be supplied to the purchaser of the medicinal product.
Pursuant to subsections 1 and 2, the Finnish Medicines Agency may issue regulations on the procedures for dispensing medicinal products from pharmacies, branch pharmacies, the pharmacy service and the pharmacy's online service.	

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The Centre for the Safety and Development of Medicinal Products may lay down rules on the procedures for the supply of a safe medicinal product with a view to its preparation for supply and delivery to the customer, verification of the accuracy of the prescription, verification of dosage, frequency and quantity of supply.	
Paragraph 57e	
A pharmacy may have a collection club to which the pharmacy can deliver and deliver medicinal products to customers for collection. The swab must be suitable for the proper and safe storage and warehousing of medicinal products. The pharmacist is responsible for the proper functioning of the collection club. The pharmacist is responsible for the proper transport conditions and storage of the medicinal products in the collection club until the customer's transport conditions and storage in the collection club until the customer collects the medicinal product from the collection club. Further provisions may be issued by government decree on the location, operation, storage of medicinal products in the collection club, transport of medicinal products and supply of medicinal products to the collection club.	
ARTICLE 58	
The price to be used for the retail sale of a medicinal product shall be in accordance with the pharmaceutical tariff to be laid down by Government decree. The price of the medicinal product at the pharmaceutical tariff shall consist of the retail price of the medicinal product, as referred to in paragraphs 2 and 3:	at retail price to be added the delivery fee per delivery item and the VAT. Medication the retail price shall be based on the wholesale price at national level declared by the holder of the marketing authorisation for the medicinal product in accordance with Paragraph 37a and the gross margin calculated on the basis of the wholesale price. The retail price of a medicinal product supplied on the basis of a medical prescription is increased by a delivery charge per batch, which is part of the pharmacy's margin. In addition, VAT is added. By way of derogation from paragraphs 1 and 2, the retail price of a medicinal product prepared in a pharmacy on the basis of a medical prescription shall: be based on: of a kind used in manufacture substances the purchase price, the manufacturing charge, the manufacturing allowance; and of a kind used packaging materials and instruments the selling price. At retail price add delivery charge and VAT per lot. The price of the self-care medicinal product at the medication tariff is composed of: medication the retail selling price and VAT. If the medicinal product referred to in this paragraph is supplied on the basis of a medical prescription, at the retail price; add a pick-up from the pick-up club of the medicine. Further provisions may be issued by government decree on the location, operation, storage of medicinal products in the collection club,

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transport of medicinal products and supply of medicinal products to the collection club.	instruments
	the selling price. At retail price add delivery charge and VAT per lot.
	The price of the self-care medicinal product at the medication tariff is composed of: medication
	the retail selling price and VAT. If the medicinal product referred to in this paragraph is supplied on the basis of a medical prescription, at the retail price;
ARTICLE 58	
The price to be used for the retail sale of a medicinal product shall be in accordance with the pharmaceutical tariff to be laid down by Government decree. The price of the medicinal product at the pharmaceutical tariff shall consist of the retail price of the medicinal product, as referred to in paragraphs 2 and 3:	adding
at retail price to be added	
the delivery fee per delivery item and the VAT. Medication	lot-by-lot the
	interchange fee; and
	value added tax. Self-
	medication
the retail price shall be based on the wholesale price at national level declared by the holder of the marketing authorisation for the medicinal product in accordance with Paragraph 37a and the gross margin calculated on the basis of the wholesale price.	the retail price shall not exceed the retail price at the pharmaceutical tariff and shall not be less than the national wholesale price for the medicinal product in accordance with Paragraph 37a. *The price must be the same for all pharmacy outlets and online services. However,* the retail price of a non-prescription medicinal product shall be the retail price in accordance with the pharmaceutical tariff in the case of: has
The retail price of a medicinal product supplied on the basis of a medical prescription is increased by a delivery charge per batch, which is part of the pharmacy's margin. In addition, VAT is added.	a medicinal product for self-care requiring additional advice or if the price is uniform at national level; has
By way of derogation from paragraphs 1 and 2, the retail price of a medicinal product prepared in a pharmacy on the basis of a medical prescription shall: be based on:	justified on grounds of medical advice required for the use of the medicinal product, potential adverse reactions to the medicinal product or public health. By way of derogation from paragraph 1 and this paragraph, the following shall be referred to in Article 23d:
of a kind used in manufacture	limited
	a range of self-medication products; of
substances	the
the purchase price, the manufacturing charge,	maximum retail price of the self-care medicinal product has
the manufacturing allowance; and	the sum of the national wholesale price
of a kind used	declared by the marketing authorisation holder in accordance
packaging materials and	with Paragraph 37a and the profit

The Act in force	*Proposal*
margin calculated on that basis, and the maximum price in accordance with the pharmaceutical tariff, shall be the maximum retail selling price plus VAT. VAT must always be added to the retail price of a medicinal product in the restricted range. If the product in the range is supplied on prescription, a delivery fee per lot is also added to the price. Further provisions on the price according to the pharmaceutical tariff, the price exemptions and the discounts to be granted shall be laid down by Government decree. If necessary, the Government Decree shall review: under this section: the rate of the medicinal product in accordance with the provisions to be laid down. What 1-6 the subsection provides, but does not provide: applicable to registered homeopathic products; registered Traditions herbal medicinal products nicotine products, which may also be sold outside pharmacies, branch pharmacies, pharmacy counters and the online pharmacy service. lot-by-lot the interchange fee; and value added tax. Self-medication the retail price shall not exceed the retail price at the pharmaceutical tariff and shall not be less than the national wholesale price for the medicinal product in accordance with Paragraph 37a. However, the retail price of a non-prescription medicinal product shall be the retail price in accordance with the pharmaceutical tariff in the case of: a medicinal product for self-care requiring additional advice or if the price is uniform at national level; justified on grounds of medical advice required for the use of the medicinal product, potential adverse reactions to	the medicinal product or public health. By way of derogation from paragraph 1 and this paragraph, the following shall be referred to in Article 23d: limited maximum retail selling price of a self-care medicinal product in the self-care range has the sum of the national wholesale price declared by the marketing authorisation holder in accordance with Paragraph 37a and the profit margin calculated on that basis, and the maximum price in accordance with the pharmaceutical tariff, shall be the maximum retail selling price plus VAT. VAT must always be added to the retail price of a medicinal product in the restricted range. If the product in the range is supplied on prescription, a delivery fee per lot is also added to the price. Further provisions on the price according to the pharmaceutical tariff, the price exemptions and the discounts to be granted shall be laid down by Government decree. If necessary, the Government Decree shall review: under this section: the rate of the medicinal product in accordance with the provisions to be laid down. What 1-6 the subsection provides, but does not provide: applicable to registered homeopathic products; registered Traditions herbal medicinal products and nicotine products, which may also be sold outside pharmacies, branch pharmacies, pharmacy counters and the online pharmacy service. Safety and security in the pharmaceutical sector; The Finnish Medicines Agency shall provide annually to the Ministry of Social Affairs and Health information on the pharmacy’s sales margin and

The Act in force	*Proposal*
other aspects of the pharmaceutical tariff. The Agency shall provide annually to the Ministry of Social Affairs and Health *information on the*	*pharmacy network, the performance of the pharmacy's tasks and the financial* situation.
ARTICLE 67	
Military pharmacies may be established for the supply of medicinal products to the armed forces. Further provisions on the establishment of a military pharmacy are laid down in a Government Decree.	
Pharmaceutical centres may be set up within the Penitentiary Service for the supply of medicinal products. Further provisions on the establishment of the Penitentiary Service's Medicine Centre are laid down in a Government Decree.	
The Centre for Medicine, established within the Prison Health Care Unit, may provide for the automated dispensing of medicinal products.	security
with the authorisation of the Centre, if the activity complies with the requirements laid down in Section 15. The authorisation may be subject to conditions concerning the manufacture, supply and use of the medicinal product and other conditions necessary for the safety of medicinal products.	
ARTICLE 77	
The Finnish Medicines Agency shall ensure that manufacturers of medicinal products and pharmaceutical substances, as well as importing entities manufacturing advanced therapy medicinal products for individual patient use, contract manufacturers and analysts of medicinal products:	preclinical
safety studies	perform
laboratories;	medicinal products
	security features storage system and storage system admin, wholesale pharmacies, pharmaceutical brokers, pharmacies, branch pharmacies, hospital pharmacies, pharmaceutical centres and military pharmacies are inspected as often as necessary for proper pharmacovigilance. In addition, the Centre shall:
	ARTICLE 67
	Military pharmacies may be established for the supply of medicinal products to the armed forces. Further provisions on the establishment of a military pharmacy are laid down in a Government Decree.
	(Repeal)
	The Centre for Medicine, established within the Prison Health Care Unit, may provide for the automated dispensing of medicinal products. security and with the authorisation of the Centre, if the activity complies with the requirements laid down in Section 15. The authorisation may be subject to conditions concerning the manufacture, supply and use of the medicinal product and other conditions necessary for the safety of medicinal products.
	ARTICLE 77
	The Finnish Medicines Agency shall ensure that manufacturers of medicinal products and pharmaceutical

The Act in force	*Proposal*
substances and importing units manufacturing advanced therapy medicinal products for individual patient use, contract manufacturers and analysts, laboratories carrying out pre-clinical safety studies on medicinal products, a system for recording the safety features of medicinal products and a system for recording them:	
admin, wholesale pharmacies, pharmaceutical brokers, dispensing *units*, pharmacies, branch pharmacies, hospital pharmacies and pharmaceutical centres, and military pharmacies shall be inspected as often as necessary for proper pharmacovigilance. In addition, the centre may inspect the pharmacy's outlet, the pharmacy's online service, the holder of a retail licence for para-therapeutics, the holder of a marketing authorisation for a medicinal product and a registration for a traditional herbal medicinal product for pharmacovigilance and premises, and medicinal products for: manufacturing manufacturers of excipients used. The Finnish Medicines Agency may carry out inspections in cooperation with the European Medicines Agency as agreed.	substances and preparations present at the site for further examination. The auditor also has the right to make video recordings during the audit.
Where necessary, the inspection may be carried out without prior notice. The inspector shall be granted access to all premises of the site which are not used on a permanent basis;	A record of the inspection shall be kept. Before adopting the minutes, the Finnish Medicines Agency shall give the auditee the opportunity to express an opinion on the audit findings. The matters to be taken into account in the inspection and the details of the inspection procedure, as well as the minutes and their retention and retention period, shall be laid down by government decree.
housing. The inspection shall include all the documents requested by the inspector and necessary for carrying out the inspection. In addition, the inspector shall be provided free of charge, at his request, with copies of the documents necessary for carrying out the inspection and with samples of the	The Finnish Medicines Agency shall issue a certificate of good manufacturing practice (GMP) or good distribution practices (GMP) to the pharmaceutical factory and wholesaler under inspection upon request if the inspection shows that the factory or wholesaler complies with the principles and guidelines of good manufacturing practice (GMP) or good distribution practices (GMP) as laid down in European Union legislation. The Finnish Medicines Agency is responsible for exporting certificates of good manufacturing practice (GMP) or good distribution practices (GMP) from a service desk, a pharmacy's online service, self-medication
	the pharmacovigilance activities and premises of the holder of the retail licence, the marketing authorisation for the medicinal product and the registration of the traditional herbal medicinal product, and the medicinal products;
	manufacturing manufacturers of excipients used. The Finnish Medicines Agency may carry out inspections in cooperation with the European Medicines Agency as agreed.
	Where necessary, the inspection

may be carried out without prior notice. The inspector shall be granted access to all premises of the site which are not used on a permanent basis;

housing.
The inspection shall include all the documents requested by the inspector and necessary for carrying out the inspection. In addition, the inspector shall be provided free of charge, at his request, with copies of the documents necessary for carrying out the inspection and with samples of the substances and preparations present at the site for further examination. The auditor also has the right to make video recordings during the audit.

A record of the inspection shall be kept. Before adopting the minutes, the Finnish Medicines Agency shall give the auditee the opportunity to express an opinion on the audit findings. The matters to be taken into account in the inspection and the details of the inspection procedure, as well as the minutes and their retention and retention period, shall be laid down by government decree.

The Finnish Medicines Agency shall issue a certificate of good manufacturing practice (GMP) or good distribution practices (GMP) to the pharmaceutical factory and wholesaler under inspection upon request if the inspection shows that the factory or wholesaler complies with the principles and guidelines of good manufacturing practice (GMP) or good distribution practices (GMP) as laid down in European Union legislation. The Finnish Medicines Agency is responsible for the export of certificates of good manufacturing practice or good distribution practices maintained by the European Medicines Agency.
A database maintained by the European Medicines Agency.

The provisions of paragraphs 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 counters and the online pharmacy service.

ARTICLE 89

A pharmaceutical factory, a licensee manufacturing or importing medicinal products for clinical trials, a laboratory conducting pre-clinical safety studies of medicinal products, a unit and a laboratory performing contract analysis or manufacturing for a pharmaceutical manufacturer, a wholesale distribution of medicinal products, a marketing authorisation or registration holder, a pharmacist, the University of Helsinki pharmacy, the University of Eastern Finland pharmacy, a hospital pharmacy and a pharmaceutical centre, to a large extent;

developed
unit manufacturing therapy medicinal products for an individual patient, retail licence holder for para-therapeutic medicinal products and
If requested, the military pharmacy must provide Lääkealan: security
and
to the Centre free
notwithstanding confidentiality provisions, information and reports relating to the import, manufacture, inspection, distribution, sale or other release for consumption of medicinal products which are necessary for the Centre to carry out the tasks provided for in this Act, in another Act or in an act of the European Union. The Centre

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shall have the right to obtain from the aforementioned bodies the information necessary for the protection of patients and other persons and otherwise 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 must provide:

and the database.

The provisions of paragraphs 1 to 6 shall not apply to registered homeopathic products, registered traditional herbal medicinal products:

nicotine products, which may also be sold outside pharmacies, branch pharmacies, pharmacy counters and the online pharmacy service.

ARTICLE 89

A pharmaceutical factory; medicines clinical

the holder of the authorisation to manufacture or import medicinal products for trial purposes, the laboratory carrying out pre-clinical safety studies on medicinal products, the entity and the laboratory carrying out the contract analysis or the contract manufacture for the manufacturer of medicinal products, the wholesale distribution of medicinal products, the holder of the marketing authorisation or registration, the pharmacist, the University of Helsinki pharmacy, the University of Eastern Finland pharmacy, the hospital pharmacy and the pharmaceutical centre, to a large extent;

developed notwithstanding confidentiality provisions, the unit manufacturing therapy medicinal products for an individual patient, the holder of a retail licence for self-treatment medicinal products, the dosage-distribution unit and the military pharmacy shall, *upon* request, provide the Finnish Medicines Agency, free of charge, with the information and explanations relating to the import, manufacture, inspection, dispensation, sale or other release for consumption of medicinal products that are necessary for the performance of the Centre's tasks laid down in this Act, in another Act or in an act of the European Union. The Centre shall have the right to obtain from the aforementioned bodies the information necessary for the protection of patients and other persons and otherwise 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 must provide: security

and to the Centre, notwithstanding confidentiality provisions, information on pharmacy activities and other business activities carried out at the same premises as the pharmacy, necessary for the development, planning and supervision of the Centre, the imposition of a quality control fee and the production of statistics. The holder of a retail licence for para-pharmaceuticals shall provide: security and notwithstanding the provisions on confidentiality, the necessary information on the sale of medicinal products for self-care by the Centre for the purposes of its development, planning and monitoring tasks and the imposition of a quality control fee. Further details may be given by government decree.

provisions divestiture

The Act in force	*Proposal*
data. The Finnish Medicines Agency may lay down more detailed rules on the procedure for the provision of information.	licence for para-pharmaceuticals shall provide: security and notwithstanding the provisions on confidentiality, the necessary information on the sale of medicinal products for self-care by the Centre for the purposes of its development, planning and monitoring tasks and the imposition of a quality control fee. Further details may be given by government decree. provisions divestiture data. The Finnish Medicines Agency may lay down more detailed rules on the procedure for the provision of information.
Section 101b	Section 101b
The Finnish Medicines Agency may impose a periodic penalty payment in order to enforce the order and prohibition laid down in Section 19a(3). On the periodic penalty payment provide for: the Act on Conditional Fines (1113/1990).	The Finnish Medicines Agency may impose a periodic penalty payment in order to enforce the order and prohibition laid down in Section 19a(3). On the periodic penalty payment provide for: the Act on Conditional Fines (1113/1990). *The Finnish Medicines Agency may impose the prohibition or order referred to in Sections 52b, 54j and 55c in order to: periodic penalty payments. On penalty payment proceedings provide for: the Act on Conditional Fines.*
ARTICLE 102	ARTICLE 102
The inspector may request rectification of the order referred to in section 78 from the Finnish Medicines Agency. See also Pharmaceutical Sector security a decision of the Centre 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 and 84b may be challenged. Notwithstanding the provisions on confidentiality, the request for rectification shall be addressed to the Centre in respect of its development, planning and supervision tasks, the imposition of a quality control fee and the identification, revenue and expenditure and other financial data necessary for the production of statistics relating to pharmacy activities and other business activities carried out in the same premises as the pharmacy. The holder of a retail	The inspector may request rectification of the order referred to in section 78 from the Finnish Medicines Agency. See also Pharmaceutical Sector security and a decision of the Centre in the cases referred *to in Sections* 2, 6, 8, 12a, 12b, 15a, 15c, 17a, 30e, 30 l, 30n, 32, 48, 51, 52a, 52b, *53, 54f,* 54j, 55c, 57c, 61, 62, 67, 76a and 84b may be

The Act in force	*Proposal*
challenged. On the objection laid down in the Administrative Procedure Act (434/2003). An appeal against a decision of an administrative court in a case referred to in Section 29(2) and Sections 49, 50, 66, 80, 80a, 80b, 88a, 93, 101 and 101a may be lodged with the Supreme Administrative Court without leave to appeal. Decisions referred to in Section 2(4), Sections 6 and 23c, Section 23e(4), Sections 30 l, 30n, 59 and 66, Section 79(3), Sections 80, 80a, 80b, 88a, 93 and 101 of the Finnish Medicines Agency, decisions referred to in Sections 68 and 71 of the Finnish Medicines Agency and orders of the inspector shall be complied with regardless of the appeal, unless the appeal authority orders otherwise. Pharmaceutical security sections 21, 21a, 21c and 23e of the Centre In accordance with subparagraph 2 decisions on the marketing authorisation of a medicinal product may be enforced before they have received: the force of res judicata; unless: the appeal authority shall order otherwise. Pharmaceutical and decisions of the Centre under Sections 40, 41, 52, 53, 54 and 54f may not be enforced until they have become final. A decision issued under Section 19a of the Ministry of Social Affairs and Health and the Finnish Medicines Agency may be enforced notwithstanding an appeal, unless the appeal authority orders otherwise. In so far as this article does not provide otherwise: on appeal the Administrative Court is subject to the provisions of the Administrative	Judicial Procedure Act (808/2019). *An appeal against a decision of an administrative court in* a case referred to in Sections 12i, 29(2), 49, 50, 66, 80, 80a, 80b, 88a, 93, 101 and 101a may be lodged with the Supreme Administrative Court without leave to appeal. Decisions referred to in Section 2(4), Sections 6 and 23c, Section 23e(4), Sections 30 l, 30n, 59 and 66, Section 79(3), Sections 80, 80a, 80b, 88a, 93 and 101 of the Finnish Medicines Agency, decisions referred to in Sections 68 and 71 of the Finnish Medicines Agency and orders of the inspector shall be complied with regardless of the appeal, unless the appeal authority orders otherwise. Pharmaceutical security and sections 21, 21a, 21c and 23e of the Centre In accordance with subparagraph 2 decisions on the marketing authorisation of a medicinal product may be enforced before they have received: the force of res judicata; unless: the appeal authority shall order otherwise. Pharmaceutical security and decisions of the Centre under Sections 40, 41, 52, 53, 54 and 54f may not be enforced until they have become final. A decision issued under Section 19a of the Ministry of Social Affairs and Health and the Finnish Medicines Agency may be enforced notwithstanding an appeal, unless the appeal authority orders otherwise. In so far as this article does not provide otherwise: on appeal the provisions of the Administrative Judicial Procedure Act (808/2019) shall apply to the administrative court. *This Act shall enter into force on 1 January 2027.*

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	However, the repeal of Section 55b shall take effect on 1 October 2028.

2.

Law

amending and temporarily amending the Law on electronic prescription

By decision of Parliament, the following is enacted:

section 3(4) and Section 13(3)(2) of the ePrescription Act (61/2007), as amended, Section 3(4) and Section 13(3)(2) are amended by Act 706/2023;

in Section 3, as partly amended by Acts 436/2010, 251/2014, 786/2021, 1232/2022 and 706/2023, a new paragraph 12 is *added*, as well as a temporarily new Section 12a and a new Sections 12b to 12c, as follows*:*

The Act in force	*Proposal*
ARTICLE 3	ARTICLE 3
Definitions	*Definitions*
In this Act:	
1) *electronic prescription means* a medical prescription made out by means of a data-processing machine and transmitted, using computer networks, to a prescription-centre;	1) *electronic prescription means* a medical prescription made out by means of a data-processing machine and transmitted, using computer networks, to a prescription-centre;
2) *prescriber means a* doctor, dentist or other health professional qualified to prescribe a medicinal product;	2) *prescriber means a* doctor, dentist or other health professional qualified to prescribe a medicinal product;
3) "*medicinal product supplier*" means a pharmacist who supplies a medicinal product from a pharmacy;	3) "*medicinal product supplier*" means a pharmacist who supplies a medicinal product from a pharmacy;
4) ' *prescription* centre' means a repository of information, consisting of electronic prescriptions stored by prescribers, prescriptions stored by pharmacies on the basis of the criteria laid down in Article 12, information on medicinal products dispensed to patients on the basis of the criteria laid down in Article 23 by social and healthcare providers, delivery information attached to prescriptions and records relating to the implementation and evaluation of medical treatment;	4) ' *prescription* centre' means a reserve of information consisting of electronic prescriptions stored by prescribers, prescriptions stored by pharmacies on the basis of the criteria laid down in Article 12, information on medicinal products dispensed to patients on the basis of the criteria laid down in Article 23 by social and healthcare providers, information on the supply of medicinal products attached to prescriptions, *on of the self-care products information,* the *contract* for the medicinal product and the labelling relating to the implementation and evaluation of the medicinal treatment;
5) *national medication list* is a patient-specific summary that is compiled in a prescription centre.	5) *national medication list* means the patient-specific summary, the prescribing records and the associated labelling;
In this Act:	

The Act in force	*Proposal*
5) (a) *in-use medicinal product means a medicinal product* prescribed on medical prescription to a patient, the use of which has not been discontinued by the indication of cessation;	prescription centre;
6) ‘ *medicinal* product database’ means a database containing information on the medicinal product, its price and its reimbursability, which is necessary for the prescription and dispensation of a medicinal product; interchangeable medicinal products; reimbursable basic creams and clinical nutrition products and other categories of products defined by decree of the Ministry of Social Affairs and Health;	5) (a) *in-use medicinal product means a medicinal product* prescribed on medical prescription to a patient, the use of which has not been discontinued by the indication of cessation;
7) *paragraph repealed by Act 14.4.2023/706.*	6) ‘ *medicinal* product database’ means a database containing information on the medicinal product, its price and its reimbursability, which is necessary for the prescription and dispensation of a medicinal product; interchangeable medicinal products; reimbursable basic creams and clinical nutrition products and other categories of products defined by decree of the Ministry of Social Affairs and Health;
8) *DDMMVV medicinal product* means:	7) *paragraph repealed by Act 14.4.2023/706.*
a) which is specified in the marketing authorisation as a ddmmyyyy medicinal product;	8) *DDMMVV medicinal product* means:
b) which is included in the list of ddmmv medicines established by the Finnish Medicines Agency; or	a) which is specified in the marketing authorisation as a ddmmyyyy medicinal product;
c) the active ingredients of which are included in a list drawn up by the Finnish Medicines Agency of medicinal substances which may be supplied only on prescription and which are accompanied by the prefixes Z, ZA, P and PA in that list; and	b) which is included in the list of ddmmv medicines established by the Finnish Medicines Agency; or
‘Pro auctore’ *means a written prescription by* which a doctor, dentist, optician or mouth hygienist prescribes a medicinal product necessary for the exercise of his profession;	c) the active ingredients of which are included in a list drawn up by the Finnish Medicines Agency of medicinal substances which may be supplied only on prescription and which are accompanied by the prefixes Z, ZA, P and PA in that list; and
9) narcotic *drug* shall mean substances included in Schedules I, II and IV of the Single Convention on Narcotic Drugs of 1961, referred to in Article 3(1)(1)(a) of the Law on Narcotic Drugs (37 3/2008), and substances included in Schedules I and II of the Convention on Psychotropic Substances of 1971, referred to in Article 3(1)(1)(b) thereof, and medicinal products containing substances referred to in Article 3(1)(5)(e) of the Law on Narcotic Drugs.	d) (a) ‘ *pro auctore’ means a written prescription by* which a doctor, dentist, optician or mouth hygienist prescribes a medicinal product necessary for the exercise of his profession;
10) *biological medicinal product* means a product that is compiled from prescriptions and associated labelling stored at a	9) narcotic *drug* means any substance included in Schedules I, II and IV of the Single Convention on Narcotic Drugs of 1961 referred to in Article 3(1)(1)(a) of the Law on Narcotic Drugs (37 3/2008) and in Schedules I and II of the Convention on Psychotropic Substances of 1971 referred to in Article 3(1) (1)(b) thereof, as well as medicinal products containing substances referred to in Article 3(1)(5)(e) of the Law on Narcotic Drugs, the active

The Act in force	*Proposal*
substance of which is a biological substance. A biological substance is a substance that is produced or extracted from a biological source and for which it is necessary to carry out physico-chemical biological analyses and to review the production process and its control in order to characterise and determine the quality of the substance. Medicinal products considered as biological medicinal products are defined in point 3.2.1.1.(b) of Part I of Annex I to Commission Directive 2003/63/EC amending Directive 2001/83/EC of the European Parliament and of the Council on the Community code relating to medicinal products for human use;	necessary to carry out physico-chemical biological analyses and to review the production process and its control in order to characterise and determine the quality of the substance. Medicinal products considered as biological medicinal products are defined in point 3.2.1.1.(b) of Part I of Annex I to Commission Directive 2003/63/EC amending Directive 2001/83/EC of the European Parliament and of the Council on the Community code relating to medicinal products for human use;
11) *biosimilar* biological a similar medicinal product that has been developed to be similar and comparable to an original biological medicinal product and for which the application for a marketing authorisation is subject to Article 10(4) of Directive 2001/83/EC of the European Parliament and of the Council on the Community code relating to medicinal products for human use and to the conditions for similar biological medicinal products set out in point 4 of Part II of Annex I to that Directive.	*11) biosimilar* biological a similar medicinal product that has been developed to be similar and comparable to an original biological medicinal product and for which the application for a marketing authorisation is subject to Article 10(4) of Directive 2001/83/EC of the European Parliament and of the Council on the Community code relating to medicinal products for human use and to the conditions for similar biological medicinal products set out in point 4 of Part II of Annex I to that Directive.
10) biological medicinal product means a product in which the active substance is a biological substance. A biological substance is a substance that is produced or extracted from a biological source and for which it is	*12) 'medicinal product contract' means a contract concluded between the health care unit responsible for the patient's medical treatment and the patient in order to centralise the patient's medical treatment in a single health care unit.*
	Paragraph 12a
	Pharmacy agreement
(New article)	*The pharmacy contracts concluded on the basis of Section 55b of the Medicines Act and stored in the brokerage service of the Finnish Pharmacists' Association have been stored in the prescription centre since 1 October 2028, when the Finnish Pharmacists' Association ceases to be responsible for keeping a register of pharmacy contracts. A pharmacy contract is an agreement between a patient and his or her treating physician by which the patient undertakes to collect the agreed medication from only one pharmacy or branch pharmacy.*

The Act in force	*Proposal*
	When dispensing prescription-only medicinal products, the pharmacy or branch pharmacy shall check with the prescription centre referred to in Section 65 of the Client Information Act that the patient: has valid currently in force pharmacy contract. If the patient has a valid pharmacy contract, only the pharmacy or branch pharmacy indicated therein may supply the medicinal product specified in the pharmacy contract. *The pharmacy or branch pharmacy may notify the dispensing of the patient and patient safety related necessary patient information for the treating physician.* *If the patient's need for care so requires, the health service may conclude a pharmaceutical contract with the patient, in which case the pharmacy contract shall be terminated.*
(New article)	Article 12b *Where appropriate, the contract may provide that the patient undertakes to collect the medicinal products provided for in the contract only from the pharmacy or branch pharmacy indicated in the contract or from the registered pharmacies or branch pharmacies.* *The healthcare service shall record the contract for medicinal products in the prescription centre referred to in Section 65 of the Client Information Act at the same time as: section 2. intended for through a contracted service.* *The Health Care Unit shall provide information on: for the patient before the right of a pharmacy or a branch pharmacy to pass on the information referred to in Section 12c(2) of this Act to a health service unit.*
(New article)	Paragraph 12c *When dispensing prescription-only medicinal products, the pharmacy or branch pharmacy shall:*

The Act in force	*Proposal*
ARTICLE 13 *Patient's right to prescribe data on the transfer* Without prejudice to the rules on confidentiality, information from the national medication directory at the prescription centre concerning medicinal products prescribed to the patient and related labelling may be disclosed to health and social care providers and prescriber for the organisation and delivery of the patient's health and medical care. However, the patient may refuse to disclose the information relating to the medicinal product prescribed to him to the abovementioned bodies and pharmacies. The issue and withdrawal of a prohibition is governed by Section 58 of the Client Information Act. If, within the meaning of Paragraph *7* (1) of the Law on the Status and Rights of Patients (785/1992), hereinafter 'the Law on Patients', a minor patient is able to decide himself or herself, on the basis of his or her age and maturity, on his or her treatment, he or she may also decide to impose the prohibition referred to in subparagraph 1 of this paragraph and to withdraw it. The guardian or legal representative of a minor shall not be entitled to issue an extradition ban. In addition, a minor within the meaning of Paragraph 51(1) of the Law on customer information has the right to prohibit a prescription centre within the meaning of Paragraph 65 of the Law on customer information from *verifying that the patient has a valid contract for a medicinal product for a specified medicinal product. Where a medicinal product contract restricts the supply of medicinal products to a specific pharmacy or branch pharmacy or to specific pharmacies or branch pharmacies, only that pharmacy or branch pharmacy or those pharmacies or branch pharmacies may supply medicinal products included in the medicinal product contract.* *Notwithstanding confidentiality provisions, a pharmacy or branch pharmacy may notify the dispensing of a medicinal product and*	*patient safety: related essential patient information for the health institution with which the medicinal product contract has been concluded.* ARTICLE 13 *Patient's right to prescribe data on the transfer* Without prejudice to the rules on confidentiality, information from the national medication directory at the prescription centre concerning medicinal products prescribed to the patient and related labelling may be disclosed to health and social care providers and prescriber for the organisation and delivery of the patient's health and medical care. However, the patient may refuse to disclose the information relating to the medicinal product prescribed to him to the abovementioned bodies and pharmacies. The issue and withdrawal of a prohibition is governed by Section 58 of the Client Information Act. If, within the meaning of Paragraph *7* (1) of the Law on the Status and Rights of Patients (785/1992), hereinafter 'the Law on Patients', a minor patient is able to decide himself or herself, on the basis of his or her age and maturity, on his or her treatment, he or she may also decide to impose the prohibition referred to in subparagraph 1 of this paragraph and to withdraw it. The guardian or legal representative of a minor shall not be entitled to issue an extradition ban. In addition, a minor within the meaning of Paragraph 51(1) of the Law on customer information has the right to prohibit the disclosure of information relating to a prescribed medicinal product to his or her guardian or other legal representative. Notwithstanding the provisions of subsection 1, the following may be disposed of: 1) The information referred to in subsection 1, if the provision of information or the right to receive information is expressly provided for by law;

The Act in force	*Proposal*
2) information on the person prescribing the medicinal product ddmmyyyy and narcotic drugs on all the medicinal products ddmmyy and narcotic drugs prescribed to the patient and on the relevant labelling;	subsection 1, if the provision of information or the right to receive information is expressly provided for by law; 2) information to the person prescribing the medicinal product ddmmyyyy and narcotic drugs on all medicinal products prescribed for the patient ddmmyy and narcotic drugs, on the labelling relating thereto *and on the agreement between the pharmacy and the medicinal product, and to the pharmacy supplying the medicinal product ddmmyy and narcotic drugs on all medicinal products prescribed for the patient ddmmyy and narcotic drugs and on the agreement between the pharmacy and the medicinal* product;
3) to the person responsible for the renewal of the prescription healthcare; or the details of the medical prescription requested by the patient for renewal to the social care provider or prescriber;	3) to the person responsible for the renewal of the prescription healthcare; or the details of the medical prescription requested by the patient for renewal to the social care provider or prescriber;
4) to the person prescribing the medicinal product, in the event of the continued existence of a medical relationship, information on the prescriptions which he or she has entered in the prescription centre, together with the particulars relating thereto and the therapeutic relationship, irrespective of the prescriptions which he or she has entered in the prescription centre on the basis of Paragraph 12(3), and the prescriptions which a nurse, pharmacist or pharmacist has entered in the prescription centre on the basis of Paragraph 5a; dosage instruction changes, rectifications of prescriptions made by pharmacists and pharmacists pursuant to Paragraph 10, and deviations from prescriptions made pursuant to Paragraph 57f of the Law on medicinal products, in which he is indicated as the prescriber of the medicinal product and the particulars relating to those prescriptions;	4) to the person prescribing the medicinal product, in the event of the continued existence of a medical relationship, information on the prescriptions which he or she has entered in the prescription centre, together with the particulars relating thereto and the therapeutic relationship, irrespective of the prescriptions which he or she has entered in the prescription centre on the basis of Paragraph 12(3), and the prescriptions which a nurse, pharmacist or pharmacist has entered in the prescription centre on the basis of Paragraph 5a; dosage instruction changes, rectifications of prescriptions made by pharmacists and pharmacists pursuant to Paragraph 10, and deviations from prescriptions made pursuant to Paragraph 57f of the Law on medicinal products, in which he is indicated as the prescriber of the medicinal product and the particulars relating to those prescriptions;
5) information for the healthcare or social care provider who drew up the document stored in the prescription centre while the care relationship continues a recipe centre records of documents and related markings;	5) information for the healthcare or social care provider who drew up the document stored in the prescription centre while the care relationship continues a recipe centre records of documents and related markings;
6) information to the healthcare or social care provider or health professional about the provision of information related to the prescription centre to their carer or other legal representative.	6) to a healthcare or social welfare provider or to a healthcare provider in emergency care situations as referred to in Section 8 of the
Notwithstanding the provisions of subsection 1, the following may be disposed of: 1) The information referred to in	

The Act in force	*Proposal*
Patients' Act; if disclosure is prohibited in accordance with paragraph 1, the information may be disclosed only if the patient has expressly indicated that it may nevertheless be disclosed in the circumstances referred to above;	and the related labelling in cases of emergency treatment as referred to in Section 8 of the Patients Act; if disclosure is prohibited in accordance with paragraph 1, the information may be disclosed only if the patient has expressly indicated that it may nevertheless be disclosed in the circumstances referred to above;
7) technical staff employed by a healthcare provider, Social Insurance Institution or information system provider with information to the extent necessary to deal with incidents and errors;	7) technical staff employed by a healthcare provider, Social Insurance Institution or information system provider with information to the extent necessary to deal with incidents and errors;
8) the prescriber of the medicinal product and the health institution acting as the employer of the prescriber or as the sponsor of the medicinal product, information on the prescriptions for biological medicinal products and the supply of biological medicinal products stored at the prescription centre which are necessary for the performance of self-monitoring under section 24a or for the provision of information and reports for the purposes of regulatory supervision under section 24b; and	8) the prescriber of the medicinal product and the health institution acting as the employer of the prescriber or as the sponsor of the medicinal product, information on the prescriptions for biological medicinal products and the supply of biological medicinal products stored at the prescription centre which are necessary for the performance of self-monitoring under section 24a or for the provision of information and reports for the purposes of regulatory supervision under section 24b; and
9) details of the healthcare or social care provider who drew up the document stored at the prescription centre for the purposes of explanations relating to the surveillance matter a recipe centre records of documents and related markings. for the professional, information on the prescriptions stored in the prescription centre	9) details of the healthcare or social care provider who drew up the document stored at the prescription centre for the purposes of explanations relating to the surveillance matter a recipe centre records of documents and related markings.
	This Act shall enter into force on 1 October 2028. Before the entry into force of this Act: knotted
	section 12a in force at the time of entry into force of this Act shall apply to pharmacy agreements until 30 September 2030 at the latest.

3.

Law

amending Section 65 of the Act on the Processing of Customer Data in Social Welfare and Healthcare

By decision of Parliament, the following is enacted:
section 65 of the Act on the Processing of Customer Data in Social Welfare and Healthcare (703/2023) is *amended* as follows: Subparagraph 1, points 9 and 10, in the version resulting from Law 703/2023,
in section 65, subsection 1, as amended by Act 703/2023, a new paragraph 11 is added as follows:

The Act in force	*Proposa*
ARTICLE 65	AR

The Act in force	*Proposal*
Social welfare and health care nationwide information system services	*Social welfare and health care nationwide information system services*
For the purposes of storing and processing customer data, the Social Insurance Institution shall organise the following: national information system services: 1) customer Data Repository; 2) log-record-keeping service; 3) the professional interface; 4) citizen interface; 5) a self-knowledge pool; 6) information management service; 7) a declaration of intent service; 8) a recipe centre; 9) the database on medicinal products; *and* 10) enquiry and Relay Service	For the purposes of storing and processing customer data, the Social Insurance Institution shall organise the following: national information system services: *1)* customer Data Repository; *2)* log-record-keeping service; *3)* the professional interface; *4)* citizen interface; *5)* a self-knowledge pool; *6)* information management service; *7)* a declaration of intent service; *8)* a recipe centre; *9)* the database on medicinal products; *10)* a query and relay service*; and* *11) pharmaceutical contract management service*.
The Licensing and Control Authority shall maintain a role and attribute information service and associated codes to enable the service provider to: to a pharmacy, The Social Insurance Institution and the Digital and Population Data Services Agency give for the use and certification of national information system services professional information on the right to pursue the profession and its validity. The National Institute for Health and Welfare shall maintain a coding service for the maintenance and distribution of national	The Licensing and Control Authority shall maintain a role and attribute information service and associated codes to enable the service provider to: to a pharmacy, The Social Insurance Institution and the Digital and Population Data Services Agency give for the use and certification of national information system services professional information on the right to pursue the profession and its validity. The National Institute for Health and Welfare shall maintain a coding service for the maintenance

The Act in force	*Proposal*
customer document data structures required for information system services.	customer document data structures required for information system services.
The Digital and Population Data Services Agency shall act in accordance with the Act on Identification and Trust Services for Social Welfare and Health Professionals and Other Personnel, Service Providers and Organisations involved in the provision of these services, their staff and IT equipment.	The Digital and Population Data Services Agency shall act in accordance with the Act on Identification and Trust Services for Social Welfare and Health Professionals and Other Personnel, Service Providers and Organisations involved in the provision of these services, their staff and IT equipment.
within the meaning of	within the meaning of
as a verifier. In order to carry out this task, the Digital and Population Data Services Agency has the right to obtain from the Central Register of Social and Health Care Professionals maintained by the National Supervisory Authority the information necessary for the issuance and revocation of the certificate, the certificate, the technical platform of the certificate and the issuance of the certificate.	as a verifier. In order to carry out this task, the Digital and Population Data Services Agency has the right to obtain from the Central Register of Social and Health Care Professionals maintained by the National Supervisory Authority the information necessary for the issuance and revocation of the certificate, the certificate, the technical platform of the certificate and the issuance of the certificate.
In order to carry out its statutory tasks, the Licensing and Control Authority shall have	In order to carry out its statutory tasks, the Licensing and Control Authority shall have
	This Act shall enter into force on 1 October 20.

Government Decree

amending the Medicinal Products Regulation

By Government decision,
section 27 of the Medicinal Products Decree (693/1987) is *amended*; and
a new Section 21d is *added* to the Decree as follows:

Paragraph 21d

A pharmacy may charge a fee for issuing the Schengen Certificate referred to in Section 55a of the Medicines Act (395/1987). The fee is EUR 11, which includes the registration of one medicinal product in the certificate.

If a certificate for two or more medicinal products is drawn up at the same time, a fee of EUR 1.50 may be charged for the next certificate for each medicinal product.

ARTICLE 27

A report of the inspection shall be drawn up, a copy of which shall be sent within 30 days to the accountable manager, pharmacist, hospital pharmacy operator, centre operator, the responsible person of the holder of the retail licence for non-prescription medicinal products or the responsible person of the dosage distribution unit concerned.

A copy of the record of the inspection shall be kept for a period of 10 years from the date of the inspection.

The inspection shall be deemed to have been completed when a copy of the inspection report has been notified to the interested party.

This Regulation shall enter into force on 1 January 2027.

Government Decree

amending Section 4 of the Government Decree on the pharmaceutical tax

By Government decision,
section 4(5) of the Government *Decree on* the Pharmaceutical Tax (713/2013), as amended by Decree 193/2022, is amended as follows:

ARTICLE 4

The pharmacy may grant the discount referred to in paragraph 1 to all customers or only to its loyalty customers.

This Regulation shall enter into force on 1 January 2027.

Ministry of Social Affairs and Health Decree

Article 3 of the Decree on the treatment of opioid addiction for withdrawal and replacement with opioid medicines
amending

In accordance with the decision of the Ministry of Social Affairs and Health,

section 3(3) of the Decree of the Ministry of Social Affairs and Health on treatment for *opioid* addiction and replacement with opioid medicines (642/2023) is amended as follows:

ARTICLE 3

Notwithstanding the provisions of subsection 2, a combination product containing buprenorphine and naloxone may be prescribed by a prescription to be supplied by a pharmacy on the basis of a pharmaceutical contract within the meaning of Paragraph 3(12) of the Electronic Prescription Act (61/2007), signed by the patient, for as long as the contract is in force. In such cases, in addition to the information provided for in Article 13 of the Decree of the Ministry of Social Affairs and Health (1088/2010) on prescribing the medicinal product, the doctor must indicate on the prescription the post, post or position held, if that information does not appear directly on the prescription without any further indication.

This Regulation shall enter into force on 1 October 2028.

br0ken!Decree of the Ministry of Social Affairs and Health amending the Decree on treatment for opioid addiction and substitution with opioid medicines

Main content

It is proposed to amend the Decree of the Ministry of Social Affairs and Health on treatment for opioid addiction and substitution with opioid medicines. The proposal forms, together with the Government proposal to Parliament for legislation on the development of pharmacy activities (HE xxx/2026 vp) and the other proposed amendments to the Decree, a package of responsible and gradual reforms of pharmacy regulation, ensuring high-quality and safe pharmacy services throughout Finland.

The Government bill (HE xxx/2026 vp) proposes to amend the Medicines Act (395/1987) and the Electronic Prescribing Act *(* E-Prescription Act, 61/2007) in order to transform the pharmacy agreement into a primarily prescribing policy. Changes to the pharmacy agreement's data management solutions would aim at improving the flow of information between pharmacies and healthcare.

The change to the regulation of the pharmacy contract requires a change in the legal reference and term to the Decree of the Ministry of Social Affairs and Health on the treatment of opioid addiction and replacement with opioid medicines in order to align it with the amendments to the Medicines Act and the Medicines Prescription Act.

It is intended to enter into force on 1 October 2028.

1. Background to the dispute and powers to adopt regulations

The proposed amendment to the Decree of the Ministry of Social Affairs and Health on

treatment for opioid addiction and replacement with opioid medicines (642/2023) (*'the opioid removal and* replacement treatment decree') relates to the records of Prime Minister Petteri Orpo's government programme on the development of pharmacy regulation. The proposal aims to reform pharmacy regulation in a responsible and gradual manner, ensuring high-quality and safe pharmacy services throughout Finland. The proposal will continue to implement and develop the Kanta medication list with a view to better compatibility and integration with patient information systems. The proposal also aims to improve the safety, effectiveness and relevance of medical treatments.

Section 28a of the Health Care Act (1326/2010), Section 6a of the Mental Health Act (1116/1990), Section 16a of the Prison Care Unit Act (1635/2015) and Section 22(3) of the Health Care Professionals Act (559/1994) give the power to issue decrees under the Act on Immunity and Replacement Care.

2. Preparatory work

The proposed amendment to the Regulation on Online Difference and Reimbursement has been prepared together with a government proposal (HE xxx/2026 vp). The amendment is based on extensive preparatory work carried out together with stakeholders in the monitoring group and study group on pharmaceutical reform led by the Ministry of Social Affairs and Health and in the official workshop on the Kanta medication list led by the THL. A more detailed description of the preparation of the package can be found in Government Bill HE xxx/2026 vp (see Section 1.2 Preparation).

The government bill (HE xxx/2026) and the related draft regulations have been discussed in the Ministerial Working Party on Employment and Entrepreneurship on 15 April 2026.

The draft regulation was the subject of a six-week consultation on 21 April. 1 June 2026, together with the Government Bill (HE xxx/2026 vp) and other proposed amendments to the Regulations.

The preparatory documents for the proposal for a regulation can be found on the website of the Government proposal for the development of pharmacy activities (STM045:00/2025) in the public project window at: (https://stm.fi/hanke?tunnus=STM045:00/2025).

3. Current status and assessment of the current status

The pharmacy contract procedure is an approach aimed at ensuring the safe treatment of patients in situations where normal practices are not sufficient, such as the delivery of treatment for withdrawal and replacement of opioid addicts. The pharmacy agreement is concluded between the patient and the doctor or treatment unit treating him and the procedure is currently carried out by restricting the supply of the medicine from the

pharmacy. Under the contract, the patient undertakes that he will only be able to collect the medication for ddmmyyyy or narcotics from the pharmacy designated in the contract. The designated pharmacy is authorised to inform other pharmacies of the validity of the contract, in which case the other pharmacies shall refrain from supplying the medicinal products concerned. In addition, the pharmacy may pass on to the patient's treating physician information necessary to assess whether the treatment has been provided. The possibility of dispensing medicinal products through a pharmacy instead of a unit of care has facilitated the daily life of the user by allowing medicinal products to be collected from an out-patient pharmacy rather than from an entity of substance use.

The pharmacy agreement is governed by Section 55b of the Medicines Act. The data management solution for the pharmacy contract procedure was implemented in 2013 as an information service operated by the Finnish Association of Pharmacists, intended as an interim solution, because implementation as part of the Kanta services was not possible at that time. The current implementation of the pharmacy agreement does not allow for the development of activities in line with national pharmacy data management principles (STM 8/2024). Needs for the development of the pharmacy contract procedure have been identified and described in the Information Management Solution Statement produced by THL (THL 12/2023).

As part of Kela's Kanta services, the approach to a prescription centre would primarily be to restrict prescription and dispensing only when this is necessary for the organisation of the treatment. In the current state, information on the pharmacy contract is available to all pharmacies, but the details are only known to the contracted pharmacy. Pharmacies other than the contracted pharmacy do not see which medicines are covered by the customer's contract and refuse to supply DDDD or narcotics and refer the patient to the contracted pharmacy.

From a physician's point of view, a restriction on the visibility of a pharmacy contract may be detrimental to treatment situations. The existence and content of a pharmacy agreement shall be known only to the parties to the agreement. A doctor who has no knowledge of a pharmacy contract may prescribe medicinal products without being aware of the contract, but the pharmacy would not be able to supply them. This can complicate the proper planning of treatment and delay its delivery. In addition, in the absence of information on the existence of a pharmacy agreement during institutionalisation, the patient may be treated with medicinal products that make it difficult to follow up or replace the patient.

4. Objectives and key proposals

The proposed amendment to the Ordonnance on Immunisation and Replacement Care is part of the Government Programme's objective of reforming pharmacy regulation and developing the Kanta medication list.

As a matter of priority, the pharmacy agreement would be transformed into a prescribing policy rather than a single pharmacy delivery model. Changes to the pharmacy agreement's data management solutions would aim at improving the flow of information between pharmacies and healthcare.

The Government bill (HE xxx/2026 vp) proposes to amend the Medicines Act and the prescription act to repeal the regulation of the pharmacy contract and to introduce the regulation of the pharmaceutical contract into the prescription act.

5. Principal impacts

The impact of the proposed amendments to the Act on Immunisation and Reimbursement Treatment has been assessed in a government bill (HE xxx/2026) together with the impact of the proposed amendments to the Medicines Act and the Act on Prescriptions.

6. Opinion feedback

[To be completed after consultation]

7. Entry into force

It is proposed that the Regulation enters into force on 1 October 2028. The regulation is intended to enter into force at the same time as the bill amending the prescription law proposed in the government bill (HE xxxx/2026 vp).

br0ken!Government Decree amending the Medicinal Products Regulation

Main content

It is proposed to amend the Government Decree on Medicinal Products (693/1987; ' *the* Decree on Medicinal Products'). The proposal forms, together with the Government proposal to Parliament for legislation on the development of pharmacy activities (HE xxx/2026 vp) and the other proposed amendments to the Decree, a package of responsible and gradual reforms of pharmacy regulation,

ensuring high-quality and safe pharmacy services throughout Finland.

The Government bill (HE xxx/2026 vp) proposes to amend the Medicines Act (395/1987) in order to allow the pharmacy, as the competent authority within the meaning of Article 75 of the Schengen Convention, to charge a fee when issuing the certificate referred to in that Article to accompany medicinal products containing narcotic drugs or psychotropic substances when travelling from one Contracting State to another. The amount of the fee would be laid down in the Medicinal Products Regulation. In addition, the Government proposal proposes amendments to the Medicines Act aimed at identifying the activity of mechanical dispensing as a separate activity from that of pharmacies. The amendment would clarify the position of both dispensing operators and customers as part of the treatment of medicinal products. As part of the amendments, the Finnish Medicines Agency will be granted the right to inspect the dosage distribution unit and the Medicines Regulation should therefore be amended to regulate the inspection protocol.

It is intended to enter into force on 1 January 2027.

8. Background to the dispute and powers to adopt regulations

The proposed amendment to the Medicines Regulation is linked to the recordings in the government programme of Prime Minister Petteri Orpo on the development of pharmacy regulation. The proposal aims to reform pharmacy regulation in a responsible and gradual manner, ensuring high-quality and safe pharmacy services throughout Finland. The objective of the proposal is to improve the safety, effectiveness and relevance of medical treatments for elderly and multi-morbid people and to further develop the dosage distribution of medicinal products in order to increase medication safety and the efficient use of human resources.

It is proposed to add new provisions to the Medicines Act so that the proposed new Article 21d of the Medicines Regulation: the basic provision and the power to issue regulations concerning the fee for the Schengen Certificate would be contained in the new section 55a of the Medicines Act proposed in Government bill HE xxx/2026 vp. sub-paragraph N(3). In addition, Article 27 of the proposal for a regulation on medicinal products: Article 77 of the Law on Medicinal Products contains the basic provision and the power to adopt regulations concerning the communication to the parties of a copy of the inspection report. sub-paragraph N(3).

9. Preparatory work

The proposed amendment to the Medicines Regulation has been prepared together with a government proposal (HE xxx/2026 vp). The amendment is

based on extensive preparatory work carried out together with stakeholders in the monitoring group and study group on pharmaceutical reform led by the Ministry of Social Affairs and Health. A more detailed description of the preparation of the package can be found in Government Bill HE xxx/2026 vp (see Section 1.2 Preparation).

The government bill (HE xxx/2026 vp) and the related draft regulations have been discussed in the Ministerial Working Party on Employment and Entrepreneurship on 15 April 2026.

The draft regulation was subject to a six-week consultation from 21 April to 1 June 2026, together with a government bill (HE xxx/2026 vp) and other proposed amendments to the regulations.

The preparatory documents for the proposal for a regulation can be found on the website of the Government proposal for the development of pharmacy activities (STM045:00/2025) in the public project window at: (https://stm.fi/hanke? ID=STM045:00/2025).

10. Current status and assessment of the current status

Schengen Certificate

The pharmacy may: he submits that he is the competent authority within the meaning of Article 75 of the Schengen Convention and issues the certificate referred to in that article for the carriage of medicinal products containing narcotic drugs or psychotropic substances when travelling from one Contracting State to another.

During the parliamentary proceedings on the amendment to the Medicinal Products Act (700/2002), it was not assessed what fee pharmacies could charge for carrying out this public administrative task. The circular of 14 January 2003 from the Ministry of Social Affairs and Health to pharmacies states that pharmacies may charge a reasonable fee for the issue of the certificate. The amount of the fee is therefore freely determined by the pharmacies. The opinion of the Constitutional Law Committee (PeVL 19/2002 vp, p. 4) assessed the relationship between regulation and mainly Article 124 of the Constitution and the transfer of public authority to the private sphere. The Constitutional Law Committee has taken the view that, by its very nature, the Schengen Certificate is issued without any particular consideration to any applicant who satisfies the conditions for obtaining it. According to the Constitutional Law Committee, given the nature of the certificate, pharmacies have sufficient specific expertise to issue it. In addition, the Constitutional Law Committee stated in its opinion that the law should indicate the technical conditions for obtaining the certificate.

The issuing of the Schengen Certificate has been interpreted as a public administrative function of the pharmacy. The Deputy Ombudsman of the Parliament, in his decision on the complaint case (16.6.2021; EOAK/1081/2020)
it is problematic that the fee for the performance of a public administrative task is determined solely on the basis of a price set by a private operator on a commercial basis. According to the Assistant Advocate General, the price of a fee may therefore vary significantly, which may give rise to unjustified discrimination between customers. A separate certificate is required for each journey, which means that the cost of obtaining a certificate can be significant for the individual on an annual basis.

Fimea monitors the annual number of Schengen Certificates issued by pharmacies. The number of certificates issued has increased considerably in recent years. In 2021, pharmacies issued a total of 1995 certificates, in 2022 a total of 8279 certificates, in 2023 a total of 10741 certificates and in 2024 a total of 16561 certificates. The basis for pricing may differ from one pharmacy to another. Pricing may be fixed-price, quantity-based or variable on a case-by-case basis and include a maximum price. The fee for a certificate typically ranges from EUR 25 free of charge. The time taken to draw up the certificate may vary considerably, and the experience of staff also has an impact on this duration. On average, it can take about 15-30 minutes to produce a certificate.

The entrustment of a public administrative task to a non-governmental body should not be permitted under Article 124 of the Constitution: in its view, it undermines fundamental rights, judicial protection or other requirements of good administration. There have been differences in the pricing of the Schengen Certificate between different pharmacies, which has led to unequal treatment of customers. In particular if the certificate has to be obtained several times a year. In order to promote equality between customers, legislation should set clear framework conditions for the pricing of the certificate.

Mechanical dispensing of medicinal products

Provisions on dosage distribution in the Medicines Act are limited. Paragraph 12a of the Law on medicinal products lays down the procedure for authorising the distribution of doses by mechanical means in pharmacies and hospital pharmacies and Paragraph 15 lays down the general conditions for the distribution of doses by mechanical means. Section 12a of the Medicines Act: according to N, the mechanical dispensing in a pharmacy and the contract manufacturing activities are subject to authorisation by Fimea. Authorisation shall be granted if the activity complies with the requirements laid down in section 15. The authorisation may be subject to conditions concerning the manufacture, supply and use of the medicinal product and other conditions necessary for the safety of medicinal products. Under the second paragraph of

that section, a pharmacist may arrange for the automatic dispensing of doses on the basis of a contract in another pharmacy authorised for the automatic dispensing of doses.

On behalf of the STM, Fimea has carried out a study (STM 2025:30) on the development needs of the mechanical dosage distribution service. In preparing the report, Fimea took into account the perspectives of stakeholders such as dosage distribution units, wellbeing services counties and private service providers, community pharmacies, the Ministry of Social Affairs and Health, the Medicines Prices Board (hila), Kela, THL and representative organisations on development needs. According to the study (STM 2025:30), the current legislation on mechanical dispensing is insufficient and does not identify the dispensing units, i.e. the operators who actually carry out the packaging of the dispensing.

The activity of packaging in the dispensing sector has grown into a large-scale activity carried out independently by the dispensing units, even though it is carried out by a pharmacist who has been granted a mechanical dispensing licence under the Medicines Act. It would be necessary for the legislation to clearly identify the dosage distribution units as a separate operator in their own right, including the conditions for authorisation, the person responsible for the activity and the framework conditions. Clearer legislation would make it easier for operators to anticipate changes in their activities and clarify the implementation of controls, which would also improve the legal position of the dispensing units. As the Medicines Act currently stands, the Finnish Medicines Agency has no explicit right of inspection over the dosage distribution unit. The right to inspect the dispensing premises was based on the right to inspect the pharmacy, even though the dispensing unit carrying out the dispensing is a separate operator attached to the pharmacy;

11. Objectives and key proposals

The proposed amendment to the Medicines Regulation is part of the Government Programme’s objective of reforming pharmacy regulation and developing dosage distribution of medicines.

The Government bill (HE xxx/2026 vp) proposes to amend the Medicines Act to allow the pharmacy to charge a fee for issuing the Schengen Certificate. This addition is necessary because the issue of the certificate is a matter of the public management of pharmacies, the pricing of which should be determined by the population on an equal basis. The fee would be based on a cost-value calculation. A power to issue regulations would also be added to the Medicines Act, according to which more detailed provisions on the fee to be charged for

the Schengen Certificate would be laid down by government decree.

Provisions on the licensing and operation of the dosage distribution unit would also be introduced in the Medicines Act. The Dose Distribution Unit would be added to the list of operators to which the Finnish Medicines Agency would have the right to inspect. An amendment to the Medicines Decree would be necessary to the section on the provision of a copy of the inspection report, to which would also be added the person responsible for the dosage distribution unit. At the same time, an addition would be made concerning the responsible person of the holder of the retail licence for para-therapeutics, who is missing from that act.

12. Principal impacts

The impact of the proposed amendments to the Medicines Regulation has been assessed in a government bill (HE xxx/2026) together with the impact of the proposed amendments to the Medicines Act.

13. Opinion feedback

[To be completed after consultation]

14. Explanatory memorandum for each provision

Article 21d. The proposed article would be new. A pharmacy could charge a fee for issuing the Schengen Certificate referred to in Section 55a of the Medicines Act (395/1987). According to subsection 1 of the section, the fee would be EUR 11, which would include the registration of one medicinal product in the certificate. The cost estimate would be based on the estimate that it would take about 15-20 minutes to produce a certificate with one record of the medicine. The cost to the pharmacy of drawing up the certificate, including staff costs based on the average salary of the pharmacist, would be approximately EUR 11. The pharmacy draws up a separate certificate for each medicinal product. Under subsection 2, if a certificate for two or more medicinal products is drawn up at the same time, a fee of EUR 1.50 could be charged for the next certificate for each medicinal product. The first certificate requires all the information to be recorded; for subsequent certificates, the pharmacy could re-use the information previously recorded. This would significantly reduce the time needed to produce the next certificates.

ARTICLE 27. It is proposed that the section be amended to include in subsection 1 of the section on the transmission of a copy of the inspection report the person responsible for the dosage distribution unit. At the same time, an addition would be made concerning the responsible person of the holder of the retail licence for para-therapeutics, who is missing from that act. For the rest, no changes are proposed to the section.

15. Entry into force

It is proposed that the Regulation enters into force on 1 January 2027. The Decree is intended to enter into force at the same time as Section 55 of the Medicines Act proposed by the Government proposal (HE xxxx/2026 vp) for legislation on the development of pharmacy activities. paragraphs 2 and 3 and Article 77: N with the amendments to subsection 1 above.

br0ken!Government Decree amending the Government Decree on the Pharmaceutical Tax

Main content

It is proposed to amend the Government Decree on the Medicinal Products Tax (713/2013). The proposal, together with the Government proposal to Parliament for legislation on the development of pharmacy activities (HE xxx/2026 vp), forms, together with the other proposed amendments to the Decree, a package of reforms to the pharmacy regulations in a responsible and gradual manner, ensuring high-quality and safe pharmacy services throughout Finland.

The Government bill (HE xxx/2026 vp) proposes to amend the Medicines Act (395/1987) so that the price of a self-care medicine would not have to be the same in all pharmacy establishments and online services in the future. The purpose of the amendment would be to allow greater price competition between pharmacies. A change in the pricing of the self-care medicinal product also requires an amendment to the Government Decree on the Pharmaceutical Tariff to align it with the amendment to the Medicines Act.

It is intended to enter into force on 1 January 2027.

16. Background to the dispute and powers to adopt regulations

The proposed amendment to the Medicines Tax Decree is linked to the records of the government programme of Prime Minister Petteri Orpo on the development of pharmacy regulation. The proposal aims to reform pharmacy regulation in a responsible and gradual manner, ensuring high-quality and safe pharmacy services throughout Finland. The proposal recognises the role of pharmacies as part of the healthcare system and the important role of pharmacies in the success of a patient's medical treatment. The reform aims to organise a more cost-effective system for the retail supply of medicinal products and to increase the conditions for price competition for medicinal products.

Section 58 of the Medicines Act (395/1987), which provides, in subsection 1, that the price to be used for the retail sale of a medicinal product shall be the price at which the fee is fixed by government decree, and, in subsection 5, that the price at which the fee is fixed, the price exemptions and the discounts to be granted are to be specified by government decree, confers the power to issue a regulation on the Medicines Tax Decree and the Government Decree amending it.

17. Preparatory work

The proposed amendment to the Medicines Tax Regulation has been prepared together with a government proposal (HE xxx/2026 vp). The amendment is based on extensive preparatory work carried out together with stakeholders in the monitoring group and study group on pharmaceutical reform led by the Ministry of Social Affairs and Health. A more detailed description of the preparation of the package can be found in Government Bill HE xxx/2026 vp (see Section 1.2 Preparation).

The government bill (HE xxx/2026 vp) and the related draft regulations have been discussed in the Ministerial Working Party on Employment and Entrepreneurship on 15 April 2026.

The draft regulation was the subject of a six-week consultation from 21 April to 1 June 2026, together with a government bill (HE xxx/2026 vp) and other draft amendments to the regulations.

The preparatory documents for the proposal for a regulation can be found on the website of the Government proposal for the development of pharmacy activities (STM045:00/2025) in the public project window at: (https://stm.fi/hanke? ID=STM045:00/2025).

18. Current status and assessment of the current status

Under Paragraph 58(4) of the Law on medicinal products, the price of a medicinal product for self-care must be the same for all pharmacy

establishments and online services. In accordance with the amendments to the Law on medicinal products and the Decree on the tariff for medicinal products, which entered into force on 1 April 2022, the regulation of the price of non-prescription medicinal products was amended by allowing pharmacies to grant their customers discounts on non-prescription medicinal products up to their own commercial margins. However, the aim was to maintain a uniform retail price for all pharmacy outlets and online services. However, the price limitation may have prevented price competition, in particular on the pharmacy's online service, which, according to studies, is currently moderate (Piira, Jussi). Price competition for non-prescription medicines on the Finnish pharmacy market. Pro gradu thesis, University of Eastern Finland 2024, available at: https://erepo.uef.fi/server/api/core/bitstreams/6ffbde61-fdd6-40a9-9e11-bd5e98e66a51/content). The low level of price competition may in part be explained by the fact that it may be difficult for a consumer to compare the prices of products between pharmacies. As online price comparison is substantially easier for the consumer, improving the operating conditions of online pharmacies could improve the consumer's position in pharmacy transactions.

The amendments to the Medicines Act and the Medicines Tax Decree, which entered into force on 1 January 2026, allowed the sale of a limited range of self-care medicinal products also outside pharmacies. That range is governed by rules different from those governing the pricing of other non-patient medicinal products, in accordance with Paragraph 4a of the Decree on the tariff for medicinal products, according to which a pharmacy and the holder of a retail licence for a non-patient medicinal product may freely determine the retail price of the non-patient medicinal product when selling a non-patient medicinal product from a limited range of non-patient medicinal products. However, the retail price may not exceed the retail price determined in accordance with the formula laid down in Paragraph 4(1).

19. Objectives and key proposals

The proposed amendment to the Medicines Tax Regulation is part of the Government Programme's objective of reforming pharmacy regulation and increasing the conditions for price competition for medicines.

In the government bill (HE xxx/2026 vp), it is proposed to amend the Medicines Act so that the price of a self-care medicine would not have to be the same in all pharmacy establishments and online services in the future. The purpose of the amendment would be to allow greater price competition between pharmacies. A change in the pricing of the self-care medicinal product also requires the amendment of Section 4(5) of the Government Decree on the Pharmaceutical Tariff to reflect the amendment to the Medicines Act.

20. Principal impacts

The impact of the proposed amendments to the Medicines Tax Decree has been assessed in a government bill (HE xxx/2026) together with the impact of the proposed amendments to the Medicines Act.

21. Opinion feedback

[To be completed after consultation]

22. Entry into force

It is proposed that the Regulation enters into force on 1 January 2027.

The Decree is intended to enter into force at the same time as Section 58 of the Medicines Act, which is proposed in the Government proposal (HE xxxx/2026 vp) for legislation on the development of pharmacy activities. N with the amendments to subsection 4 above.