1 The proposals and their impacts

1.1 Main proposals

The proposals seek to clarify the content of pharmacy services with regard to the operations that must be carried out in a pharmacy. The proposals aim to establish uniform principles for the requirements imposed on pharmacy operations and to safeguard the position of medicine users so that consistent service could be obtained regardless of the pharmacy concerned. Clarifying the content of pharmacy services will also support future assessments of the funding needs for service provision and the adequacy of such funding. The regulatory amendments concerning guidance and counselling on pharmacological treatment are intended to improve the effectiveness of counselling so that successful medicinal treatment is supported on the basis of individual needs through the expertise of the pharmaceutical staff of pharmacies. A more precise definition of guidance and counselling on pharmacological treatment will also clarify the conditions for developing services that go beyond these activities. The amendments proposed to the regulation of pharmacy operations would highlight the role of pharmacies as part of the pharmacological treatment process in relation to other social welfare and healthcare services.

The proposal suggests making greater use of the expertise of pharmacies' pharmaceutical staff as part of successful pharmacological treatment and to support both customers' independent self-care and self-care planned together with a healthcare professional.

To support successful pharmacological treatment, amendments are proposed to the legislation concerning pharmacy agreements. The provisions of the Medicines Act concerning pharmacy agreements are proposed to be amended from regulating the dispensing of medicines to regulating the prescribing of medicines and to focus on a single healthcare service unit. As a rule, medicines covered by the agreement could be collected from any pharmacy unless it would be justified to restrict dispensing to only one or a few pharmacies. In addition, to prevent medicine wastage and to manage distribution, the dispensing of distributed packages would generally need to be centralised to a single pharmacy only. The Act would also be amended with regard to the information management of medicine agreements, for example by transferring the maintenance of agreements from the server of the Association of Finnish Pharmacies to the Prescription Centre maintained within the Kanta Services. It is proposed that the name 'pharmacy agreement' be changed to 'medicine agreement'.

The aim of the proposals is to ensure high-quality and equitable pharmacy services in Finland by clarifying the requirements imposed on pharmacy operations. The proposal would add provisions to the Medicines Act on the qualitative and operational requirements of pharmacy activities by introducing obligations that support patient safety, concerning the pharmacy's operating instructions and the reporting and handling of adverse events. The proposed amendments also safeguard customers' equal status by adding to the Medicines Act a provision granting the Government the authority to issue regulations on price controls related to the issuance of Schengen certificates.

The proposal also includes changes to the pharmacy licensing system that would enhance the functionality of the nationwide pharmacy network and ensure the social sustainability of its maintenance. The aim is to reform branch pharmacy regulations to better meet actual regional needs and to involve the providers of social welfare and healthcare services in assessing the pharmacy services required in the area. It is proposed to exempt pharmacy pick-up lockers from location-based regulation.

The proposal would enable holders of retail marketing authorisations for non-prescription medicinal products to provide an online service. In addition, pharmacies' remote services would be streamlined by improving the regulation of online pharmacy services and the conditions for their provision. The amendments would allow more flexible cooperation between pharmacies in the supply of medicinal products. The conditions for price competition in medicines would be strengthened by amending the Medicines Act to allow pricing in online pharmacies to differ from that in brick-and-mortar pharmacies.

In addition, amendments are proposed to the Medicines Act to recognise automated dose dispensing as an activity separate from pharmacy operations, which would clarify the role of both dose dispensing operators and customers within the context of pharmacological treatment and regulatory oversight.

1.2 Principal impacts

1.2.1 Economic impact

1.2.2 Economic impact on government finances and public finances

The proposal is estimated to have indirect economic effects on the state or public finances due to changes in the use of medicines. A reduction in unnecessary pharmacological treatment, achieved through customer-focused guidance and advice on medication, and improved cooperation and operational practices between pharmacies and social and health services, may reduce the financial burden on the state and health insurance holders due to lower Kela reimbursements for medicines. The proposal may also affect the success of pharmacological treatment, which has been assessed in more detail in section 1.11.5 on the economic impact on social welfare and healthcare services.

The proposals concerning changes to the branch pharmacy regulation may have a minor impact on the state's tax revenue. They would streamline Fimea's ability to convert an authorised branch pharmacy into a condition of a pharmacy licence, potentially leading to more authorised branch pharmacies becoming a condition of a pharmacy licence. This may impact pharmacy tax revenue, as operating a branch pharmacy as a condition of a pharmacy licence entitles the holder to a larger deduction from the pharmacy tax base than operating one as an authorised branch pharmacy. However, the impact would likely be minimal, as this would not be the primary means of maintaining a nationwide network of pharmacies, and a branch pharmacy that is currently a right could only be made a condition of a pharmacy licence if justified to ensure the continuity of pharmacy services in an area. Decisions on making the establishment of a branch pharmacy a condition of a pharmacy licence would be made on a case-by-case basis.

The proposed information management solution for medicine agreements would require the development of national information management services. This proposal includes the phase 3 part of the medicinal product agreement, the development costs of which are estimated at approximately EUR 0.4 million for the Social Insurance Institution (Kela)'s Kanta services. The costs of phase 3 development of information management for pharmacological treatment within the Kanta Services will amount to approximately EUR 4 million in total during 2026–2029. The costs will be covered from budget item 4.23.33.01.25 of the State budget. According to the Social Insurance Institution (Kela), the maintenance costs of the reforms to the Kanta system are included in the existing system maintenance costs, meaning that the development of phase 3 will not incur any new maintenance costs.

1.2.3 Economic impact on households

The proposal is estimated to have economic impacts on customers who use medicines. The amendment aims to improve the success of pharmacological treatments, which can enhance the customer's financial situation through reduced medicine use or improved work and functional capacity resulting from successful treatments. For example, nationally harmonised guidance and counselling on pharmacological treatment may improve the success of medicinal treatment, and the moderate development of medicinal treatment costs for customers using automated dose dispensing services may be supported through amendments to the regulation governing such services and the establishment of operating practices.

Price competition for over-the-counter medicines would be strengthened by extending the pharmacy's obligation to offer the most affordable over-the-counter medicine, allowing different prices across a pharmacy's various service channels, and enabling online sales of over-the-counter medicines through retail outlets outside pharmacies. The change may improve the financial position of medicine users if the prices of over-the-counter medicines decrease. The Proposal may therefore have a positive impact on the position of households. The change may also, to a limited extent, increase unnecessary consumption of over-the-counter medicines and thus weaken the position of households, as guidance and advice related to medication and, consequently, support for product selection could not be provided through the online service of retail outlets in the same way as through a pharmacy's online service.

The costs incurred by customers using medicinal products containing narcotic or psychotropic substances and travelling abroad may be affected, depending on the fee charged by the pharmacy from which the Schengen certificate was requested. The impact on the population is likely to be small, as the proposed pricing is based on an estimate of the cost price, mainly labour costs, which appears to have been the basis for pharmacy pricing in many cases at present.

1.2.4 Economic impact on pharmacies

The proposed definition of the tasks of pharmacies would affect pharmacy operations, the activities of authorities, namely authorisation and registration practices and supervision, as well as the evaluation and guidance of pharmacy operations. Defining the tasks of pharmacies would provide a framework for pharmacy operations and clarify the core tasks of pharmacies and the principles under which pharmacy activities are conducted. The changes are expected to have minimal economic impact on pharmacies, as their core functions would remain unchanged.

Where pharmacies provide services other than those carried out on the basis of a pharmacy licence, registration in the Soteri register is required. The registration fee consists of charges for the service provider and the service unit, and the amount varies depending on the company's legal form and size. For example, the fee for health services provided at a single establishment would be at least EUR 1 060 and no more than EUR 1 800, depending on the size of the pharmacy or whether the registration is sought for a separate limited company. It is also possible to apply for a joint registration of a service unit, which costs EUR 1 280 and includes one service point, up to four service sectors, and up to five service providers. The Soteri registration fee may further reduce pharmacies' willingness to develop health services through regional cooperation, such as consultation or assessment services based on pharmaceutical expertise, which have so far been limited. However, it should be noted that a significant proportion of pharmacies already offer health services based on partnerships. Clarifying the conditions for providing services may also increase some pharmacies' willingness to offer health services and, at the same time, boost demand for them, especially if cooperation were agreed upon within the wellbeing services county. If the provision of health services in pharmacies were to increase significantly from current levels, it would have a strengthening effect on the financial position of pharmacies.

The changes proposed to streamline online service operations would improve the profitability of the online service business. The proposed changes to the implementation of the online service will enhance all pharmacies' ability to offer their services online. Pharmacies could offer the online service with lower investment and maintenance costs if it were produced collaboratively. An online service also streamlines pharmacy operations and adds flexibility, allowing customers to place part of their orders independently, while the pharmacy can direct staff to process online orders when there are fewer customers in the physical store. The operational capabilities of an online pharmacy would also be improved by expanding the area where pick-up lockers are located, which could facilitate offering the online service beyond the pharmacy's own local area. The pharmacist should continue to ensure the appropriateness of the pick-up lockers, which is why it is likely that pharmacies would not place them too far outside their own local area, despite the easing of regulations. On one hand, the impact on competition between pharmacies in this regard is likely to be limited. On the other hand, enabling the expansion of price competition in non-prescription medicines through the online service may increase competition between pharmacies. Online services provided by holders of retail licences for over-the-counter medicines outside the pharmacy sector may also reduce the share of over-the-counter medicine sales accounted for by pharmacies and intensify price competition among different operators. However, the impact is likely to be minimal, as the range of over-the-counter medicines available from retailers outside pharmacies is significantly narrower than that of pharmacies.

An increase in customers purchasing medicines through online pharmacy services may have different economic impacts on different pharmacies. Pharmacies that invest in providing online services and in the smoothness and customer orientation of their service processes, or that enter into cooperation agreements with various operators, may benefit from increased sales of medicines and other products through online services. However, the sales of pharmacies that do not develop their online services may decrease if their customer base shifts to purchasing medicines and other pharmacy products through another pharmacy's online service. It would not be possible to assess in advance which pharmacies would benefit from or suffer due to the growth of online services, and pharmacies themselves would have the opportunity to influence the change through their own operations.

On one hand, the proposed changes to online service operations may lead to changes in the market, concentrate demand on those pharmacies that invest in and develop their services, and reduce the number of operators in the online pharmacy market. As a result, competition may weaken in the longer term. On the other hand, the current state of online pharmacy services is already highly polarised, with large-scale operations concentrated due to investment needs and the operating environment of the pharmacy system. Enabling cooperation through a legislative amendment could bring new pharmacies into the online pharmacy business and thereby increase competition in the market. New business models can improve service and also support local services by allowing pharmacies that, as independent operators, would be too small to invest and meet the customer service requirements of the online environment to participate in the online service.

However, enabling cooperation may lead to the concentration of certain aspects of online service operations, for example in platform solutions or pharmacological guidance and advisory services.

The proposed amendment concerning the monitoring of the performance of pharmacy tasks and the reporting and handling of adverse incidents may have economic impacts on pharmacies. Any investment needs in a pharmacy may relate to consistent monitoring, reporting and change management, staff induction and training costs, or the costs of acquiring an information system. However, the overall impact is estimated to be limited, and with regard to the incident procedure, it would only apply to a small number of pharmacies, as currently, almost all pharmacies have incident reporting and handling procedures in place (Working Group Report VN/14650/2023 of the Ministry of Social Affairs and Health. A plan of measures to ensure medication safety and treatment success during pharmacy substitution of biological medicinal products. Available at https://api.hankeikkuna.fi/asiakirjat/7ee12781-84ec-4157-9980-0f6514035aad/e2263b92-e22e-4075-a067-2df0d88f4d6a/RAPORTTI_20250509082610.PDF). Monitoring pharmacy operations at a general level is likely already, under the current framework, a key part of business monitoring, continuous development and management.

The proposed changes to the content of pharmacological guidance and advice provided by pharmacies may result in induction and training costs for pharmacy staff. Despite this, it should be noted that Fimea's order on the supply of medicinal products already included obligations relating to the content of medicinal product advice, corresponding to the proposed clarifications. Furthermore, under the Act on Health Care Professionals, pharmaceutical personnel are already required to continuously maintain and develop their professional skills, and under the Medicines Act, the pharmacist has been responsible for ensuring that all pharmacy staff participate sufficiently in continuing professional education. The cost of training and induction for pharmacies would depend on how the above-mentioned obligations have been fulfilled previously and on when the pharmaceutical staff completed their initial training. It would also be significant to consider when the pharmacy personnel completed their basic degrees, as the university education reforms carried out over the past decade have made the learning outcomes of these degrees better support the skills required by the proposed changes.

Changes in the content of guidance and counselling on pharmacological treatment may also affect a pharmacy's financial position because competition based on service quality may increase, which could influence the number of customers. Although the proposal aims to standardise pharmacy operations, customer-oriented counselling would also mean that its specific content could vary between pharmacies. Pharmacies that maintain the expertise of their personnel and invest in customer-oriented service would benefit financially from this, while pharmacies where guidance and counselling do not reach the same service level may suffer from increased competition. The pharmacy's ability to enhance the customer experience, as well as the guidance and advice provided through its online pharmacy, can also affect customer numbers, which is quite typical in business overall.

1.2.5 Economic impact on public social services and health care

Medication errors cause significant costs for social and healthcare services. According to a Finnish study, the annual cost of work related to investigating medication errors has been estimated at approximately EUR 15.5 million. (Kanninen JC, Ojala R, Ahonen J, Kautiainen H, Holm A, Valkonen 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.). In pharmacological treatment, the operating practices and information management of various actors have been developed in a long-term manner, including through the introduction of the Kanta Medication List and the expansion of its data content during the current government term (HE xx/2026). The measures proposed herein support the objectives related to the development of the Kanta Medication List and further strengthen the previously conducted assessment of its economic impacts.

Studies show that harm from medication errors impacts an estimated one in five hospital patients in Western nations, and in Finland it has been estimated to account for up to one quarter of emergency department visits among older people (Laatikainen 2020, Adverse drug events in healthcare). In addition, there are estimates in literature that better adherence to medication improves treatment effectiveness and reduces the use of other healthcare services, particularly in the case of 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 drug group. For example, according to a recent publication, adherence to asthma medication in Finland is at a good level (Salmela, Petri; Pakkasela, Johanna; Juntunen, Pekka et al. Adherence to asthma medication and asthma control in Finland. BMC Pulm Med (2026). Available: https://doi.org/10.1186/s12890-026-04223-0). In contrast, adherence among

psychiatric patients is considered to be significantly poorer (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-oriented focus of pharmacoceutical guidance and counselling provided in connection with the dispensing of medicines, and make it clearer that pharmacy operations should form a safe, high-quality, effective and economically efficient whole from the perspective of the medicine user, social and healthcare services, and society. The guidance and advice provided in pharmacies should, in all situations, aim to reinforce the advice given within healthcare. Additionally, during discussions at the pharmacy, it is possible to revisit matters that remain unclear to the user of the medicinal product. These changes have the potential to improve the success of pharmacological treatment, reduce the use of unnecessary medicines, and decrease emergency visits caused by medication-related problems. In Finland, it has been estimated that pharmaceutical work carried out in pharmacies reduces the use of public health services by EUR 855 million annually (a study commissioned by the Association of Finnish Pharmacies: The value of pharmaceutical work carried out by pharmacies. Esior Oy, 2024). The assessment will focus particularly on the effects of self-care and prescription medicine advice, as well as the impact of deviations and the review of their interactions. The magnitude of the impact depends on the extent to which pharmacies have already acted when dispensing medicines with the aim of influencing the factors mentioned above. Furthermore, a key factor is how determinedly cooperation between pharmacies and social welfare and healthcare services will be promoted across different regions as these changes are implemented. The handling of discrepancies identified in pharmacies, as proposed, supports the identification of and learning from problems related to medicine use.

If the competence of pharmacy personnel is not ensured, or if the wellbeing services county has not made agreements with pharmacy operators on the provision of medication guidance and advice in outpatient care as required by the proposed changes, it is possible that the customer-focused advice offered by pharmacies may differ from that provided within healthcare. The risk may increase particularly when using medicines outside the terms of their marketing authorisation, or in the case of medicines supplied under special authorisation or compounded in a pharmacy. Conflicting guidance and counselling on pharmacological treatment may weaken the chances of successful treatment and thereby increase costs for social and healthcare services. However, the impact is assessed to be small, and its realisation would require that a pharmacy neglects its obligations, for example regarding cooperation with the wellbeing services county or maintaining the competence of its staff.

The impacts of the proposed measures are also influenced by the extent to which, in addition to legislative development, other means are introduced to support the provision of medication counselling that meets customer needs in different regions. Such measures include national information guidance and support for increased regional cooperation between wellbeing services counties and pharmacies. At the national level, there is currently no systematic monitoring of medication practices and counselling, treatment adherence, and reported medication-related adverse events. However, development projects are underway with the aim of supporting data-driven management in the development of regional practices and cooperation.

The proposed changes to automated dose dispensing may have an impact on social welfare and healthcare operations. The proposal aims to clarify the requirements set for the operations. In dose dispensing operations, patient safety must be ensured, which would be specifically designated as the responsibility of a responsible person identified in the regulation. When appropriately implemented, automated dose dispensing can support the successful treatment of patients on multiple medications and reduce the time healthcare professionals spend on medicine dispensing, as well as reduce dispensing errors.

1.2.6 Economic impact on grocery stores and other businesses

The amendments proposed in the proposal would enable the online services of holders of retail licences for over-the-counter medicines, thereby improving their ability to expand service channels for the sale of over-the-counter medicines. This change may increase medicine sales by these operators and enhance price competition between them. The magnitude of the change depends on the product range sold, i.e. the extent to which pharmaceutical companies apply for licences to sell over-the-counter medicines outside pharmacies for those medicinal products for which this would be possible. The proposed change on the expansion of the sales channel for non-prescription medicines could increase the consumption of these medicines compared to the current situation, which would benefit pharmaceutical companies financially.

The proposed amendment concerning the online service of holders of retail licences for over-the-counter medicines requires the development of information systems and data management to support online transactions. No separate regulation is proposed for data management; instead, the General Data Protection

Regulation (GDPR) would apply to the service. Accordingly, the holder of a retail licence for a limited range of over-the-counter medicines must ensure, through technical and organisational measures, the implementation of data protection, data security, and the rights of data subjects in the online service it provides. In connection with the sale of a limited range of over-the-counter medicines, a customer register will be created containing personal and medicinal product data that are sensitive in nature. In addition to the processing and storage of data, attention must be paid to ensuring the proper transmission of order and delivery confirmations containing personal and medicinal product information. A suitable way to provide such information in practice could be, for example, an electronic transaction service into which a customer purchasing medicines online logs in, and through which they are able to access the aforementioned sensitive information.

Enabling cooperation in online pharmacy services also with actors outside pharmacies may create new types of business activities, for example for private entrepreneurs with pharmaceutical training. The proposed changes would make it possible for a pharmacy to agree, for example, on the provision of pharmacological guidance and counselling in its online service with a company that has the capacity to provide such counselling. Allowing cooperation could expand business opportunities in the pharmacy sector, where the number of operators is limited. At the same time, entering into such cooperation may require investment in the necessary information systems and data management. If a pharmacy provides pharmacological guidance and counselling related to dispensing medicines in cooperation with another operator, all parties involved in dispensing medicines must have consistent data protection safeguards and technical information security procedures in place. The procedures and processing of data must be equivalent to those required of pharmacies in relation to medicine dispensing.

The proposed changes to automated dose dispensing of medicines may affect the financial position of companies providing such services. However, the licensing requirements, quality standards for operations, and principles for determining the medicine selection introduced into regulation would not change the current requirements, and therefore the economic impacts on existing operators are assessed as minor. If, due to the proposed regulation, changes were made to the medicine selection in a dose dispensing unit that weaken its financial position, costs could be passed on within the service chain as service fees charged for dose dispensing from the pharmacy or the purchaser of the service. The proposed changes do not give rise to separate development costs related to data management or information systems, provided that the activity complies with the regulation. In future, both the pharmacy and the automated dose dispensing unit it uses must ensure the appropriate implementation of data protection, data security, and data subject rights in the service. The process of automated dose dispensing must comply with the general legislation governing the processing of health data, and the systems and operating models must meet the requirements of the General Data Protection Regulation and GMP guidelines.

The proposed data management solution for the pharmaceutical agreement would relieve the Finnish Pharmacists' Association of its maintenance responsibilities and the associated costs related to the intermediary server for pharmacy agreements, as well as the related contract, support, and access management procedures.

1.2.7 Impact on people and society

The proposed amendments aim to clarify the roles and organisation of pharmacies so that they form a safe, high-quality, effective, and economical system for medicine users, social and healthcare services, and society as a whole. By clarifying the guidance and advice on medication, it would be possible to utilise the expertise of a pharmacy's pharmaceutical staff to support successful pharmacological treatment and, at the same time, to identify medication-related problems during the guidance and advice provided at the point of dispensing. The proposed changes could reduce the burden on medicine users related to their medication (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 to improve the success of pharmacological treatment (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), when the efforts of pharmaceutical staff are used for patient-centred counselling.

It is proposed that the pharmacy must offer, when dispensing medication, the opportunity for a pharmacist or chief pharmacist to give guidance and advice on pharmacological treatment, aiming to ensure the correct and safe use of the medicine and to support successful treatment outcomes. Under current regulation, when supplying medicinal products, pharmacy staff are required, through advice and guidance, to ensure that the medicine user is aware of the correct and safe use of the medicine. The customer must always have the

possibility to receive counselling. The proposed wording would continue to allow the medicine user to choose whether they wish to receive counselling. On one hand, if the proposed amendment in the proposal were to result in medicine users declining counselling more often than at present, the proposal could weaken the support these users receive for the implementation of their treatment. On the other hand, it should be noted that in practice, even under the current situation, it has been possible to refuse counselling, and the proposal is not expected to lead to an immediate change in this regard. Refusal of counselling may be low-risk in situations where medication has been long established and is well balanced. Refusal of counselling may also result from the sensitivity of the matter, in which case willingness to receive counselling may increase if it were offered, for example, via a written chat service. It is also possible that, following the proposed amendment, pharmacies could better focus than at present on advising and counselling those individuals who have an increased need for support in achieving successful pharmacological treatment. Such individuals would include, for example, multimorbid patients taking several different medicines, or persons initiating a new medicine. Medicine users who have difficulties maintaining treatment balance and who do not wish to receive verbal guidance and counselling may also benefit from new ways of obtaining information to support their pharmacological treatment. The changes would enable pharmacies to develop methods of guidance and counselling, which could help allocate pharmacy resources to counselling those who benefit most. Such solutions could benefit different language groups, and the accessibility of counselling services could also serve as a competitive advantage for pharmacies.

Pharmacies must also continue to offer the possibility of counselling to all who wish to receive it. Refusal of counselling may be more pronounced in the case of medicine orders placed via online services, as if counselling is not immediately available, it may be perceived as a delay in obtaining the medicine. It would be difficult to assess the impact in advance, and much would depend on how pharmacies practically fulfil their obligation to provide advice. Pharmacies should also be able to support the use of medicines in their online services through various digital solutions, not only through advice and guidance provided by healthcare professionals. When medicine prices are regulated, the importance of service quality in the customer experience is emphasised, which in terms of counselling, would mean that the medicine user is supported in an appropriate manner.

Several of the proposed changes will improve customers’ access to medicines. Changes to the regulation of branch pharmacies will improve the availability of medicines in the branch pharmacy’s service area; online sales by holders of retail licences for self-care medicines will enhance availability, as will changes to the pharmacy’s online services. In the online service, enabling cooperation can improve the customer's ability to order both self-care and prescription medicines from the pharmacy's online service, as pharmacies would have a better opportunity to keep the service available for longer opening hours. The quality of advice and other services provided through the online service can also improve when it is possible to deliver these services collaboratively. Relaxing regulation on the locations of pick-up lockers may increase the number of lockers or change the locations of existing lockers to better suit customer needs. The change can make it easier to collect ordered medicines and thus make visiting the pharmacy more convenient.

The amendments proposed in the bill to Fimea’s regulatory powers regarding the reporting and handling of medicinal product recalls, as well as the handling of product defects and suspected counterfeit medicines, will improve medicinal safety and, more broadly, patient safety. The position of medicinal product users would improve compared to the current situation, as the legal basis for precautions related to the safety of medicinal products would be strengthened.

The proposed changes would transfer the responsibility for assessing the functionality, location and adequacy of pharmacy services from the current municipality to the authority responsible for organising social and healthcare services, thereby ensuring the compatibility and interoperability of pharmacy services with other social and healthcare services. For example, as part of its organisational duties, the welfare services county could assess where pharmacies should be located within the region and how the outpatient pharmacological treatment process should be organised, taking pharmacies into account as well. The proposed changes could improve the success of patients’ treatment and the availability of medicines, provided that the welfare services county succeeds in integrating pharmacy services more effectively into the patient’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 would strengthen the continuous development of pharmacies’ operating practices and the enhancement of medication safety through monitoring pharmacies’ own operations and reporting and handling any identified deviations. The requirement to record and review near-miss incidents improves the potential to proactively strengthen practices that promote medication safety, thereby helping to prevent adverse treatment events affecting patients. This impact is partly related to how national data collection on

hazardous incidents and the associated information management develop. The proposed changes would strengthen local work. Currently, there is no designated authority responsible for collecting information on medication-related adverse events and providing national guidance to ensure medication safety.

The changes to the information management solution for the medicine agreement included in the proposal may help patients cope in situations where standard procedures for prescribing and dispensing medicines are not sufficient, for example due to a risk of misuse or for other reasons. Transferring the maintenance of the pharmacy agreement system from the Finnish Pharmacists' Association's server to the Kanta Services would make the use of agreement-related data more flexible. In addition to the transfer of maintenance, the amendment would also mean that the medicine agreement would in future be an agreement between the patient and a healthcare unit, and that the dispensing of agreement medicines would no longer necessarily be restricted to a single pharmacy. Both changes would improve the patient's situation. The changes would not alter the nature of the agreement, which would still be concluded by mutual consent between the parties. With the support enabled by the medicine agreement, patients' success in pharmacological treatment may improve and the risk of medication misuse may decrease, thereby potentially reducing costs and harms caused by medicines and creating better conditions for successful treatment.

Impacts on data protection

In connection with the sale of a limited range of over-the-counter medicines, a customer register will be created containing personal and medicinal product data that are sensitive in nature. Their handling involves special considerations.

This Government proposal concerns the processing of personal data related to pharmacy and medicine agreements in social and healthcare services and pharmacies, and it 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 impacts on the protection of personal data.

The Association of Finnish Pharmacies (hereinafter SAL) has operated the pharmacy agreement intermediary server and been responsible for related contract management, support, and access control procedures. The use of pharmacy agreements in patient care has required a separate personal data register, which has been maintained by the Association of Finnish Pharmacies on the basis of a separate agreement. The proposal provides that the maintenance of pharmacy agreements would be transferred in a single implementation from the Association of Finnish Pharmacies to the Prescription Centre of the Kanta Services operated by the Social Insurance Institution of Finland. The pharmacy agreements would be transferred in one go from SAL to the Prescription Centre on 1 October 2028, meaning that only one information system would be in use after the entry into force of the Act.

According to the proposed transitional provision, pharmacy agreements could be concluded until 30 September 2028. New agreements would be concluded as medicine agreements under the Prescription Act from 1 October 2028 onwards. Before the entry into force of this Act, the personal data related to pharmacy agreements maintained by SAL would be transferred, following the now proposed legislative amendment, to the Social Insurance Institution of Finland (Kela), to the Prescription Centre of the Kanta Services, on 1 October 2028. After the transfer of the data, Kela would act as the controller of personal data related to pharmacy agreements, as referred to in Section 18 of the Prescription Act. SAL's right to process personal data as a controller would cease once the data are transferred on 1 October 2028.

A healthcare service unit would be obliged to record the medicine agreement in the Prescription Centre as of 1 October 2028. The Kanta Medication List therefore centralises certain data on a person's outpatient pharmacological treatment in the national Prescription Centre. From a data protection perspective, the implementation of the Kanta Medication List already provided for in earlier legislation means that the data are automatically visible whenever a healthcare professional handles medication data, and that the patient's right to prohibit access to medication-related data results in a partial loss of control for the patient. The data are transferred through automated system queries, and data minimisation becomes more difficult to ensure. When disclosure prohibitions apply in future to a medication in use rather than to an individual prescription, the patient can no longer prevent a single prescription from being visible, but the effect of the prohibition extends to the entire continuum of that medication. The patient would need to understand the broader impact of their restrictions, as the system would provide less granular control than before. In addition, certain statutory information would always be displayed regardless of any restrictions.

The proposed amendment would mean that the number of persons entitled to view the data would increase compared with the current situation. A growing number of social and healthcare professionals would have

the right to process the same data, which could increase the complexity of access management and the risk that data are processed in situations where this is not necessary, as well as the number of personnel who may access sensitive information. The workload of access control and log monitoring could increase. This could pose a risk that an employee sees information they do not need for their care duties and that misuse may become harder to detect as usage volumes grow. Furthermore, supervision could become more complex. The appeal of the centralised data repository, and consequently the risk of misuse, may increase.

The rights of data subjects are set out in Articles 15–22 of the General Data Protection Regulation. Which rights a data subject may exercise at any given time depends on the legal basis under Article 6(1) and Article 9(1) of the General Data Protection Regulation on which the personal data is processed. If the legal basis for processing personal data is Article 6(1)(c) and Article 9(2)(h), data subjects have the following rights under the General Data Protection Regulation: the right to receive information about the processing of personal data (Articles 13–15), the right of access to data (Article 15), the right to rectification (Article 16), the right to restriction of processing (Article 18), and the right not to be subject to automated decision-making without a lawful basis (Article 22).

The Government proposal would not affect the rights of data subjects under the General Data Protection Regulation. However, the proposal would have an impact on the patient's right, as provided in the Prescription Act, to prohibit the inclusion of pharmacy and medicine agreement-related data.

The proposed provisions are assessed in relation to the principles of lawfulness, fairness and transparency; purpose limitation; data minimisation and accuracy; storage limitation; and integrity and confidentiality. These principles are already implemented in the current Client Data Act, and the proposal would not in itself affect them, although the proposed limitation of the patient's right to prohibit processing would affect the extent to which data can be disclosed under section 13 of the Prescription Act.

The processing of pharmacy and medicine agreement data would be based in pharmacies and social and healthcare services on Article 6(1)(c) of the General Data Protection Regulation (legal obligation of the controller) and Article 9(2)(h) (processing is necessary for the purposes of preventive or occupational medicine, medical diagnosis, the provision of health or social care or treatment, or the management of health or social care systems and services on the basis of Member State law). In addition to the mentioned criteria, processing at the pharmacy for the dispensing of medicines is based on a request from the patient or a person acting on their behalf, in accordance with section 11(1) of the Prescription Act.

Article 9(3) of the General Data Protection Regulation requires that processing for the purposes set out in point (h) be carried out by a professional who is subject to a statutory duty of confidentiality under the law of a Member State. Section 17 of the Act on Health Care Professionals (559/1994) prescribes the confidentiality obligations of healthcare professionals. Section 90 of the Medicines Act lays down the confidentiality obligations of the pharmacist and their assistant. With regard to the processing of client data, pharmacies are subject to the principles governing the processing of customer data set out in Chapter 2 of the Client Data Act. Therefore, pharmacies must comply with the obligation of confidentiality under section 4 and the duties of nondisclosure and prohibition of improper use under section 5 of the Client Data Act. The confidentiality obligation of social welfare professionals is stipulated in section 15 of the Act on the Status and Rights of Social Welfare Clients (812/2000).

The appropriateness and proportionality of processing personal data in relation to its purpose is ensured by limiting the right of social and health care professionals and others who handle client records to access only the client data necessary for performing statutory duties. Defining access rights under the Client Data Act and the Client Data Decree according to statutory duties protects the legitimate expectations of data subjects regarding the processing of personal data in social and health care.

The principle of transparency requires that information about the processing of personal data is provided to the data subject clearly and understandably. The Prescription Act refers, regarding information on national information system services, to section 68 of the Client Data Act, which requires the service provider to inform the client of their rights and about the national information system services related to their client data, as well as the general principles of operation of these services.

The principle of purpose limitation requires that the purposes of processing personal data are defined in advance and that personal data are collected only for specific, explicit, and lawful purposes. Healthcare client data is processed in accordance with the applicable Client Data Act and the Prescription Act to fulfil statutory duties. An additional requirement for disclosing data from the national medication list is the statutory right of prohibition under the Prescription Act. A new exception to the patient's right of prohibition 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 client data is restricted both by defining access rights and by verifying the context or the care relationship.

The personal data processed must be accurate for the intended purpose and updated as necessary. According to the Client Data Act, the integrity, immutability, and non-repudiation of documents must be ensured in the processing, transfer, and storage of client data.

Personal data must be retained only for as long as it is necessary for the purposes for which the personal data are processed. Retention periods for client documents are laid down in the annex to the Act on Electrical Processing of Client Data in Social and Healthcare (hereinafter 'Client Data Act').

The principle of integrity and confidentiality requires that, when processing personal data, appropriate security is ensured, including protection against unauthorised and unlawful processing, as well as accidental loss, destruction or damage, by means of suitable technical or organisational measures. The technical and organisational measures already in force under the Client Data Act prevent abuse and unlawful access to customer and patient data. The service provider or any other controller processing client data must maintain a register of the users of its information systems and customer registers used in the processing of client data, as well as their access rights. Under the current Client Data Act, persons processing client data, service providers, IT devices, and national information system services must be reliably identified in the electronic processing of client data. The Client Data Act lays down provisions on the audit logs collected on the use and disclosure of client data and on the supervision of those logs. The collection of usage and disclosure log data and log monitoring ensure that the data subject or another person carrying out log monitoring can afterwards verify who has accessed their data and address any potential misuse. The Act already contains provisions on requirements concerning social and healthcare information systems, which also apply to the national information system services provided by Kela. The Act includes provisions on information security plans, the implementation of self-monitoring of information security, the registration of social and healthcare information systems, post-deployment monitoring of information systems, and essential requirements for information systems, including demonstrating compliance and certification of information systems as well as information security assessment. In addition, the Act contains provisions on the supervision and inspection of social and healthcare information systems.

This proposal seeks to limit the patient's right to prohibit under section 13 of the Prescription Act. If a patient could exercise their right to prohibit in relation to a pharmacy and medicine agreement, this would in practice lead to a situation comparable to the agreement lapsing, as the agreement details would no longer be available to other prescribers or the dispensing pharmacy. This restriction in national law aims to prevent the pharmacy and medicine agreement between the patient and the healthcare service unit from being rendered void. The restriction concerns the limited use of data; specifically, information from the pharmacy and medicine agreement when prescribing or dispensing prescription-only and narcotic medicines.

For pharmacies, the visibility of information on prescription-only and narcotic medicines would correspond to the scope of the right to access information held by those prescribing such medicines. The proposed restriction on the patient's right to prohibit access in pharmacies would be justified because, when dispensing medicines, it is necessary to know about other prescription-only and narcotic medicines due to the risk of harmful interactions.

1.2.8 Impact on the authorities

The proposed changes would not increase the workload of the authorities or require an immediate increase in resources. However, implementation of the changes may initially require concentrating resources on tasks such as updating guidelines and regulations. Fimea should also provide guidance and advice to pharmacy and dose dispensing operators regarding the proposed legislative amendment. It would also be appropriate for the Finnish Supervisory Agency to inform operators about proposals falling within its remit.

In the longer term, the proposals as a whole would clarify and streamline authorities' operations and increase their predictability. For example, key aspects related to automated dose dispensing have previously been based on regulations or guidelines, which has led to interpretative challenges. The law does not recognise dose dispensing as the type of activity it has become, which has been attempted to be controlled through regulations and guidelines, resulting in a practically challenging legal situation. With clearer regulation, the supervision of operators and consequently their activities would also become more consistent, as the regulation would more clearly define, for example, the expectations and quality requirements set for the activity.

The proposed changes would also clarify the authority's powers and its ability to steer the pharmacy service network, such as by making the designation and conversion of branch pharmacies a condition of the pharmacy licence. However, in the initial phase after the Act enters into force, there may be applications to convert branch pharmacies, which could temporarily increase Fimea's workload.

The proposed changes would require updates to several of Fimea's regulations, such as those concerning online pharmacy services, the supply of medicines, and product defects. In the future, it may be appropriate to support the implementation of certain matters through authority guidelines rather than through regulations. The proposed amendments would allow for new regulatory powers, such as in relation to automated dispensing. This will temporarily increase the demand for resources in public administration but may streamline the work of the authorities in the longer term.

The proposal sets out a consolidation of pharmacies' responsibilities and clarifications regarding the organisation of their operations, aiming to create a safe, high-quality, effective, and cost-efficient system for medicine users, the social welfare and healthcare sector, and society as a whole, and identifies development needs related to the supervision and information governance of pharmacies. Development should be carried out in a controlled and long-term manner. As part of this development, it may be necessary for the Finnish Medicines Agency (Fimea) to issue guidance, for example on quality-related indicators and criteria for pharmacy operations, as information on service quality is currently insufficient. Fimea may also need to provide guidance on cooperation between pharmacies and social and healthcare services.

Development is also linked to Fimea's statutory task of providing the Ministry of Social Affairs and Health with the necessary information for assessing pharmacy funding (the medicine tariff). Fimea already has ongoing development projects related to the collection of financial data submitted by pharmacies and other information related to pharmacy operations, which support the implementation of the proposed changes.

In assessing the impacts on public authorities, it should be noted that Fimea's statutory task is to develop the functioning and safety of the pharmaceutical sector, pharmacy operations, and other pharmaceutical services, and the proposed changes in this submission would only clarify Fimea's tasks with regard to pharmacy operations.

The proposed changes may increase the need for cooperation between Fimea and the Finnish Supervisory Agency in supervision and, for example, in coordinating informational guidance provided via websites. Where pharmacies provide services other than those carried out on the basis of a pharmacy licence, registration in the Soteri register would be required. Cooperation in online pharmacy services would also allow certain tasks related to the dispensing of medicines to be carried out in collaboration with an operator registered in the Soteri register. Supervision of such cooperation would be carried out jointly by two different authorities, with the Finnish Medicines Agency (Fimea) supervising the pharmacy and the Finnish Supervisory Agency supervising the Soteri-registered company. The primary responsibility for the online service would remain with the pharmacy, and under the proposal Fimea would have the possibility to prohibit cooperation if it were contrary to regulation. A similar division of supervisory responsibilities is already in place, as Fimea supervises pharmacy operations and the Finnish Supervisory Agency supervises pharmaceutical personnel working in pharmacies.

1.2.9 Impacts on employment

The proposed measures may have some employment-related impacts. The proposed regulation of cooperation in online pharmacy services could increase demand for work related to medication guidance and counselling services, and expand the operations of companies providing such services, as certain stages of medicine dispensing could be carried out in cooperation with another company. Digital solutions related to online services may also increase compared with the current situation, affecting companies providing such solutions. However, the increased use of digital solutions may in some pharmacies lead to improved efficiency compared with the current situation and a reduction in staffing levels, or changes in the organisation of staff work. It is also possible that investment in online services could result in an increase in staffing in pharmacies. The wider use of online services could also lead to more diverse job roles in the pharmacy sector.

In pharmacies that do not develop their online services, sales may decline if their customer base shifts to purchasing medicines and other pharmacy products from another pharmacy. This could result in a need to reduce staff in pharmacies where medicine sales decrease from the current level. It is also possible that cooperation in online services would to some extent change the operations of cooperating pharmacies compared with the current situation, with a greater focus on medicine logistics if counselling related to dispensing is provided in cooperation. This may have a negative impact on staff retention and attractiveness.

It would not be possible to assess in advance which pharmacies would benefit from or suffer due to the growth of the use of online services, and pharmacies themselves would have the opportunity to influence the change through their own operations.

1.2.10 Impacts on municipalities and wellbeing services counties, regional development and rural impacts

The proposed changes would affect the operations of municipalities and wellbeing services counties. The responsibility for assessing the functionality, location and adequacy of pharmacy services would be transferred from municipalities to the authority responsible for organising social and healthcare services. However, it may be appropriate for the wellbeing services county to consult the relevant municipality in its assessment. The proposed change would help ensure the compatibility and interoperability of pharmacy services with other social and healthcare services and would improve the wellbeing services county's ability to influence pharmacy services in its area. The change may also strengthen cooperation between wellbeing services counties and pharmacies. Such cooperation may streamline processes and, for example, support the planning of service networks.

The change may reduce municipalities' ability to influence pharmacy services in their area. However, it should be noted that there should be structures in place for cooperation between municipalities and wellbeing services counties in the region, and that the wellbeing services county would still be able to consult the municipality in its assessment. Municipalities continue to have responsibilities related to the promotion of health and wellbeing, as well as local expertise, which may also be useful in assessing pharmacy services for the population within the wellbeing services county. It should also be noted that decisions on pharmacy licences and location areas would remain the responsibility of Fimea.

The proposed changes may have an impact on rural areas. Changes related to branch pharmacy regulation may improve the conditions for maintaining branch pharmacies and thereby enhance the availability of medicines in rural areas. Changes concerning cooperation in online services may impact pharmacies operating in rural areas in such a way that, by participating in cooperation, they may increase medicine sales compared with the current situation for those rural customers who would otherwise order their medicines online, but for whom the nearest pharmacy has not offered an online service. On the other hand, if the use of online services becomes more widespread than at present, it is also possible that the financial position of a rural pharmacy may weaken if its customers shift to purchasing medicines through another pharmacy's online service. Such a decline would be more likely in situations where rural pharmacies are unable to develop their business operations and cooperation with other pharmacies or with the regional wellbeing services county.

1.2.11 Impact on information management

The proposal has impacts on information management at the Finnish Medicines Agency (Fimea) and in Kela's Kanta Services. The assessment of changes in authorities' information management has been carried out in accordance with the Ministry of Finance's recommendation on assessing changes in information management (VM 2024:21). Information management impacts have been assessed for the following proposed changes: enabling cooperation in online pharmacy services; transfer of pharmacy and medicine agreement data management into the Kanta Services; changes in Fimea's licensing and supervisory information management related to the online service for a restricted selection of over-the-counter medicines and automated dose dispensing; and changes to Fimea's data access rights concerning automated dose dispensing. The changes described above would affect the data content of the Kanta Services Prescription Centre, system architecture, and information flows, as well as the registers maintained by Fimea.

Enabling cooperation in online pharmacy services

Enabling cooperation in online pharmacy services would require new information in the Prescription Centre regarding the dispensing of medicines to customers. In addition to a new data field, the change would require that entries related to medicine dispensing in the Prescription Centre be recorded at different times and by different organisations and individuals. This would enable process monitoring and traceability in situations where a medicine user's pharmacy transaction involves cooperation made possible by the amendment to the Medicines Act. If the dispensing of a medicine is split into two parts, the pharmacy where the customer initiates the transaction would, under the proposed amendment, have overall responsibility for the dispensing process. This would mean that the pharmacy would also act as the controller for all records related to dispensing and delivery. Similarly, the operator with whom the pharmacy cooperates under a contractual arrangement would act as a processor of personal data. Any entity processing data related to the supply of medicines should have information systems in place that comply with the Medicines Act, the Act on the Supervision of Healthcare and Social Welfare Services.

The proposed amendment would expand the Prescription Centre's data set, improving the coverage of medicine supply data at local and regional levels. The new data field may enable, for example, the creation of an indicator on the security of medicine supply from the Prescription Centre's data set.

Pharmacy and medicine agreement

Under the proposed changes, responsibility for maintaining pharmacy agreements would be transferred from the Association of Finnish Pharmacies to the Social Insurance Institution of Finland, to be managed within the national data management service of the Kanta services at the Prescription Centre.

Under section 18 of the Prescription Act, the Prescription Centre is a joint register maintained by the Social Insurance Institution of Finland, pharmacies, service providers issuing electronic prescriptions, and independent prescribers. The responsibilities of the data controllers would also be divided with regard to the information in pharmacy and pharmaceutical contracts in the same way as stipulated in section 18.

The Social Insurance Institution of Finland is responsible for the availability and integrity of the data held in the Prescription Centre, ensuring the data remains unaltered, and for the storage and disposal of the data. The Association of Finnish Pharmacies' responsibility as data controller for maintaining personal data in pharmacy agreements, along with other processing rights, will cease when the data is transferred on 1 October 2028. Pharmacy agreements will be removed from the SAL server according to specific operational procedures once SAL's storage responsibility has ended.

The operating model for the pharmaceutical contract would differ from that of the pharmacy contract. Instead of the prescriber, the party to the contract would be the healthcare service unit with which the patient has a treatment relationship. The healthcare service unit would be responsible for the content of the agreement. The healthcare service unit would have an obligation to record the medicine agreement in the Prescription Centre through a new agreement service (user interface) in accordance with section 12c of the Prescription Act. The new agreement service would be intended solely for the management of agreements and for use only within healthcare. The healthcare service unit would act as a joint controller together with Kela in accordance with section 18 of the Prescription Act, and therefore the unit would be responsible for the accuracy of the data entered into the medicine agreements.

The medicine agreement would guide the dispensing of medicines in pharmacies. The medicine user could use any pharmacy, unless the agreement specifies that dispensing is centralised to one or a few pharmacies. The dispensing pharmacy would be responsible for the accuracy of the dispensing data recorded in the Prescription Centre, including data related to medicine and pharmacy agreements.

The operating model established under the legislation would take into account situations where a customer arrives at a pharmacy with an old pharmacy agreement under the Medicines Act after 1 October 2028, in which case the pharmacy would contact the healthcare unit and instruct them to draw up a new agreement. Pharmacy agreements would remain valid until 30 September 2030, meaning they would remain in force for two years after the entry into force of the Act, unless a new medicine agreement had been concluded. During the two-year transitional period, all agreement patients should, in principle, have some form of healthcare contact with a healthcare service unit, where the agreement data would be updated to be up to date.

The operating model established under the legislation would also take into account situations in which a patient still had a pharmacy agreement, but the prescriber did not see a need to conclude a new medicine agreement and did not have the right to terminate the pharmacy agreement, as it had been concluded with another physician. However, unrevoked pharmacy agreements would expire no later than 30 September 2030 under the proposed amendment to the Prescription Act.

The interoperability of information systems and the utilisation of data in relation to pharmaceutical and pharmacy agreements would comply with the applicable legislation (e.g. the Client Data Act and the Prescription Act). The Prescription Centre and pharmacy systems would become active simultaneously on 1 October 2028. The intention is that, when the Act enters into force, a national contract service interface (web interface) would be available, allowing healthcare providers to manage contracts (create new medicinal product agreements and terminate pharmacy agreements). Provisions on the new agreement service maintained by the Social Insurance Institution of Finland for the management of medicine agreements would be laid down in the Client Data Act.

Fimea's registers and the right to information

As a result of these changes, the sale of certain over-the-counter medicines would also be permitted outside pharmacies, including through online services. Operators must notify Fimea before commencing the sale of over-the-counter medicines via the online service. Fimea maintains a register of sales locations for a limited range of non-prescription medicines. Adding information via the online service would constitute a change to the register maintained by Fimea.

Under the proposed changes, a new register of holders of licences for automated dose dispensing would be established at Fimea. As part of licensing supervision, Fimea would collect new data on operators providing automated dose dispensing services. Key information would include the name of the company providing automated dose dispensing, contact details, and details of the responsible person. As a result of the proposals, Fimea's right to obtain information would also be extended to cover holders of licences for automated dose dispensing, who would be required, notwithstanding confidentiality provisions and free of charge, to provide Fimea with the information necessary for the performance of its duties. Fimea would be the controller of the data sets formed from the above-mentioned information. The collected data would be used by Fimea for the supervision of automated dose dispensing, the processing of licences, and other tasks under the Medicines Act and the Act on the Finnish Medicines Agency and the Development Centre for Pharmaceuticals.

The new licensing register would contain personal data that would be retained permanently. The rights of data subjects would comply with the rights laid down in the General Data Protection Regulation. The amendment would not affect the publicity or confidentiality of documents. The data in the register would be processed confidentially. Fimea has a statutory duty of confidentiality under the Act on the Openness of Government Activities (621/1999) and the Act on the Finnish Medicines Agency and the Development Centre for Pharmaceuticals. The register would compile data based on electronic transactions. The data would be protected through management of access rights, technical safeguards for databases and servers, physical security of premises, access control, communication security, and data backup. The right of access to and processing of data would be role-based. Fimea is also obliged to maintain statistics related to its field, publish key figures, and produce assessments. The information in the register could be used and published as part of these official duties.

Work on establishing a new licensing system, register, or supervisory framework has not yet begun, so details concerning data management and register changes will be clarified during the implementation of the Act. However, Fimea already has several similar operator registers. In terms of operators, this would constitute a new data set, which could be implemented either by establishing a new register or by expanding an existing operator register. In addition, the proposed change would also have impacts on other Fimea registers, such as wholesale distribution registers, as well as reporting carried out, for example, on the distribution of sales by operator and region, sales development, and market shares.