Government proposal to Parliament for an Act amending the Act on Mandatory Reserve Supplies of Medicines

MAIN CONTENT OF THE PROPOSAL

The Government proposal would amend the Act on Mandatory Reserve Supplies of Medicines to effectively safeguard the availability and security of supply of medicines through the mandatory reserve supplies of medicines would effectively safeguard also in the future. The aim of the proposal is a flexible, balanced and up-to-date reserve supply system.

The proposal includes updating the therapeutic classes subject to the reserve supply obligation. Under the proposal, the Finnish Medicines Agency (Fimea) could, upon application, grant permission to maintain reserve supplies below the required level in situations where the consumption of a product subject to the reserve supply obligation has decreased very significantly in relation to the entity subject to the obligation. The proposal also seeks to expand the right of entities subject to the reserve supply obligation to reduce their mandatory reserve supplies on their own initiative.

The Act is intended to enter into force on 1 January 2027.

In connection with the entry into force of the Act, the Government Decree on Mandatory Reserve Supplies of Medicines is also intended to be updated.

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EXPLANATORY NOTE

1 Background and preparatory work

1.1 Background

According to the Government Programme of Prime Minister Petteri Orpo, the legislation on mandatory reserve supplies of medicines will be reformed. The Government Programme further states that the Act on Mandatory Reserve Supplies of Medicines will be revised and that the necessary additional measures will be taken to safeguard the availability of medicines and security of supply.

The Government Programme also includes a commitment to reduce medicinal waste and pharmaceutical waste. This commitment has been taken into account in the preparation of the Government proposal.

1.2 Preparatory work

The Government Proposal was prepared by the Ministry of Social Affairs and Health as official work. For the preparation of the proposal, an internal working group was established within the Ministry. The group's first meeting was held in December 2024.

On 14 April 2025, the Ministry of Social Affairs and Health organised a stakeholder consultation on the reform of the Act on Mandatory Reserve Supplies of Medicines. Representatives of pharmaceutical industry organisations and companies, wellbeing services counties, pharmacies, social and healthcare organisations, and public authorities were invited to participate. Following the consultation, certain stakeholders also submitted written statements.

Between November and December 2025, 15 consultation sessions were organised to hear clinical experts in medicine, focusing in particular on the need to revise the list of medicinal substances subject to mandatory reserve supplies. The consultation sessions were organised by therapeutic class. Some stakeholders also submitted written statements in connection with these consultations.

On 12 March 2026, the Ministry of Social Affairs and Health organised a stakeholder consultation focusing in particular on medicinal substances subject to mandatory reserve supplies, pharmaceutical procurement procedures, and the compensation payable to entities subject to the mandatory reserve supplies, as well as the related compensation procedure. The same stakeholder groups as those invited to the consultation held on 14 April 2025 were invited to participate.

During the preparation of the proposal, certain stakeholders also submitted proposals and comments on their own initiative outside the consultation processes referred to above. In addition, the Ministry of Social Affairs and Health requested information from various public authorities to support the preparation of the proposal. The preparation also drew on reports prepared by the Finnish Medicines Agency (Fimea) in 2023 and 2024 (FIMEA/2023/005784 and FIMEA/2024/003994).

2 Current situation and assessment

2.1 Legislation and practice

2.1.1 Mandatory reserve supplies of medicines

Mandatory reserve supplies of medicines are primarily governed by the Act on Mandatory Reserve Supplies of Medicines (979/2008) (hereinafter the *Act on Mandatory Reserve Supplies*) and the Government Decree on Mandatory Reserve Supplies of Medicines (1114/2008) (hereinafter the *Decree on Mandatory Reserve Supplies*).

According to section 1 of the Act on Mandatory Reserve Supplies, the purpose of the act is to ensure, by means of mandatory reserve supplies, the availability of and possibility to use medicines in situations in which the normal availability of medicines is more difficult or has been hindered. According to section 2 of the Act on Mandatory Reserve Supplies of Medicines, the Act applies to pharmaceutical manufacturers, importers of medicinal products, health institutions and the Finnish Institute for Health and Welfare, which are required to maintain reserve supplies of medicinal substances and medicinal products, as well as excipients, additives and packaging materials used in the manufacture of medicinal products, as provided in the Act or pursuant to it.

Section 3 of the Act on Mandatory Reserve Supplies of Medicines provides for definitions. Under that section, a *health institution* means a health centre, hospital or separate healthcare unit maintained by a municipality, joint municipal authority or the Åland regional authority; an institution referred to in the Act on Special Care for Persons with Intellectual Disabilities (519/1977); a state mental hospital; or a private healthcare service provider that provides hospital services to a municipality, joint municipal authority or the Åland regional authority.

Section 4 of the Act on Mandatory Reserve Supplies of Medicines lays down provisions on reserve supply arrangements and on the medicinal substances and medicinal products covered by the Act. The section specifies the therapeutic classes whose medicinal substances and medicinal products are subject to the stockpiling obligation. More detailed provisions on the medicinal substances included in those therapeutic classes that are subject to the stockpiling obligation are laid down by Government Decree. The detailed list of medicinal substances is set out in section 1 of the Government Decree on Mandatory Reserve Supplies of Medicines. Every two years, the Finnish Medicines Agency (Fimea) must submit to the Ministry of Social Affairs and Health a report on the need to revise the list of medicinal substances set out in the Government Decree.

Where necessary, the Finnish Medicines Agency shall determine, by product designation, which medicinal products contain the medicinal substances specified in the Government Decree and in which those medicinal substances are of primary therapeutic significance. The Finnish Medicines Agency (Fimea) may also decide, for individual medicinal substances and medicinal products, that the stockpiling obligation does not apply to all pharmaceutical forms.

On 6 May 2025, the Finnish Medicines Agency confirmed an updated list of medicinal products subject to the stockpiling obligation. The list comprises a total of 1 350 medicinal products.

Pursuant to section 4a of the Act on Mandatory Reserve Supplies of Medicines, the mandatory reserve supplies referred to in the Act must be located either at premises in Finland operated by the entity subject to the stockpiling obligation or at premises in Finland operated by a contract distributor that has concluded a distribution and storage agreement with that entity.

Sections 5–8 of the Act on Mandatory Reserve Supplies of Medicines lay down the stockpiling obligations applicable to entities subject to the stockpiling obligation. Among other things, those sections provide for the calculation of the average consumption on which the quantity of the stockpiling obligation is based.

Section 9 of the Act on Mandatory Reserve Supplies of Medicines lays down provisions on the duration of the stockpiling obligation. The stockpiling obligation determined on the basis of the sales or consumption during the preceding year, in accordance with sections 5–8, remains in force for one calendar year.

Section 10 of the Act on Mandatory Reserve Supplies of Medicines contains provisions on the fulfilment of the stockpiling obligation in special cases. For special reasons, the Finnish Medicines Agency (Fimea) may, upon application, decide that an entity subject to the stockpiling obligation may fulfil that obligation, in whole or in part, by undertaking to ensure an equivalent level of security of supply by other means. More detailed provisions on the conditions and requirements for substituting the stockpiling obligation may be laid down by Government Decree. Such provisions are set out in section 2 of the Government Decree on Mandatory Reserve Supplies of Medicines. In addition, the Finnish Medicines Agency has issued guidance on the application procedure (Fimea Guideline 2/2017; Fimea 004690/00.01.02/2016).

In 2025, the Finnish Medicines Agency (Fimea) issued six decisions concerning the fulfilment of the stockpiling obligation in special cases, all of which related to medicinal products for human use. Each of those decisions concerned either an importer or a pharmaceutical manufacturer.

Exemptions from the stockpiling obligation are governed by section 11 of the Act on Mandatory Reserve Supplies of Medicines, under which the Finnish Medicines Agency (Fimea) may, upon application, exempt an entity subject to the stockpiling obligation, in whole or in part, from that obligation, provided that the exemption does not compromise the security of supply of medicines. An exemption may be granted only if, in addition, compliance with the stockpiling obligation would cause the entity subject to the stockpiling obligation particular difficulties or if maintaining the reserve supplies is manifestly unnecessary. More detailed provisions on the grounds on which an entity subject to the stockpiling obligation may be exempted from that obligation may be laid down by Government Decree. Such provisions are set out in section 3 of the Government Decree on Mandatory Reserve Supplies of Medicines.

The Finnish Medicines Agency may issue more detailed regulations concerning the information to be provided and the application procedure for obtaining an exemption from the stockpiling obligation. The Finnish Medicines Agency has issued more detailed regulations on this matter (Fimea Regulation 1/2017; Fimea 004690/00.01.02/2016).

In 2025, the Finnish Medicines Agency issued 31 exemption decisions, all of which related to medicinal products for human use. Of those decisions, 22 concerned importers or

pharmaceutical manufacturers, while the remainder concerned operators responsible for health institutions. Twenty-seven exemption decisions were based on the finding that maintaining reserve supplies was manifestly unnecessary. In practice, these applications concerned a change of importer, whereby the stockpiling obligation was transferred directly from one undertaking to another. Four decisions were based on the limited extent of the stockpiling obligation.

Section 12 of the Act on Mandatory Reserve Supplies of Medicines provides for compensation payable to entities subject to the stockpiling obligation. Compensation for maintaining mandatory reserve supplies shall be paid to a pharmaceutical manufacturer, an importer of medicinal products or the person on whose behalf the importer's mandatory reserve supplies are maintained. The amount of the compensation is calculated by applying the reference rate of the Bank of Finland referred to in section 12 of the Interest Act (633/1982), increased by two percentage points, to the capital tied up in the acquisition of the goods held in the mandatory reserve supplies. The compensation payable for maintaining the solutions referred to in section 4(1), point 2, is two percentage points higher than the compensation payable for maintaining other medicinal products.

Section 13 of the Act on Mandatory Reserve Supplies of Medicines lays down provisions on the payment of compensation. Compensation for maintaining mandatory reserve supplies is paid annually in arrears on the basis of a written application submitted to the National Emergency Supply Agency. The compensation is paid from the National Emergency Supply Fund. Further provisions on the matter are laid down in section 4 of the Government Decree on Mandatory Reserve Supplies of Medicines.

In recent years, the National Emergency Supply Agency has paid compensation to entities subject to the stockpiling obligation as follows: approximately EUR 2.0 million in 2021; approximately EUR 2.0 million in 2022; approximately EUR 1.7 million in 2023; approximately EUR 4.4 million in 2024; and approximately EUR 5.4 million in 2025. Between 2023 and 2025, between 43 and 46 compensation payments were made each year.

The Supreme Administrative Court has issued judgment KHO:2018:22 concerning compensation. The National Emergency Supply Agency had rejected an application for compensation for mandatory reserve supplies of medicinal products on the grounds that the stockpiling obligation had not been fulfilled due to unauthorised reductions below the required levels of mandatory reserve supplies for certain medicinal products. On average, those shortfalls had been significant. Following an appeal by the applicants, the Administrative Court annulled the decision of the National Emergency Supply Agency as lacking a legal basis and referred the matter back to the Agency for reconsideration. The Supreme Administrative Court found that, although the shortfalls in the stockpiling obligation had been significant in respect of certain medicinal products subject to the obligation, they had been less substantial in respect of certain other medicinal products, and, in the case of some medicinal products, no shortfall had occurred at all. The Supreme Administrative Court held that the National Emergency Supply Agency could not reject the application in its entirety. Instead, entitlement to compensation for maintaining mandatory reserve supplies, based on compliance with the stockpiling obligation, had to be assessed separately for each medicinal product. The Supreme Administrative Court upheld the operative part of the Administrative Court's judgment.

Section 15 of the Act on Mandatory Reserve Supplies of Medicines lays down provisions on maintaining reserve supplies below the required level. The reserve supplies of any product subject to the stockpiling obligation may not fall below the level required under the Act. However, the mandatory reserve supplies of a health institution referred to in section 7 may fall below the required level where the use of those reserve supplies is necessary for the operation of the healthcare unit owing to a supply disruption. Immediately after the end of the supply disruption, the health institution shall fill the reserve to meet the obligation level.

Upon application, the Finnish Medicines Agency may grant a party subject to the stockpiling obligation authorisation to reduce mandatory reserve supplies below the level required under this Act if a product held as mandatory reserve supplies, or another product subject to the stockpiling obligation, is at risk of becoming unsuitable for its intended use during its storage period. The Finnish Medicines Agency may also grant authorisation to reduce mandatory reserve supplies below the required level if, due to a temporary supply disruption affecting a product subject to the stockpiling obligation, the production or operations of the party subject to the stockpiling obligation are at risk of being interrupted or substantially reduced without recourse to the mandatory reserve supplies, provided that granting such authorisation does not jeopardise security of supply. When granting permission to maintain reserve supplies below the required level, the Finnish Medicines Agency shall determine the extent of the permitted shortfall and the period within which the entity subject to the stockpiling obligation must replenish its reserve supplies to the level required under the Act.

In addition, the Finnish Medicines Agency has issued more detailed regulations on the matter (Fimea Regulation 1/2017; Fimea 004690/00.01.02/2016).

In 2025, the Finnish Medicines Agency (Fimea) granted a total of 406 permits to maintain reserve supplies below the required level, of which 387 concerned medicinal products for human use and the remainder veterinary medicinal products. Almost all of those permits (404) were granted to importers or pharmaceutical manufacturers. Of the permits granted, 404 were issued due to a temporary shortage, while two permits were granted solely for reasons relating to shelf life. In some cases, the permit was based on a combination of factors, namely reserve supplies due to expire during the reserve supply year together with a simultaneous ahortage, as a result of which batches with a longer remaining shelf life were not available in Finland. In addition to the permits granted, the Finnish Medicines Agency (Fimea) rejected six applications in 2025 because they had been submitted retrospectively.

Where an availability disruption is prolonged, operators may apply for an extension of the permit by submitting a new application requesting a longer period and/or a greater permitted shortfall. The number of such extension applications exceeded 60 in 2025.

During the period 2021–2025, most permits were granted for shortfalls of between 21% and 50%, with the exception of 2024, when the majority of permits concerned shortfalls of between 81% and 100%. During the same period, most permits were granted for shortfalls lasting less than three months.

Section 16 of the Act on Mandatory Reserve Supplies of Medicines lays down provisions on the use of mandatory reserve supplies in exceptional situations. Under that section, where there are widespread shortages of medicinal substances, medicinal products, excipients or additives used in the manufacture of medicinal products, or packaging materials, which are beyond the control of pharmaceutical manufacturers or importers, or where there is a likely

threat of such problems, the Ministry of Social Affairs and Health may, in order to safeguard security of supply and on a proposal from the Finnish Medicines Agency, decide that the quantity of products subject to the stockpiling obligation may be reduced below the level required under the Act. The Ministry decision may prescribe the applications and amounts of the goods subject to the obligation. The decision shall indicate a date by which the size of the mandatory reserve shall again comply with this Act.

In 2025, the Ministry of Social Affairs and Health adopted a total of three decisions under the powers conferred by that section. All three decisions concerned the same medicinal products.

2.1.2 Other systems for maintaining reserves of medicines

The security of supply of medicines may also be safeguarded through reserve systems other than the mandatory reserve supply system. Such national reserve systems include, for example, government reserve stocks and safety stocks. In addition, reserve systems also exist at the EU level, such as stockpiling under the rescEU framework.

Government reserve stocks are governed by the Act on the National Emergency Supply Agency and the Measures Necessary to Secure Security of Supply (107/2026) (hereinafter the Act on Security of Supply). Pursuant to the first sentence of section 10(1) of the Act on Security of Supply, government reserve stocks shall be maintained for materials that are essential for the livelihood and protection of the population, the functioning of the economy, production supporting national defence and security, and the fulfilment of Finland's international obligations relating to security of supply.

According to the detailed explanatory notes for the Government proposal relating to that provision, government reserve stocks are intended to ensure preparedness for serious disruptions under normal conditions and for emergency conditions. They are intended to be used only where no commercial stocks, safety stocks or mandatory reserve supplies of the material concerned are available. Accordingly, government reserve stocks are intended to constitute a measure of last resort in relation to the other available means of safeguarding the availability of a particular material.

Pursuant to section 12(1) of the Act on Security of Supply, notwithstanding section 11, the Ministry of Social Affairs and Health shall decide on the release and distribution of medicines, medical devices, personal protective equipment and other goods used in social welfare and healthcare that are held in government reserve stocks. Medicines, medical devices, personal protective equipment and other goods used in social welfare and healthcare that are held in government reserve stocks may be released where: 1) their release is necessary to ensure appropriate treatment and care of the population or the prevention of disease, and there are insufficient commercial stocks, mandatory reserve supplies or safety stocks of the goods concerned in Finland; 2) the conditions for their release under section 73 of the Act on Communicable Diseases (1227/2016) are met; 3) or they are used for the provision of international assistance to another State, the European Union or an international organisation, or for cooperation with another State, the European Union or an international organisation outside the territory of Finland, and their release is not required on the basis of point 1 or 2.

Pursuant to subsection 2 of that section, the decision of the Ministry of Social Affairs and Health on the release and distribution of the goods referred to in subsection 1 may include

provisions concerning their distribution, intended use, quantities, charges and other matters relating to their distribution.

Safety stocks are governed by the Act on Security Stockpiling (970/1982). Pursuant to section 1(1) of the Act on Security Stockpiling, safety stocks may be established and maintained for the purpose of storing raw materials, supplies and products that are essential for securing the livelihood of the population and maintaining production activities in the event of disruptions to foreign trade, as provided in the Act. Pursuant to section 2 of the Act on Security Stockpiling, a safety stock means a stock of goods maintained by an undertaking maintaining such stocks (a *safety stock holder*) on the basis of an agreement, in addition to the stocks required for its normal business operations.

Pursuant to section 8(5) of the Act on Security Stockpiling, where an authorisation for the use of a safety stock concerns a safety stock of medicines or medicinal substances, the authority granting the authorisation must consult the Ministry of Social Affairs and Health and the Finnish Medicines Agency before granting the authorisation.

The stockpiling arrangements under rescEU are governed, in part, by Decision No 1313/2013/EU of the European Parliament and of the Council on a Union Civil Protection Mechanism. Pursuant to Article 12(1), first subparagraph, of that Decision, rescEU is established to provide assistance in overwhelming situations where the overall existing capacities at national level and the capacities pre-committed by Member States to the European Civil Protection Pool are insufficient to ensure an effective response to the different types of natural and man-made disasters referred to in Article 1(2).

Finland maintains two rescEU reserves: a CBRN reserve, intended to ensure preparedness for threats and incidents involving chemical (C), biological (B), radiological (R) and nuclear (N) agents; and a Medical/CBRN reserve, intended to ensure preparedness for cross-border health threats and for emergency and crisis situations. Finland's rescEU reserves are intended for use by EU Member States and countries participating in the Union Civil Protection Mechanism where the requesting country's own resources are insufficient to respond to the emergency or crisis situation.

2.2 EU law

Public health largely falls within the competence of the Member States of the European Union. However, pursuant to Article 4(2)(k) of the Treaty on the Functioning of the European Union (*TFEU*), shared competence between the Union and the Member States applies, inter alia, to common safety concerns in public health matters, for the aspects defined in the Treaty. Furthermore, pursuant to Article 6(a) TFEU, the Union has competence to carry out actions to support, coordinate or supplement the actions of the Member States. Those actions relate, at European level, to the protection and improvement of human health. In addition, public health is governed by Article 168 TFEU.

The internal market, in turn, falls within the shared competence of the Union and the Member States pursuant to Article 4(2)(a) TFEU. Under Article 35 TFEU, quantitative restrictions on exports and all measures having equivalent effect shall be prohibited between Member States. However, pursuant to Article 36 TFEU, the provisions of Articles 34 and 35 do not preclude prohibitions or restrictions on imports, exports or goods in transit that are justified on grounds of public morality, public policy or public security, the protection of the health and life of

humans, animals or plants, the protection of national treasures possessing artistic, historic or archaeological value, or the protection of industrial and commercial property. Such prohibitions or restrictions shall not, however, constitute a means of arbitrary discrimination or a disguised restriction on trade between Member States.

The Court of Justice of the European Union (CJEU) held in Case C-148/15 that, in so far as a national measure concerns the field of public health, it has consistently ruled that the protection of human health and life ranks foremost among the interests protected by the Treaty on the Functioning of the European Union (TFEU) and that it is for the Member States to determine the level at which they intend to ensure the protection of public health and the manner in which that level is to be achieved. Since that level of protection may vary from one Member State to another, the Member States must be allowed a margin of discretion in this regard.

The CJEU further held that a restriction on trade between Member States may, in particular, be justified under Article 36 TFEU where it is necessary to ensure a reliable supply of medicinal products for essential medical purposes, in so far as that objective falls within the protection of human health and life. Although the objective of ensuring a reliable and high-quality supply of medicinal products throughout the national territory is, in principle, capable of falling within the scope of Article 36 TFEU, national legislation that is liable to restrict a fundamental freedom guaranteed by the TFEU, such as the free movement of goods, can be justified only if it is appropriate for securing the attainment of the legitimate objective pursued and does not go beyond what is necessary to achieve that objective. (Case C-148/15.)

As the Court of Justice has previously held, it is for the national authorities to produce, in each individual case, the evidence necessary for that purpose. Accordingly, the grounds relied on by a Member State to justify a restrictive measure must be supported by an analysis of the suitability and proportionality of the measure adopted by that State, together with specific evidence capable of substantiating its arguments. It follows that, when examining national legislation in the light of the justification relating to the protection of human health and life under Article 36 TFEU, a national court must determine, on the basis of objective evidence such as statistical data and other specific information or by other appropriate means, whether the evidence produced by the Member State reasonably demonstrates that the measures chosen are suitable for attaining the objectives pursued and whether those objectives could be achieved by measures that are less restrictive of the free movement of goods. (Case C-148/15.)

If the mandatory reserve supply system for medicines were to be regarded as constituting a restriction or a measure within the meaning of Article 35 TFEU, Article 35 would nevertheless not preclude mandatory reserve supplies of medicines to the extent that they fall within the prohibitions or restrictions permitted under Article 36 TFEU.

Legislative initiatives are currently under way within the European Union that may be relevant to the mandatory reserve supply system for medicines. On 26 April 2023, the European Commission adopted the proposal for a Regulation forming part of the pharmaceutical package (COM(2023)193 final). The proposed Article 134 may be relevant to the mandatory reserve supply system for medicines.

In addition, on 11 March 2025, the Commission published a proposal for a Critical Medicines Act (COM(2025)102 final). In particular, the proposed Article 20 is relevant to the mandatory

reserve supply system for medicines. Pursuant to Article 20(1) of the proposed Regulation, measures relating to security of supply applied in one Member State must not have adverse effects on other Member States. In particular, Member States must avoid such effects when proposing and determining the scope and timing of requirements imposed on undertakings to maintain contingency stocks. Pursuant to Article 20(2) of the proposed Regulation, Member States must ensure that any requirements imposed on undertakings in the supply chain to maintain contingency stocks are proportionate and comply with the principles of transparency and solidarity.

On 20 May 2025, the World Health Organization adopted the Pandemic Agreement. Article 14(6) of the Pandemic Agreement may be relevant to the mandatory reserve supply system for medicines in the event of a pandemic. That provision states: “During a pandemic emergency, each Party should avoid maintaining national stockpiles of pandemic-related health products that unnecessarily exceed the quantities anticipated to be needed for domestic pandemic preparedness and response”. The Pandemic Agreement has not yet entered into force in Finland.

2.3 Assessment of the current situation

In response to comments received from stakeholders, consideration has been given during the preparation of the proposal, inter alia, to whether the purpose clause in section 1 of the Act on Mandatory Reserve Supplies of Medicines should be clarified. However, the current statement of purpose is considered sufficiently flexible and therefore appropriate to retain. The system of mandatory reserve supplies of medicines, which safeguards the supply of medicines both during serious disruptions under normal conditions and in emergency conditions, should therefore be maintained.

With regard to section 2 of the Act on Mandatory Reserve Supplies of Medicines, consideration has been given to whether the scope of application of the Act should be extended to cover additional categories of operators. It has been concluded that extending the scope of application to new categories of operators would not be appropriate.

The definition of a health institution in section 3 of the Act on Mandatory Reserve Supplies of Medicines should be updated to reflect the changes made to the organisation of social welfare and healthcare services. As a result of the social welfare and healthcare reform, the references to municipalities and joint municipal authorities should be updated. The same need for updating applies more generally throughout the Act on Mandatory Reserve Supplies of Medicines and the Government Decree on Mandatory Reserve Supplies of Medicines.

The therapeutic classes defined in section 4 of the Act on Mandatory Reserve Supplies of Medicines determine the scope of the medicinal substances that may be specified in section 1 of the Government Decree on Mandatory Reserve Supplies of Medicines as being subject to the stockpiling obligation. During the preparation of the proposal, it was concluded that the inclusion of certain medicinal substances intended to be added to the Government Decree requires the expansion of certain therapeutic classes set out in section 4 of the Act. It has also been concluded that certain therapeutic classes should otherwise be updated. Furthermore, the current power to issue decrees in that section permits more detailed provisions to be adopted only in respect of medicinal substances. However, the Government Decree on Mandatory Reserve Supplies of Medicines already includes medicinal substances for which the stockpiling obligation is limited to specific pharmaceutical forms. The power to issue decrees

should therefore be updated to permit more detailed provisions to be adopted also in respect of pharmaceutical forms.

In addition, the list of medicinal substances in section 1 of the Government Decree on Mandatory Reserve Supplies of Medicines is outdated. The list was last updated in 2012 and no longer fully reflects current needs.

With regard to section 4a of the Act on Mandatory Reserve Supplies of Medicines, it has been concluded during the preparation of the proposal that, in order to safeguard security of supply, mandatory reserve supplies should continue to be located exclusively in Finland and that the current arrangements should therefore be retained. In addition, consideration has been given to possible amendments concerning the location of mandatory reserve supplies within Finland.

Pursuant to section 6 of the Act on Mandatory Reserve Supplies of Medicines, importers are required to maintain mandatory reserve supplies of antimicrobial agents corresponding to ten months' average consumption. This may create challenges in rotating stocks within the shelf life of the medicinal products. It is therefore considered appropriate to moderately reduce the level of the stockpiling obligation in this respect.

In addition, if HIV medicines included within the category of antimicrobial agents were added to the list of medicinal substances in the Government Decree on Mandatory Reserve Supplies of Medicines, pharmaceutical manufacturers and importers would, under the current Act, be required to maintain mandatory reserve supplies corresponding to ten months' average consumption, while operators responsible for health institutions would be required to maintain mandatory reserve supplies corresponding to six months' average consumption. Requiring mandatory reserve supplies of HIV medicines at those levels would entail considerable additional costs. It would therefore be appropriate to provide for a lower mandatory reserve supply requirement for HIV medicines than for other antimicrobial agents.

The wording of section 7(3) of the Act on Mandatory Reserve Supplies of Medicines should also be clarified with regard to sales to the Åland Islands. Furthermore, pursuant to section 1(2) of the Government Decree on Mandatory Reserve Supplies of Medicines, the stockpiling obligation for the cancer medicines referred to in section 1(1), point 13, applies only to health institutions. However, the Act on Mandatory Reserve Supplies does not contain a clear power to issue decrees providing that, by Government decree, it may be expressly stipulated that the stockpiling obligation in respect of certain medicinal substances referred to in section 4(1)(13) rests solely with the operator of a health institution.

Section 8 of the Act on Mandatory Reserve Supplies of Medicines, which governs the stockpiling obligation of the Finnish Institute for Health and Welfare, currently excludes influenza vaccines from the scope of that obligation. However, it is possible that the national vaccination programme may be expanded to include vaccines administered seasonally in the same manner as influenza vaccines. It may therefore be appropriate to exclude such vaccines from the scope of the obligation in advance. Moreover, limiting the exclusion to vaccines does not take into account the possibility that medicinal products similar to vaccines could in future be included in the national vaccination programme.

During the preparation of the proposal, it was also suggested that the provision under which the quantity of the Finnish Institute for Health and Welfare's stockpiling obligation is based on consumption during the first half of the preceding year should be repealed. According to the

information received, consumption during the first part of the year does not, in the case of certain vaccines, correspond to the actual average consumption over a six-month period.

Neither sections 5–8 of the Act on Mandatory Reserve Supplies of Medicines nor any other provisions of the legislation on mandatory reserve supplies contain an exception to the rules for calculating the stockpiling obligation where medicinal products are procured, for example, for national government reserve stocks or for common EU stockpiles located in Finland. However, such procurement already contributes in itself to safeguarding the security of supply of medicines. It would therefore be justified to provide that such procurement should not be taken into account when calculating the average consumption on which the stockpiling obligation is based.

In addition, consideration has been given during the preparation of the proposal to whether the stockpiling obligation for hospital-only medicinal products should be transferred from importers and pharmaceutical manufacturers to operators responsible for health institutions. In view of the current state of the public finances, such a change has not been considered feasible.

With regard to sections 5–9 of the Act on Mandatory Reserve Supplies of Medicines, consideration has been given to whether the determination of the stockpiling obligation should be made more responsive to real-time changes. The current model has been considered appropriate to retain, inter alia because a more real-time approach could reduce the stability of the mandatory reserve supply system. Moreover, the stockpiling obligation is already recalculated annually and, in certain situations, may also be revised during the calendar year.

With regard to section 2 of the Government Decree on Mandatory Reserve Supplies of Medicines, which supplements section 10 of the Act, it has been concluded that the wording of subsection 2 unnecessarily restricts the possibility of substituting a medicinal product with another strength or pharmaceutical form.

Section 3 of the Government Decree on Mandatory Reserve Supplies of Medicines, which supplements section 11 of the Act, does not provide for situations in which the Finnish Institute for Health and Welfare may be exempted from the stockpiling obligation. During the preparation of the proposal, it was considered that, like other entities subject to the stockpiling obligation, the Finnish Institute for Health and Welfare should also be eligible for an exemption where the obligation is minimal. In addition, the provisions of section 3 of the Government Decree are not, in all respects, consistent with the regulation-making power conferred by the Act.

Section 12 of the Act on Mandatory Reserve Supplies of Medicines, which governs the compensation payable to entities subject to the stockpiling obligation, does not provide for a cap on the Bank of Finland reference rate under the Interest Act used as the basis for calculating the compensation. It has been considered during the preparation of the proposal that an interest rate cap could be appropriate in situations where interest rates rise substantially above their current level.

At present, the capital tied up in the acquisition cost of the goods held in the mandatory reserve supplies is determined separately on the basis of the lowest capital value recorded during each half of the calendar year. Consequently, even a short-term reduction during a six-month period may result in the compensation for that period being calculated on the basis of

the reduced amount, although the level of the mandatory reserve supplies may have been higher for most of the period. A more frequent reference period than six months would make it possible for the compensation to reflect the actual maintenance of the reserve supplies more accurately.

The preparation of the proposal also concluded that, in the current public finance situation, there are no grounds for increasing the level of compensation or extending eligibility for compensation to additional categories of recipients.

With regard to section 13 of the Act and section 4 of the Government Decree, which govern the payment of compensation, it has been considered that the current requirement that applications be submitted by the end of January following the reserve supply year is unnecessarily restrictive. It is therefore considered appropriate to extend the application period. In addition, it has been considered that the requirement to attach an auditor's certificate to the application could be replaced by a less burdensome procedure.

More generally, as regards the provisions on compensation and its payment, it may be observed that where an entity subject to the stockpiling obligation has maintained reserve supplies below the level required by the legislation, it is justified that compensation be paid only in respect of the reserve supplies actually maintained. Conversely, where reserve supplies have been maintained in excess of the level required by the legislation, it is equally justified that compensation be paid only to the extent required by the legislation. It may also be noted, as regards the compensation application procedure, that the applicant is responsible for the accuracy of the information provided.

Section 15 of the Act on Mandatory Reserve Supplies of Medicines does not currently allow importers and pharmaceutical manufacturers to maintain reserve supplies below the required level on their own initiative without prior authorisation. However, for minor shortfalls, a right to maintain reserve supplies below the required level without prior authorisation could be considered appropriate in order to reduce the administrative burden associated with the permit procedure.

At present, that section allows the mandatory reserve supplies of a health institution to fall below the required level where the use of the mandatory reserve supplies is necessary for the operation of the health institution owing to a supply disruption. The current regulation does not, however, allow entities to maintain reserve supplies below the required level on their own initiative in situations where only such a product subject to the obligation is available on the market that would in any case expire during the storage period. It is considered appropriate that health institutions should be able, in such situations, to fall below the required level on their own initiative.

It should also be noted that the Finnish Institute for Health and Welfare does not have a corresponding right, equivalent to that of health institutions, to reduce its reserve stocks on its own initiative. Taking into account, inter alia, the status of the Finnish Institute for Health and Welfare as a public authority and the need to ensure the smooth implementation of the national vaccination programme, it is considered justified that it should also have a corresponding right to that of health institutions. With regard to the Finnish Institute for Health and Welfare, it is also considered justified that it should be able to reduce its reserve stocks on its own initiative in situations where a disease preventable by vaccination threatens to cause an epidemic of a communicable disease.

The legislation on mandatory reserve supplies does not take into account situations where an undertaking responsible for supplying medicinal products to public healthcare loses a pharmaceutical procurement tender. In such cases, the undertaking that has lost the tender remains subject to the stockpiling obligation, even though there may no longer be corresponding demand for the medicinal products, which may in turn lead to unnecessary waste of medicines. In addition, in other situations where consumption of a product subject to the obligation ceases, it could be justified, from the perspective of reducing medicinal waste, to provide relief from the stockpiling obligation. The mandatory reserve supply system should therefore be amended to allow for easing of the obligation in such situations, provided that doing so does not jeoparise the security of supply.

Section 16 of the Act on Mandatory Reserve Supplies of Medicines does not clearly regulate the obligations of entities subject to the stockpiling obligation to provide information and comply with supervision requirements. Such obligations may be considered necessary for safeguarding security of supply, and current practice should therefore be clarified in legislation.

The Act on Mandatory Reserve Supplies of Medicines does not provide for the possibility of using mandatory reserve supplies for the provision of international assistance. In certain situations, however, it may be appropriate to use reserve supplies for international assistance, provided that Finland’s own security of supply is not significantly jeopardised.

The Act on Mandatory Reserve Supplies of Medicines does not provide for the possibility of requesting rectification of decisions. In line with recommendations on administrative appeals, the use of a rectification request procedure should be extended, where appropriate, to decisions taken under the mandatory reserve supply legislation.

The Act and the Government Decree on Mandatory Reserve Supplies of Medicines also contain relatively limited provisions on the exchange of information between the Finnish Medicines Agency (Fimea) and the National Emergency Supply Agency. It has therefore been assessed during the preparation whether more comprehensive provisions should be adopted in this regard. However, the need to extend the regulation in this respect remains unclear.

In addition, certain regulation-making powers under the Act do not fully correspond to what is provided in the Government Decree. Certain references to specific provisions of the Act are also outdated.

3 Objectives

The Government proposal aims to ensure that the mandatory reserve supply system for medicines continues to effectively safeguard the availability of medicines and security of supply also in the future. The aim of the proposal is a flexible, balanced and up-to-date reserve supply system.

Flexibility refers to the ability of the mandatory reserve supply system for medicines to take into account various changes, such as changes in consumption resulting from pharmaceutical procurement tenders, as well as operational needs such as the use of reserve stocks in situations involving shortages. Balance refers to the need for the mandatory reserve supply system for medicines to strike a balance between, on the one hand, interests related to the security of medicine supply and, on the other hand, the attractiveness of the Finnish

pharmaceutical market. Up-to-dateness means, in this context, that the medicinal products covered by the mandatory reserve supply system correspond to current treatment guidelines and clinical practices, as well as preparedness objectives.

4 The proposals and their impacts

4.1 Main proposals

The proposal aims to update the therapeutic classes covered by the stockpiling obligation under the Act on Mandatory Reserve Supplies of Medicines.

Under the proposal, the Finnish Medicines Agency (Fimea) could, upon application, grant permission to maintain reserve supplies below the required level in situations where the consumption of a product subject to the reserve supply obligation has decreased very significantly in relation to the entity subject to the obligation. The amendment would allow the reduction of medicinal waste, for example in connection with public hospital procurement tenders and changes in treatment guidelines.

It is proposed that pharmaceutical manufacturers and importers be granted a right to deviate from the obligation on their own initiative in cases of minor shortfalls, in order to reduce the administrative burden associated with the permit procedure. In addition, it is proposed that the right of health institutions to deviate from the obligation on their own initiative be extended. It is further proposed that the Finnish Institute for Health and Welfare be granted the right to reduce its reserve stocks on its own initiative in the event of supply disruptions affecting vaccines or in the event of a threat of a communicable disease epidemic. This amendment takes into account the role of the Finnish Institute for Health and Welfare as an authority and ensures the smooth implementation of the national vaccination programme and the prevention of epidemics of communicable diseases.

It is also proposed that certain procurements, such as purchases for national reserve stocks or EU joint stockpiles located in Finland, would not be taken into account when calculating the average consumption on which the stockpiling obligation is based. Such procurements already contribute to security of supply in itself.

A five-percent interest rate cap is proposed to be introduced into the Act in relation to compensation, in order to safeguard the financial capacity of the National Emergency Supply Fund. In addition, it is proposed that the reference period used in the calculation of compensation be changed from half-year periods to quarterly periods.

The stockpiling obligation for HIV medicines is proposed to be reduced to a level corresponding to three months' average consumption for all obligated entities, in order to contain costs. The obligation for importers to maintain antimicrobial reserves corresponding to ten months' average consumption is proposed to be reduced to eight months in order to reduce medicinal waste. For the Finnish Institute for Health and Welfare, it is also proposed that the basis for calculating the reserve supply obligation be removed.

With regard to decisions taken by the Ministry of Social Affairs and Health, it is proposed that the Act be clarified to provide that the Ministry may impose information and supervision obligations on entities subject to the stockpiling obligation, in order to safeguard security of

supply. It is also proposed that the Ministry be empowered to grant permission for deviations from the obligation for the purpose of providing international assistance.

A rectification request procedure is proposed to be introduced for certain decisions under the Act on Mandatory Reserve Supplies of Medicines.

4.2 Principal impacts

4.2.1 Economic impact

The proposed amendments to the Act on Mandatory Reserve Supplies of Medicines are expected to have some economic impacts on public finances and on undertakings.

As regards public finances, it is uncertain whether the proposal will contribute to an overall increase or decrease of costs. Costs may increase, for example, due to the proposed change in the reference period for compensation from half-year periods to quarterly periods (section 12) and the introduction of a rectification request procedure (section 20a). On the other hand, costs may decrease due, inter alia, to the proposed interest rate cap (section 12), should interest rates rise significantly above current levels, and the proposal to exclude certain procurements from the calculation of the average consumption on which the stockpiling obligation is based (section 8a). No funding has yet been allocated for the proposed changes.

As regards undertakings, the amendments to the Act on Mandatory Reserve Supplies of Medicines are, overall, expected to reduce costs. Costs arising from mandatory reserve supplies of medicines are expected to decrease, for example, due to the proposed reduction of the reserve supply obligation for antimicrobial agents (section 6), the exclusion of certain procurements from the calculation of average consumption (section 8a), and the proposed right for importers and pharmaceutical manufacturers to deviate from the obligation on their own initiative (section 15). Costs for undertakings may, however, increase due to the proposed interest rate cap (section 12), should interest rates rise significantly above current levels. Overall, the net economic impact remains uncertain.

4.2.2 Other effects on people and society

4.2.2.1 Impact on public authorities

The proposal is expected to have a significant overall impact on public authorities. The impacts will affect, in addition to public-sector entities subject to the reserve supply obligation, the supervisory authorities under the Act on Mandatory Reserve Supplies of Medicines, as well as the Ministry of Social Affairs and Health. The financial impacts on authorities have been described above.

For public healthcare service providers, the proposal would mean that municipalities and joint municipal authorities would no longer be included among them. References in the Act on Mandatory Reserve Supplies of Medicines to municipalities and joint municipal authorities would be replaced with references to wellbeing services counties, the City of Helsinki, and the HUS Group. This change would reflect the structural reforms in the way social and healthcare service is organised (the “sote reform”). Through this, the identity of entities subject to the reserve supply obligation would change. However, the practical impact of this change is

reduced by the fact that, following the sote reform, wellbeing services counties have been responsible for maintaining pharmaceutical reserve supplies.

In addition, the proposal would extend the right of public health institutions to deviate from the obligation on their own initiative (section 15). Furthermore, the proposed amendments affecting all parties subject to the stockpiling obligation, such as the proposed authorisation to reduce mandatory reserve supplies below the required level on the grounds of a significant decrease in consumption (section 15), will also affect operators of public health institutions. The financial impacts on wellbeing services counties have already been described above.

For the Finnish Institute for Health and Welfare, it is proposed that the basis for calculating the reserve supply obligation be removed (section 8). In addition, the Finnish Institute for Health and Welfare would be able to deviate from the obligation on its own initiative in certain situations (section 15). All general amendments applicable to obligated entities, such as the proposal to exclude certain consumption from the calculation of average consumption used as the basis for the reserve supply obligation (section 8a), would also apply to the Finnish Institute for Health and Welfare.

For the Finnish Medicines Agency (Fimea), the proposal would expand its powers to grant exemptions from the reserve supply obligation (section 15). In addition, the proposal allowing obligated entities to deviate from the obligation more extensively on their own initiative, without requiring authorisation from Fimea, would likely reduce the number of applications submitted to Fimea and thereby reduce the administrative workload associated with permit processing. The obligation for Fimea to notify obligated entities of the consumption excluded from the calculation of average consumption (section 8a) would, however, cause a minor increase in workload.

For the National Emergency Supply Agency, the proposed interest rate cap and the shortening of the compensation reference period from half-year periods to quarterly periods (section 12) would affect its compensation procedures.

The introduction of a rectification request procedure (section 20a) would affect both Fimea and the National Emergency Supply Agency, as such a procedure is not currently used for any type of decision. It would also affect the entities appealing decisions by Fimea and the National Emergency Supply Agency.

For the Ministry of Social Affairs and Health, it is proposed that the Ministry could in future also decide on the use of reserve stocks in special situations where reserve supplies are used for international assistance (section 16). In addition, it is proposed that the content of the Ministry’s decisions be clarified with regard to information and supervision obligations.

4.2.2.2 Other impacts

Some of the proposals are relevant from the perspective of the protection of property and freedom to conduct a business of private entities subject to the reserve supply obligation. According to section 18, subsection 1 of the Constitution, everyone has the right, as provided by the law, to earn their livelihood by the employment, occupation, or commercial activity of their choice. According to section 15, subsection 1 of the Constitution, everyone’s property is protected.

Such proposals include, for example, the proposal to update the therapeutic classes of medicines subject to the reserve supply obligation (section 4) and the proposal granting the Ministry of Social Affairs and Health the right to impose information and supervision obligations (section 16). However, the fundamental and human rights impacts of the above-mentioned proposals are not solely negative. The underlying aim of these measures is to safeguard the security of medicine supply, which is closely linked to the public authorities' duty under section 19(3) of the Constitution to promote the health of the population.

In addition, the proposal includes amendments that would reduce existing restrictions on the property rights and freedom to conduct a business of private entities subject to the reserve supply obligation. Such measures include, for example, the proposed reduction of the reserve supply obligation for antimicrobial medicines for importers (section 6), and the proposal allowing pharmaceutical manufacturers and importers to reduce their reserve supplies on their own initiative in certain situations (section 15).

5 Other options for implementation

5.1 Alternatives and their impacts

During the preparation, the therapeutic classes under the Act on Mandatory Reserve Supplies of Medicines, and in particular the active substances listed in the Government Decree, have been assessed. It has been concluded that they should be updated in order to achieve a current and effective medicinal reserve supply system. An alternative option considered is to not update the therapeutic classes and active substances at all. The lists of therapeutic classes and active substances were last updated in 2012 and no longer fully correspond to current needs. In addition to changes in treatment practices, the global political situation has become more tense since 2012, which further highlights the importance of security of medicine supply. Failure to carry out the update would mean that the objective of an up-to-date reserve supply system would not be achieved.

The preparation has also examined situations related to public pharmaceutical procurement processes, in which the supplier of a medicinal product changes as a result of competitive tendering. In this context, the preparation has utilised, inter alia, reports by the Finnish Medicines Agency (Fimea) and consulted representatives of other authorities regarding competition and procurement legislation.

It has been concluded that the issues identified should be addressed through a new basis for granting exemptions from the reserve supply obligation. According to the proposal, the Finnish Medicines Agency (Fimea) could also grant an exemption if the consumption of a product subject to the obligation decreases significantly for the obligated party, provided that granting the exemption does not jeopardise security of supply. This proposal is linked to the objective of a more flexible reserve supply system.

As an alternative solution, a more real-time determination of the obligation has been assessed. Such a model would mean that the obligation of a company losing a procurement tender would decrease more rapidly than at present, allowing the company to reduce its stock more quickly. In assessing a more real-time model, consideration was given to a model in which the obligation period would be six months instead of a calendar year, as well as a model in which the obligation could be adjusted twice per year instead of once.

However, it remains unclear to what extent a moderate shift towards real-time adjustment would resolve the specific issues related to public pharmaceutical procurement. In addition, the broader effects of such a reform on the reserve supply system beyond procurement situations remain uncertain. By contrast, the proposed exemption basis would more precisely target procurement-related issues without broadly altering the system.

A second alternative considered for procurement situations is a transition model. Under this option, the company losing a procurement tender would begin reducing its obligation at the same time as the winning company would be required to increase its obligation, even if the winning company had no prior consumption on which the obligation would normally be based. The advantage of this model is that it would not jeopardise the security of supply, as the total stock level of the medicinal product would remain unchanged even if the losing company begins to reduce its stock.

On the other hand, the implementation of such a transition model would raise several unresolved issues. It would need to be determined how much and over what period the obligation could be reduced. It would also be necessary to assess when the transition period would begin and what role procurement appeal procedures would have in determining the timing. In addition, it would be necessary to determine how much the winning company would be required to increase its stock. The current reserve supply obligation is based on previous consumption, and under this model the winning company would need to build up stock from a different baseline. Assessing the transition model would require these questions to be answered and a broader impact assessment than has been carried out in this context. In any case, the exemption mechanism granted by the Finnish Medicines Agency is considered more compatible with the current reserve supply system, in which the Agency is already empowered under the existing Act to grant exemptions from the reserve supply obligation.

5.2 Legislation and other means in place in other countries

Security of medicine supply has been safeguarded in Finland, as well as in other countries, through various arrangements.

In Sweden, the Government submitted in spring 2025 a proposal on preparedness in health care and medical services (2024/25:167). The proposal suggests that regions and municipalities should be required to stockpile medical supplies, such as medicines, for healthcare services that they are obliged to provide under the proposed legislation. The proposal includes an enabling provision allowing the Government to issue regulations on the content and scope of such stockpiling. The proposed amendments are intended to enter into force on 1 January 2027.

In Norway, the Regulation on Wholesale Distribution of Medicinal Products (FOR-1993-12-21-1219) requires pharmaceutical wholesalers supplying medicines to pharmacies to maintain additional stock in Norway. The medicines covered by the stockpiling obligation are listed in an annex to the regulation. According to the Norwegian Medicines Agency (Direktoratet for medisinske produkter), there are also national hospital medicine stockpiles regulated through agreements between regional health authorities and a wholesale distributor.

In Denmark, an amendment to the Medicines Act concerning mandatory stockpiling of critical medicines was adopted in summer 2024. As a result, entities placing certain critically important medicines for human use on the Danish market are required to maintain a national

safety stock of those medicines in Denmark. The Danish Medicines Agency (Lægemiddelstyrelsen) determines more detailed provisions on the stockpiling obligation, including the required stock levels.

In Germany, a law aimed at preventing supply shortages of off-patent medicines and improving the availability of paediatric medicines was adopted in summer 2023. In certain agreements concerning off-patent medicines, a requirement has been introduced to maintain a stock corresponding to six months of consumption.

6 Feedback

(Pending consultation)

7 Provision-specific rationale

Section 3 *Definitions.* It is proposed that the definition of "operator of a health institution" in subsection 1, point 4 be amended to replace references to municipalities and joint municipal authorities with references to wellbeing services counties, the City of Helsinki, and the HUS Group. The purpose is to take account of the changes in the organisation of social and healthcare services resulting from the health and social services reform. The proposal would effectively change who is considered subject to the reserve supply obligation. Provisions on the organisation of social and healthcare services are laid down, inter alia, in the Act on the Organisation of Social and Health Care Services (612/2021) and in the Act on the Organisation of Social and Health Care and Rescue Services in the Uusimaa Region (615/2021).

Section 4 *Storage methods, pharmaceutical substances and products.* The therapeutic classes referred to in subsection 1 are proposed to be updated. The inclusion of certain active substances proposed to be added to the Government Decree requires that the current therapeutic classes be amended accordingly. In addition, linguistic changes are proposed to certain therapeutic classes in order to align them with current terminology and improve clarity.

Subsection 1, point 1 is proposed to be amended for the reserve supply obligation to cover the following therapeutic class: antimicrobial medicines. The proposal is primarily a linguistic change. In practice, the provision would correspond to the current regulation.

Subsection 1, point 3 is proposed to be amended for the reserve supply obligation would to cover the following therapeutic classes: among cardiovascular medicines and diuretics, medicines for coronary artery disease, medicines for heart failure and arrhythmias, antihypertensive medicines, lipid-lowering medicines, and diuretics. The proposal would extend the reserve supply obligation to lipid-lowering medicines. The inclusion of medicines for coronary artery disease is primarily a linguistic clarification.

Subsection 1, point 5 is proposed to be amended for the reserve supply obligation to cover the following therapeutic classes: among analgesics and antirheumatic medicines, opioids, non-steroidal anti-inflammatory drugs, anilides and gabapentinoids, as well as medicines for rheumatoid arthritis. The proposal would expand the obligation with regard to pain

management medicines. It would also extend the reserve supply obligation to other medicines for rheumatoid arthritis beyond pain-relieving medicines. The current reference to antipyretic medicines in the provision is proposed to be removed for linguistic reasons.

Subsection 1, point 7 is proposed to be amended by adding reference to vaccines included in the national vaccination programme and other medicines. The purpose is to harmonise the Act and the Government Decree on mandatory reserve supplies of medicines. Under the Government Decree, the obligation already covers vaccines included in the national vaccination programme imported or procured by the Finnish Institute for Health and Welfare, with the exception of influenza vaccines. However, the current provision only refers to vaccines for the prevention and treatment of hepatitis A and B, rabies, and tetanus. The national vaccination programme, however, also includes other vaccines beyond those mentioned above.

The proposal would also include other medicines covered by the national vaccination programme. The intention is to anticipate situations where the national vaccination programme may include medicinal products whose classification as vaccines is open to interpretation. These may include antibody-containing medicinal products. In future, medicines other than vaccines would also fall within the scope of the obligation, provided they are included in the national vaccination programme.

Subsection 1, point 9 is proposed to be amended for the reserve supply obligation to cover the following therapeutic classes: among medicines for gastrointestinal diseases, medicines used in the treatment of gastric and duodenal ulcers, medicines for inflammatory bowel diseases, and bile acid-related medicines. The proposal would extend the obligation to medicines for inflammatory bowel diseases and bile acid-related medicines.

Subsection 1, point 10 is proposed to be amended for the reserve supply obligation to cover the following therapeutic classes: among psychotropic medicines, antipsychotic, anxiolytic and antidepressant medicines, as well as mood stabilisers. The proposal would extend the reserve supply obligation to mood-stabilising medicines. In addition, the concept of “neurotic medicines” is proposed to be replaced with the more modern term “anxiolytic medicines”, and the concept of “depression medicines” with “antidepressant medicines”.

Subsection 1, point 11 is proposed to be amended for the reserve supply obligation to cover the following therapeutic classes: among neurological medicines, anti-epileptic medicines and medicines for Parkinson’s disease. The proposal is in practice a linguistic amendment.

Subsection 1, point 12 is proposed to be amended for the reserve supply obligation to cover the following therapeutic classes: among ophthalmological medicines, medicines for glaucoma, antimicrobial eye medicines and corticosteroids administered to the eye, as well as mydriatic eye drops and local anaesthetic eye drops. The proposal would extend the reserve supply obligation to corticosteroids administered to the eye, as well as mydriatic and anaesthetic eye drops.

The proposal also includes an amendment to subsection 3 to include medicinal dosage forms in the enabling provision. According to the proposed wording, the Government Decree would provide more detailed provisions on the active substances included in the therapeutic classes referred to in subsection 1, including their dosage forms, which fall within the scope of the reserve supply obligation. The aim is to clearly enable the Government Decree on mandatory

reserve supplies of medicines to restrict the reserve supply obligation of certain active substances to specific dosage forms. Even under the current Government Decree, the reserve supply obligation for certain active substances is already limited to specific dosage forms. For example, in the case of adrenaline, the obligation applies only to its intravenous form.

Section 5 *Stockpiling obligation of a pharmaceutical factory.* Subsection 1, point 1 is proposed to be amended to require a reserve supply obligation for HIV medicines of three months instead of ten months. The proposal is linked to the amendment proposed in the Government Decree, under which HIV medicines would be included within the scope of the obligation. "HIV medicines" refers to medicines used in the treatment of HIV infection caused by the human immunodeficiency virus. A shorter three-month stockpiling period than for other antimicrobial medicines is justified in particular by the significant costs arising from the reserve supply obligation for HIV medicines.

Section 6 *Pharmaceutical manufacturer's reserve supply obligation.* It is proposed that subsection 1 of the section be amended in its entirety. The provision would otherwise correspond to the current section 6(1) of the Act, but the importer's reserve supply obligation would, with regard to antimicrobial medicines, be reduced from ten months to eight months. The purpose of the amendment is to reduce the amount of medicinal waste arising from the mandatory reserve supply of antimicrobial medicines. In addition, it is proposed that a corresponding amendment be made to the importer's reserve supply obligation for HIV medicines as in the case of pharmaceutical manufacturers, i.e. that the reserve supply obligation for HIV medicines would in future be three months instead of ten months. The proposal is linked to the amendment proposed in the Government Decree, under which HIV medicines would be included within the scope of the obligation. A shorter three-month stockpiling period than for other antimicrobial medicines is justified in particular by the significant costs arising from the reserve supply obligation for HIV medicines.

In addition, the proposed subsection 1, point 3 would provide that the importer's reserve supply obligation would not, however, apply to other medicines included in the national vaccination programme. The intention is to anticipate situations where the national vaccination programme may include medicinal products whose classification as vaccines is open to interpretation. These may include antibody-containing medicinal products.

Section 7 *Storage obligation of the health institution.* Subsection 1, point 1 is proposed to be amended by adding a provision stating that the reserve supply obligation of the operator of a health institution would not, however, apply to other medicines included in the national vaccination programme. The intention is to anticipate situations where the national vaccination programme may include medicinal products whose classification as vaccines is open to interpretation. These may include antibody-containing medicinal products.

The same provision is also proposed to be amended with regard to HIV medicines in the same manner as for pharmaceutical manufacturers and importers, i.e. the reserve supply obligation for HIV medicines would in future be three months. At present, the reserve supply obligation is six months, but HIV medicines are not included in the Government Decree's list of active substances subject to the reserve supply obligation. The proposal is linked to the amendment proposed in the Government Decree, under which HIV medicines would be included within the scope of the obligation. A shorter three-month stockpiling period than for other antimicrobial medicines is justified in particular by the significant costs arising from the reserve supply obligation for HIV medicines.

Subsection 3 is proposed to be amended to replace references to municipalities and joint municipal authorities with references to wellbeing services counties, the City of Helsinki, and the HUS Group. The purpose is to take account of the changes in the organisation of social and healthcare services resulting from the health and social services reform. Provisions on the organisation of social and healthcare services are laid down, inter alia, in the Act on the Organisation of Social and Health Care Services and in the Act on the Organisation of Social and Health Care and Rescue Services in the Uusimaa Region.

The provision is also proposed to be clarified by adding a reference to the Åland Islands. The purpose of the proposal is to clarify the scope of the storage obligation in situations where a private healthcare service provider sells services to the Åland Islands. According to section 3(1)(4) of the current Act on compulsory stockpiling, a health institution refers, among other things, to a private healthcare service provider that provides healthcare services to the Åland Islands. However, the provision at hand does not currently define for which consumption a private healthcare service provider that provides healthcare services to the Åland Islands is subject to the stockpiling obligation. It is not appropriate for the stockpiling obligation of such a private healthcare service provider to cover all of its pharmaceutical consumption.

In addition, the provision is proposed to be amended to replace the reference to section 4(1)(4) or (5) of the Act on Planning of Social and Health Care and State Subsidies (733/1992), concerning outsourced services or service vouchers, with a general reference to outsourced services or service vouchers without a statutory reference. Due to the social and health care reform, the referenced Act has been repealed by the Act on the Implementation of the Reform of Social and Health Care and Rescue Services and Related Legislation (616/2021). The purpose of the proposal is not to change the stockpiling obligation of private healthcare service providers.

A new subsection 5 is proposed to be added. The section would provide for the power to issue decrees. The proposal states that, by Government Decree, more detailed provisions may be issued on which medicinal substances included in the medicinal groups referred to in section 4(1)(13) are required to be stocked exclusively by the operator of a health institution. The purpose of the amendment is to explicitly enable the regulation corresponding to section 1(2) of the current Government Decree on compulsory stockpiling.

Section 8 *Stockpiling obligation of the Finnish Institute for Health and Welfare.* The section is also proposed to be amended with a reference to other medicines in addition to vaccines. The purpose of this change is to take into account in advance a situation in which medicinal products may be added to the national vaccination programme, but where their classification as vaccines could be legally ambiguous. These may include antibody-containing medicinal products. In future, medicines other than vaccines would also fall within the scope of the obligation, provided they are included in the national vaccination programme.

In addition, the section would be amended to exclude, in addition to influenza vaccines, vaccines that are administered on a seasonal basis in a manner corresponding to influenza vaccines from the stockpiling obligation. The purpose of the amendment is to prepare in advance for situations where the National Vaccination Programme may in the future include vaccines that are administered seasonally in the same manner as influenza vaccines. At present, no such vaccines are included in the National Vaccination Programme. Mandatory reserve supplies of such vaccines would not be appropriate, as vaccines from the previous season may no longer be effective against the mutated pathogens of the following season.

Seasonal administration does not mean that the vaccine is always administered during a particular season of the year.

In addition, the section is proposed to be amended by removing the basis for calculating the stockpiling obligation, namely the reference stating that the quantity subject to the stockpiling obligation is determined on the basis of consumption during the first half of the previous calendar year. The objective of the amendment is to ensure that average consumption is calculated in a manner that more accurately reflects the actual average consumption over a six-month period.

Section 8a *Consumption that is not taken into account in the calculation of consumption.* This proposed section would be completely new. According to the proposal, when calculating the average consumption forming the basis for determining the quantity subject to the stockpiling obligation, the procurement of medicinal products for the State emergency stockpiles or other equivalent stockpiles shall not be taken into account. The Finnish Medicines Agency shall notify the parties subject to the stockpiling obligation of the consumption referred to above. The purpose of the section is to facilitate compliance with the stockpiling obligation in respect of non-recurring consumption of medicinal products that, in itself, already contributes to safeguarding security of supply. The section would apply to all parties subject to the stockpiling obligation.

The section would expressly refer to the procurement of medicinal products for the State emergency stockpiles. State emergency stockpiles are provided for in the Act on Safeguarding Security of Supply. The other equivalent stockpiles referred to in the provision could include national stockpiles or, for example, joint EU stockpiles, such as rescEU stockpiles.

According to the proposal, the Finnish Medicines Agency shall notify the parties subject to the stockpiling obligation of the consumption referred to above. The purpose of the provision is to enable a party subject to the stockpiling obligation that is earlier in the procurement chain for the procurements referred to in the section to obtain information on such procurements for the purpose of calculating average consumption. In addition, the Finnish Medicines Agency's notification procedure promotes a uniform interpretation of the provisions. It is not intended that the Finnish Medicines Agency should identify to the parties subject to the stockpiling obligation the specific stockpile for which the medicinal products have been procured. It is sufficient that the Finnish Medicines Agency notifies them of the quantity of consumption that is not to be taken into account when calculating average consumption.

In accordance with section 14 of the current Act on Mandatory Reserve Supplies for Medicines, a party subject to the stockpiling obligation would annually submit to the Finnish Medicines Agency information on the consumption referred to in the proposed section.

Section 10 *Organisation of the mandatory reserve supplies in special cases.* It is proposed that subsection 2 of the section be amended for the regulation-making authorisation to also permit the adoption of more detailed provisions on the application procedure for compensation. The purpose of the amendment is to clarify the legal basis for the provisions contained in section 2 of the current Decree on Mandatory Reserve Supplies concerning the information and supporting documentation to be provided in an application.

Section 11 *Exemption from the stockpiling obligation.* It is proposed that subsection 1 of the section be amended by adding a provision requiring the Finnish Medicines Agency to determine the period for which an exemption is to remain valid.

At present, the second sentence of subsection 2 of section 3 of the current Decree on Mandatory Reserve Supplies lays down provisions on the period of validity of an exemption decision. The intention is to elevate the provisions concerning the validity of the decision to the level of an Act. The power to issue decrees in the current subsection 1 only concerns the grounds on which a party subject to the stockpiling obligation may be exempted from that obligation. However, the provisions would not be transferred to the Act without amendment. During the legislative drafting process, it has been assessed that, in view of the administrative burden associated with the application procedure, it would be appropriate for an exemption to be granted for a period extending beyond the end of a calendar year. As at present, an exemption could also be granted to take effect during the course of a calendar year.

Section 12 *Compensation payable to a party subject to the stockpiling obligation.* It is proposed that subsection 1 of the section be amended by introducing an interest rate cap. The purpose of the amendment is to safeguard the financial sustainability of the National Emergency Supply Fund. Under the proposal, the reference rate of the Bank of Finland would be taken into account only up to five percentage points. If the reference rate of the Bank of Finland were to exceed five percentage points, the portion exceeding five percentage points would not be taken into account when calculating the amount of compensation. The proposed interest rate cap would apply only to the reference rate of the Bank of Finland. Accordingly, the proposal does not mean that the amount of compensation itself would be limited to five percentage points, even if the combined total of all percentage components affecting the amount of compensation were to exceed five percentage points.

It is also proposed that subsection 3 of the section be amended to consider, for the purposes of determining compensation, the principal amount on a quarterly basis rather than separately for each half of the calendar year. The purpose of the amendment is to ensure that the compensation more accurately reflects the actual level of stockholding during the calendar year. The amendment would mean, for example, that a shortfall occurring in February would no longer result, as is currently the case, in the compensation for the entire first half of the calendar year being calculated on the basis of that shortfall.

Section 15 *Reduction below the required level of mandatory reserve supplies.* It is proposed that the section be revised in its entirety. Under proposed subsection 1, the stock of a product subject to the stockpiling obligation held by a party subject to the stockpiling obligation may not fall below the quantity required under this Act. The proposed provision corresponds to the first sentence of subsection 1 of the current section 15.

Subsection 2 would lay down the circumstances in which a party subject to the stockpiling obligation may nevertheless reduce its stock below the required level without prior authorisation from the Finnish Medicines Agency. The permitted circumstances would be specified separately for each category of party subject to the stockpiling obligation.

It is proposed that manufacturers and importers of medicinal products be granted a new right to reduce their mandatory reserve supplies independently. Once per calendar year, the mandatory reserve supplies of a manufacturer or importer of medicinal products could fall by no more than 10% below the required level for a period not exceeding two weeks due to an

shortage of medicinal products. The reduction shall be notified to the Finnish Medicines Agency within two weeks from the date on which it commenced. The purpose of the amendment is to reduce the administrative burden associated with applying for authorisation in situations where the risks to security of supply are limited. Application of the provision requires that both the condition relating to the extent of the reduction and the condition relating to its duration are fulfilled simultaneously. Accordingly, the provision would not apply if the reduction continued for more than two weeks, even where the reduction did not exceed 10%. Such a reduction would be permitted only once during a calendar year and only as a result of an shortage of medicinal products. The notification obligation would apply only to manufacturers and importers of medicinal products.

The provision concerning health institutions would correspond in part to the current subsection 1 of section 15. However, it is proposed that the wording be clarified by replacing the term “supply disruption” with the term “shortage”, which is more consistent with the terminology used, for example, in the Medicines Act (395/1987). In addition, it is proposed that the provision be expanded to allow a health institution to independently reduce its mandatory reserve supplies where a product subject to the stockpiling obligation, other than one already included in the mandatory reserve supplies, is at risk of becoming unsuitable for its intended use before it can be placed into storage. The purpose is to enable a health institution to reduce its mandatory reserve supplies without prior authorisation where only products with a short shelf life are available on the market. A product subject to the stockpiling obligation other than one already included in the mandatory reserve supplies means a product subject to the stockpiling obligation that has not yet been placed in the mandatory reserve supplies but is being procured for that purpose.

In addition, it is proposed that the Finnish Institute for Health and Welfare be granted a new right to reduce its mandatory reserve supplies independently. Under the proposal, the mandatory reserve supplies of the Finnish Institute for Health and Welfare may fall below the required level where the use of the mandatory reserve supplies is necessary because of an shortage of vaccines or where a vaccine-preventable disease threatens to cause an epidemic of a communicable disease. The purpose of the amendment is to take account of the role of the Finnish Institute for Health and Welfare as a public authority and to facilitate the effective implementation of the National Vaccination Programme. The amendment is also intended to ensure that vaccines included in the National Vaccination Programme and held as mandatory reserve supplies can be used where there is a threat of an epidemic of a communicable disease. Where there is a threat of such an epidemic, it may become necessary to reduce the mandatory reserve supplies even if there is no shortage of the vaccine concerned.

The subsection would also provide that, once the shortage or the threat of an epidemic of a communicable disease has ended, the party subject to the stockpiling obligation shall, without delay, replenish its stocks to the required level.

Proposed subsection 3 would correspond in substance to subsection 2 of the current section 15. However, as in subsection 2, it is proposed that the terminology be clarified by replacing the term “supply disruption” with the term “shortage”.

In addition, the subsection would introduce a new ground for granting authorisation to reduce the mandatory reserve supplies, under which the Finnish Medicines Agency may grant such authorisation where the consumption of a product subject to the stockpiling obligation by the

party subject to the stockpiling obligation decreases to a very significant extent and the granting of the authorisation does not jeopardise security of supply.

The purpose of the amendment is to reduce the potential waste of medicinal products resulting from a substantial decline in consumption. The new ground for authorisation is intended in particular to facilitate a reduction of the stockpiling obligation in situations where a manufacturer or importer of medicinal products that has previously supplied medicinal products to the public healthcare system loses a new procurement procedure, as a result of which its consumption is no longer at the previous level. The amendment would make it possible, under the legislation on mandatory reserve supplies, for a greater proportion of the remaining mandatory reserve supplies to be released for use in such situations than is currently permitted. In addition, the proposed provision could apply, for example, where the use of a particular medicinal product has been discontinued as a result of changes in treatment recommendations and clinical practice.

The proposed provision concerns the consumption of the individual party subject to the stockpiling obligation and not a reduction in overall consumption at the general level. Furthermore, application of the provision requires that the reduction in consumption be very significant. Where the party subject to the stockpiling obligation continues to have any material level of consumption of the product concerned, the provision would not apply.

A further condition for granting the authorisation is that doing so does not jeopardise security of supply. This requires an overall assessment, taking into account, for example, the size of the mandatory reserve supplies, their proportion of the total medicinal product stocks in Finland, and the extent and duration of the proposed reduction. If security of supply would be jeopardised, authorisation to reduce the mandatory reserve supplies may not be granted, including in the public healthcare procurement situations referred to above.

Proposed subsection 4 would correspond to subsection 3 of the current section 15.

Section 16 *Use of mandatory reserves in special circumstances.* It is proposed that the section be amended to also allow a decision of the Ministry of Social Affairs and Health to impose information and monitoring obligations on parties subject to the stockpiling obligation. The purpose of the amendment is to clarify the legal basis for the current practice under which the Ministry of Social Affairs and Health has required, in its decisions, parties subject to the stockpiling obligation to inform their customers of the purposes of use specified in the decision and to monitor unusual sales and distribution in order to ensure that products released from mandatory reserve supplies are used solely for the purposes specified in the decision. The purpose of the information and monitoring obligations is to ensure that products released from mandatory reserve supplies are used only for the purposes specified in the decision.

In addition, it is proposed that a new subsection 2 be added to the section. Under the proposed subsection, the Ministry of Social Affairs and Health may also adopt a decision referred to in subsection 1 for the purpose of providing international assistance. Such a decision may be adopted only if it does not significantly jeopardise security of supply.

The purpose of the amendment is to enable the use of mandatory reserve supplies for the provision of international assistance. In situations involving international assistance, the Ministry of Social Affairs and Health could decide that the quantity of products subject to the stockpiling obligation may fall below the level prescribed by this Act. However, the Ministry

would not decide whether international assistance is to be provided. Decision-making concerning the provision of international assistance is governed by the Act on Decision-making on the Provision of International Assistance, International Cooperation or Other International Activities (418/2017). By decision of the Ministry, mandatory reserve supplies could, for example, be released for the purpose of providing assistance through the European Union Voluntary Solidarity Mechanism.

Such a decision may be adopted only if it does not significantly jeopardise security of supply. Accordingly, the release of mandatory reserve supplies of medicinal products for international assistance where this would significantly jeopardise Finland's security of supply would not be permitted. However, a decision may be adopted even if security of supply would be affected to a limited extent.

Section 20a *Appeal for amendment.* This proposed section would be completely new. It would specify the decisions of the Finnish Medicines Agency and the National Emergency Supply Agency in respect of which a request for administrative review may be submitted. These would include a decision on compensation for the stockpiling obligation referred to in section 10 of the Act on Mandatory Reserve Supplies, a decision on exemption from the stockpiling obligation referred to in section 11, a decision on the payment of compensation referred to in section 13, and a decision on the reduction below the required level of mandatory reserve supplies referred to in proposed subsection 3 of section 15. The procedure governing requests for administrative review is laid down in the Administrative Procedure Act (434/2003).

8 Regulation at the level of secondary legislation

In connection with the entry into force of the Act, the Government Decree on Mandatory Reserve Supplies of Medicines is also intended to be updated.

It is proposed that the list of medicinal substances in section 1 of the Decree on Mandatory Reserve Supplies of Medicines be updated. The list was last updated in 2012 and no longer fully reflects current needs. A transitional period is proposed for the medicinal substances to be added to the decree, during which the stockpiling obligation applicable to the newly added medicinal products would increase gradually.

On the basis of the information available, it has been estimated during the legislative drafting process that updating the list of medicinal substances contained in the Decree on Mandatory Reserve Supplies will increase costs to the State by approximately EUR 30 million, spread over the period 2027–2030. Thereafter, the update of the list of medicinal substances will continue to give rise to smaller recurring costs associated with maintaining mandatory reserve supplies and with the compensation paid by the National Emergency Supply Agency. No funding has yet been allocated for the proposed amendments, and their implementation is subject to the availability of final funding.

Updating the list of medicinal substances will also increase costs for undertakings. According to one estimate, the current total value of medicinal products subject to the mandatory reserve supplies obligation held by pharmaceutical companies and importers of medicinal products for retail sale is approximately EUR 170 million. As a result of updating the list of medicinal substances, the total value of medicinal products held as mandatory reserve supplies is estimated to increase to approximately EUR 220 million, corresponding to an additional cost of approximately EUR 50 million for undertakings.

It is proposed that the wording of section 2 of the Decree on Mandatory Reserve Supplies be clarified. It is proposed that section 3 of the Decree on Mandatory Reserve Supplies be amended to also grant an exemption to the Finnish Institute for Health and Welfare in certain circumstances. In addition, it is proposed that subsections 2 and 3 of that section be repealed.

As regards section 4 of the Decree on Mandatory Reserve Supplies, it is proposed that the requirement for an auditor's certificate be replaced by a requirement for a declaration by the responsible director or another equivalent responsible person. In addition, compensation would be calculated on a quarterly basis instead of by reference to the two halves of the calendar year. Amendments are also proposed to the timing of applications for compensation and the payment of compensation.

Furthermore, it is proposed that the Decree on Mandatory Reserve Supplies be amended to reflect the terminology resulting from the health and social services reform and that references to statutory provisions be updated.

9 Entry into force

It is proposed that the Act enter into force on 1 January 2027. Entry into force at the beginning of the calendar year is justified by the fact that, under section 9 of the current Act on Mandatory Reserve Supplies, the stockpiling obligation applies for the duration of a calendar year. It is therefore appropriate that the proposed amendments take effect at the beginning of the 2027 stockpiling period.

By way of exception, however, it is proposed that the proposed section 12 enter into force only on 1 January 2028. The purpose of this deferred entry into force is to clarify which legislative provisions apply to the compensation payable for mandatory reserve supplies maintained during 2026. The different date of entry into force means that it will only be in 2028, when compensation is paid for the maintenance of mandatory reserve supplies during 2027, that compensation will be calculated in accordance with the proposed section 12.

In connection with the entry into force of the Act, it is intended to update the Decree on Mandatory Reserve Supplies.

10 Implementation and monitoring

As regards the functioning of the Act, particular attention should be paid to monitoring the extent to which the proposed new ground for authorising a reduction below the required level, based on a very significant decrease in consumption, resolves the problems associated with public procurement procedures for medicinal products. If the proposed ground for authorisation does not alleviate those problems to a sufficient extent, it may be justified to examine more broadly the relationship between public procurement procedures for medicinal products and the mandatory reserve supplies system, as well as possible ways of resolving the problems associated with such procurement procedures.

11 Relationship to the Constitution and the legislative procedure

The proposal provides for updating the groups of medicinal products covered by the stockpiling obligation under the Act on Mandatory Reserve Supplies. In addition, in connection with the update of the Act on Mandatory Reserve Supplies, it is intended to update the list of medicinal substances contained in the Decree on Mandatory Reserve Supplies.

These proposals are relevant in relation to the protection of property guaranteed under section 15 of the Constitution. According to section 15, subsection 1 of the Constitution, everyone's property is protected. The proposals are also relevant in relation to the freedom to engage in commercial activities guaranteed under section 18 of the Constitution. Under the first sentence of subsection 1 of section 18 of the Constitution, everyone has the right, in accordance with the law, to earn a livelihood by employment, occupation or commercial activity of their own choice. Furthermore, the proposals are relevant in relation to section 80 of the Constitution, according to the second sentence of subsection 1 of which the general principles governing the rights and obligations of individuals, as well as matters that otherwise fall within the scope of an Act under the Constitution, must be laid down by an Act.

The provisions of fundamental rights extend indirectly to legal persons, since the absence of legal personality may involve encroaching on the rights of the individual underlying the legal person (Government Act 309/1993 vp).

In its opinion on the Government proposal for Acts amending the Medicines Act, the Act on Mandatory Reserve Supplies for Medicines and the Communicable Diseases Act, the Constitutional Law Committee stated that the proposed regulation is relevant in relation to the freedom to engage in commercial activities guaranteed under section 18 of the Constitution and the protection of property guaranteed under section 15 of the Constitution. The proposed legislative amendments seek to ensure the adequacy and availability of medicinal products in all circumstances and to guarantee equal access to medicinal products for all those who need them in exceptional situations. Pharmaceutical safety and ensuring the availability of medicinal products and medical supplies are closely linked to the duty of the public authorities under subsection 3 of section 19 of the Constitution to promote the health of the population. The proposed regulation is supported by compelling and acceptable grounds. (PeVL 17/2020.)

The Constitutional Law Committee has also stated in its established case-law that compensation for restrictions on the use of property is only one element in the overall assessment of whether a restriction on property rights is permissible from the perspective of the constitutional protection of property (Constitutional Law Committee Opinion PeVL 10/2014).

The parties subject to the stockpiling obligation affected by the present proposals are legal persons. Accordingly, the constitutional provisions on fundamental rights apply to them only indirectly. Furthermore, ensuring the availability of medicinal products constitutes an acceptable ground for restricting fundamental rights. Manufacturers of medicinal products, importers of medicinal products and persons on whose behalf an importer's mandatory reserve supplies are maintained are also paid compensation for maintaining mandatory reserve supplies, which reduces the constitutional concerns raised by the proposed amendments from the perspective of fundamental rights. As regards the proposal introducing an interest rate cap, it should be noted that the cap would apply only if interest rates were to increase significantly from their current level.

The Act on Mandatory Reserve Supplies lays down the groups of medicinal products covered by the stockpiling obligation, while the Decree on Mandatory Reserve Supplies contains more detailed provisions on the medicinal substances included within those groups. Accordingly, the grounds for the restrictions on fundamental rights are laid down at the level of an Act. The proposed amendments to the groups of medicinal products covered by the Act on Mandatory Reserve Supplies have been drafted so as to be clearly defined and sufficiently precise.

The proposal to amend the Act on Mandatory Reserve Supplies so as to empower the Ministry of Social Affairs and Health to impose information and monitoring obligations on parties subject to the stockpiling obligation is also relevant from the perspective of the freedom to engage in commercial activities. The purpose of the proposal is to ensure that goods drawn from compulsory stocks are used only for the purpose specified in the decision; the proposal therefore has a compelling and valid justification.

The effects of the proposal on fundamental rights are also discussed above in section 4.2.2.2.

According to section 27 of the Act on the Autonomy of Åland (1144/1991), the State has legislative competence in matters related to medicines.

Consequently, the legislative proposal may be processed in the normal legislative procedure.

Resolution

Based on the foregoing, the following Government Proposal is submitted to Parliament for approval:

Act

amending the Act on Mandatory Reserve Supplies

In accordance with the decision of Parliament

section 3(1)(4), section 4(1)(1), (3), (5), (7) and (9)–(12) and subsection 3, section 5(1)(1), section 6(1), section 7(1)(1) and subsection 3, section 8, section 10(2), section 11(1), section 12(1) and (3), and sections 15 and 16 of the Act on Mandatory Reserve Supplies for Medicines (979/2008) are *amended*, of which section 4(1)(7), (9) and (12) were last amended by Act 294/2012, section 4(3), section 11(1) and section 15 by Act 776/2009, and section 16 by Act 554/2020; and

a new section 7(5), sections 8a and 20a are *introduced* to the Act as follows:

Section 3

Definitions

For the purposes of this Act:

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4) *health institution* means a health centre, hospital or separate healthcare unit maintained by a wellbeing services county, the City of Helsinki, the HUS Group or the Province of Åland, an institution referred to in the Act on Special Care for Persons with Intellectual Disabilities (519/1977), a State mental hospital, and a private healthcare service provider supplying hospital care services to a wellbeing services county, the City of Helsinki, the HUS Group or the Province of Åland.

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Section 4

Storage methods, pharmaceutical substances and products

The stockpiling obligation applies to the medicinal substances and medicinal products belonging to the following groups of medicinal products:

1) Antimicrobials;

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3) from among medicinal products for cardiovascular diseases and diuretics: medicinal products for coronary artery disease, medicinal products for heart failure and cardiac arrhythmias, antihypertensive medicinal products, lipid-modifying agents, and diuretics;

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5) from among analgesics and antirheumatic medicinal products: opioids, non-steroidal anti-inflammatory drugs, anilides and gabapentinoids, and medicinal products for rheumatoid arthritis;

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7) from among antidotes, vaccines, immune sera and immunoglobulins: essential medicinal products used in the treatment of poisoning, immune sera and vaccines used for the treatment and prevention of hepatitis A and B, rabies and tetanus, vaccines and other medicinal products included in the National Vaccination Programme, and normal human immunoglobulin;

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9) from among medicinal products for gastrointestinal diseases: medicinal products used in the treatment of gastric and duodenal ulcers, medicinal products for inflammatory bowel diseases, and bile acid preparations;

10) from among psychotropic medicinal products: antipsychotics, anxiolytics, antidepressants, and mood stabilisers;

11) from among neurological medicinal products: antiepileptics and medicinal products for Parkinson's disease;

12) from among ophthalmological medicinal products: medicinal products for glaucoma, antimicrobial medicinal products and corticosteroids for ophthalmic use, as well as mydriatic and ophthalmic anaesthetic eye drops.

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More detailed provisions on the medicinal substances, including their pharmaceutical forms, falling within the groups of medicinal products referred to in subsection 1 and subject to the stockpiling obligation shall be laid down by Government decree. Every two years, the Finnish Medicines Agency (Fimea) must submit to the Ministry of Social Affairs and Health a report on the need to revise the list of medicinal substances set out in the Government Decree. Where necessary, the Finnish Medicines Agency shall determine, by product designation, which medicinal products contain the medicinal substances specified in the Government Decree and in which those medicinal substances are of primary therapeutic significance. The Finnish Medicines Agency (Fimea) may also decide, for individual medicinal substances and medicinal products, that the stockpiling obligation does not apply to all pharmaceutical forms.

Section 5

Stockpiling obligation of a pharmaceutical factory

A manufacturer of medicinal products shall maintain mandatory reserve supplies of imported medicinal substances and the excipients, additives and packaging materials used in the manufacture of medicinal products from those substances or, instead thereof, of the medicinal products manufactured by the manufacturer, as follows:

1) a quantity corresponding to the average consumption for ten months of the medicinal products referred to in section 4(1)(1) and (2); however, in the case of medicinal products for the treatment of HIV infection, only a quantity corresponding to the average consumption for three months.

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Section 6

Importer's stockpiling obligation

An importer of medicinal products shall maintain mandatory reserve supplies of imported medicinal products as follows:

1) a quantity corresponding to the average consumption for eight months of the medicinal products referred to in section 4(1)(1); however, in the case of medicinal products for the treatment of HIV infection, only a quantity corresponding to the average consumption for three months;

2) a quantity corresponding to the average consumption for ten months of the medicinal products referred to in section 4(1)(2);

3) a quantity corresponding to the average consumption for six months of the medicinal products referred to in section 4(1)(3)–(7), excluding vaccines and other medicinal products included in the National Vaccination Programme; and

4) a quantity corresponding to the average consumption for three months of the medicinal products referred to in section 4(1)(8)–(14).

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Section 7

Storage obligation of the health institution

The operator of a health institution shall maintain mandatory reserve supplies of the medicinal products used in the health institution as follows:

1) a quantity corresponding to the average consumption for six months of the medicinal products referred to in section 4(1)(1) and (3)–(7), excluding vaccines and other medicinal products included in the National Vaccination Programme; however, in the case of medicinal products for the treatment of HIV infection, only a quantity corresponding to the average consumption for three months.

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The stockpiling obligation of a private healthcare service provider applies only to the consumption of medicinal products relating to services provided to a wellbeing services county, the City of Helsinki, the HUS Group or the Province of Åland. Such services include services procured by a wellbeing services county, the City of Helsinki, the HUS Group or the Province of Åland through outsourced service arrangements or by means of a service voucher.

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More detailed provisions may be laid down by Government decree on which medicinal substances included in the group of medicinal products referred to in section 4(1)(13) are to be stockpiled exclusively by the operator of a health institution.

Section 8

Stockpiling obligation of the Finnish Institute for Health and Welfare

The National Institute for Health and Welfare shall be obliged to store vaccines and other medicines included in the national vaccination programme in quantities equivalent to the average consumption of six months. The obligation does not apply to influenza vaccines or to vaccines that are administered on a seasonal basis in a corresponding manner. Where the

National Vaccination Programme is amended, the quantity corresponding to six months' consumption shall be estimated.

Section 8a

Consumption to be disregarded when calculating consumption

When calculating the average consumption forming the basis for determining the quantity subject to the stockpiling obligation, the procurement of medicinal products for State emergency stockpiles or other equivalent stockpiles shall not be taken into account. The Finnish Medicines Agency shall notify the parties subject to the stockpiling obligation of the consumption referred to above.

Section 10

Organisation of the mandatory reserve supplies in special cases

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More detailed provisions on the conditions, requirements and application procedure for substitution of the stockpiling obligation may be laid down by Government decree.

Section 11

Exemption from the stockpiling obligation

The Finnish Medicines Agency (Fimea) may, upon application, exempt an entity subject to the stockpiling obligation, in whole or in part, from that obligation, provided that the exemption does not compromise the security of supply of medicines. An exemption may be granted only if, in addition, compliance with the stockpiling obligation would cause the entity subject to the stockpiling obligation particular difficulties or if maintaining the reserve supplies is manifestly unnecessary. More detailed provisions on the grounds on which an entity subject to the stockpiling obligation may be exempted from that obligation may be laid down by Government Decree. The Finnish Medicines Agency shall determine the period for which the exemption remains valid.

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Section 12

Compensation payable to a party subject to the stockpiling obligation

Compensation for maintaining mandatory reserve supplies shall be paid to a pharmaceutical manufacturer, an importer of medicinal products or the person on whose behalf the importer's mandatory reserve supplies are maintained. The amount of compensation shall be calculated on the basis of the reference rate of the Bank of Finland referred to in section 12 of the Interest Act (633/1982), taken into account up to a maximum of five percentage points, plus two percentage points, applied to the capital tied up in the acquisition of the goods held as mandatory reserve supplies. The compensation payable for maintaining the solutions referred to in section 4(1), point 2, is two percentage points higher than the compensation payable for maintaining other medicinal products.

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As capital tied up in the acquisition cost of the goods held as mandatory reserve supplies, the lowest actual amount of capital during each quarter of the calendar year shall be taken into account separately.

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Section 15

Reduction below the required level of mandatory reserve supplies

The reserve supplies of any product subject to the stockpiling obligation may not fall below the level required under the Act.

However, the mandatory reserve supplies of a manufacturer or importer of medicinal products may fall by no more than 10% below the required level for a period not exceeding two weeks, once per calendar year, due to an shortage of medicinal products. The reduction shall be notified to the Finnish Medicines Agency within two weeks from the date on which it commenced. However, the mandatory reserve supplies of a health institution may fall below the required level where the use of the mandatory reserve supplies is necessary for the operation of the health institution because of an shortage of medicinal products, or where a product subject to the stockpiling obligation, other than one already included in the mandatory reserve supplies, is at risk of becoming unsuitable for its intended use before it can be placed into storage. However, the mandatory reserve supplies of the Finnish Institute for Health and Welfare may fall below the required level where the use of the mandatory reserve supplies is necessary because of an shortage of vaccines or where a vaccine-preventable disease threatens to cause an epidemic of a communicable disease. Once the shortage or the threat of an epidemic of a communicable disease has ended, the party subject to the stockpiling obligation shall, without delay, replenish its stocks to the required level.

Upon application, the Finnish Medicines Agency may grant a party subject to the stockpiling obligation authorisation to reduce mandatory reserve supplies below the level required under this Act if a product held as mandatory reserve supplies, or another product subject to the stockpiling obligation, is at risk of becoming unsuitable for its intended use during its storage period. The Finnish Medicines Agency may also grant authorisation to reduce the mandatory reserve supplies where the consumption of a product subject to the stockpiling obligation by the party subject to the stockpiling obligation decreases to a very significant extent and the granting of the authorisation does not jeopardise security of supply. The Finnish Medicines Agency may also grant authorisation to reduce mandatory reserve supplies below the required level if, owing to a temporary shortage affecting a product subject to the stockpiling obligation, the production or operations of the party subject to the stockpiling obligation would be at risk of interruption or substantial reduction without the use of the mandatory reserve supplies, provided that granting such authorisation does not jeopardise security of supply. When granting permission to maintain reserve supplies below the required level, the Finnish Medicines Agency shall determine the extent of the permitted shortfall and the period within which the entity subject to the stockpiling obligation must replenish its reserve supplies to the level required under the Act.

The Finnish Medicines Agency may issue more detailed provisions on the submission and content of applications for authorisation to reduce mandatory reserve supplies below the required level.

Section 16

Use of mandatory reserves in special circumstances

Where there are widespread problems in the availability of medicinal substances, medicinal products, excipients or additives used in the manufacture of medicinal products, or packaging materials, which are beyond the control of pharmaceutical manufacturers or importers, or where there is a likely threat of such problems, the Ministry of Social Affairs and Health may, in order to safeguard security of supply and on a proposal from the Finnish Medicines Agency, decide that the quantity of products subject to the stockpiling obligation may be reduced below the level required under the Act. The Ministry's decision may specify the purposes for which, and the quantities in which, products subject to the stockpiling obligation may be used, as well as the information and monitoring obligations of the party subject to the stockpiling obligation. The decision shall indicate a date by which the size of the mandatory reserve shall again comply with this Act.

The Ministry of Social Affairs and Health may also adopt a decision referred to in subsection 1 for the purpose of providing international assistance. Such a decision may be adopted only if it does not significantly jeopardise security of supply.

Section 20a

Appeals

A request for administrative review may be made in respect of a decision referred to in section 10, section 11, section 13 or section 15(3). The Administrative Procedure Act (434/2003) provides for requests of administrative review.

This Act enters into force on [day] [month] 20[year]. However, section 12 will not enter into force until 1 January 2028.

Helsinki, xx xx 20xx

Prime Minister

First name Last name

..Minister First name Last name

Act

amending the Act on Mandatory Reserve Supplies

In accordance with the decision of Parliament

section 3(1)(4), section 4(1)(1), (3), (5), (7) and (9)–(12) and subsection 3, section 5(1)(1), section 6(1), section 7(1)(1) and subsection 3, section 8, section 10(2), section 11(1), section 12(1) and (3), and sections 15 and 16 of the Act on Mandatory Reserve Supplies for Medicines (979/2008) are *amended*, of which section 4(1)(7), (9) and (12) were last amended by Act 294/2012, section 4(3), section 11(1) and section 15 by Act 776/2009, and section 16 by Act 554/2020; and

a new section 7(5), sections 8a and 20a are *introduced* to the Act as follows:

Existing Act	*Proposal*
	Section 3
Definitions	*Definitions*
For the purposes of this Act:	For the purposes of this Act:
1) *party subject to the stockpiling obligation* means a manufacturer of medicinal products, an importer of medicinal products, the operator of a health institution, and the Finnish Institute for Health and Welfare;	1) *party subject to the stockpiling obligation* means a manufacturer of medicinal products, an importer of medicinal products, the operator of a health institution, and the Finnish Institute for Health and Welfare;
2) *stockpiling obligation* means the obligation under this Act to maintain stocks of medicinal substances and medicinal products, devices used for the administration of medicinal products, excipients and additives used in the manufacture of medicinal products, and packaging materials;	2) *stockpiling obligation* means the obligation under this Act to maintain stocks of medicinal substances and medicinal products, devices used for the administration of medicinal products, excipients and additives used in the manufacture of medicinal products, and packaging materials;
3) *mandatory reserve supplies* means the stocks of products that a party subject to the stockpiling obligation is required to maintain in Finland under this Act; and	3) *mandatory reserve supplies* means the stocks of products that a party subject to the stockpiling obligation is required to maintain in Finland under this Act; and
4) *health institution* means a health centre, hospital or separate healthcare unit maintained by a municipality, joint municipal authority or the Province of Åland, an institution referred to in the Act on Special Care for Persons with Intellectual Disabilities (519/1977), a State mental hospital, and a private healthcare service provider supplying	4) *health institution means a health centre, hospital or separate healthcare unit maintained by a wellbeing services county, the City of Helsinki, the HUS Group* or the Province of Åland, an institution referred to in the Act on Special Care for Persons with Intellectual Disabilities (519/1977), a State

Existing Act	*Proposal*
hospital care services to a municipality, joint municipal authority or the Province of Åland.	mental hospital, and a private healthcare service provider supplying hospital care services *to a wellbeing services county, the City of Helsinki, the HUS Group*, or the Province of Åland.
Medicinal product, medicinal substance and medicinal preparation are defined in sections 3–5 of the Medicines Act (395/1987).	Medicinal product, medicinal substance and medicinal preparation are defined in sections 3–5 of the Medicines Act (395/1987).
Section 4	Section 4
Storage methods, pharmaceutical substances and products	*Storage methods, pharmaceutical substances and products*
The stockpiling obligation applies to the medicinal substances and medicinal products belonging to the following groups of medicinal products:	The stockpiling obligation applies to the medicinal substances and medicinal products belonging to the following groups of medicinal products:
1) from among antimicrobials: antibiotics, sulfonamides and other synthetic antimicrobial medicinal products;	1) *antimicrobials*;
2) from among medicinal products used in the treatment of electrolyte and fluid balance disorders and for parenteral nutrition: basic infusion solutions, nutritional solutions and albumin solutions;	2) from among medicinal products used in the treatment of electrolyte and fluid balance disorders and for parenteral nutrition: basic infusion solutions, nutritional solutions and albumin solutions;
3) from among medicinal products for cardiovascular diseases and diuretics: medicinal products for angina pectoris, medicinal products for heart failure and cardiac arrhythmias, antihypertensive medicinal products, and diuretics;	3) from among medicinal products for cardiovascular diseases and diuretics: medicinal products for *coronary artery disease*, medicinal products for heart failure and cardiac arrhythmias, antihypertensive medicinal products, *lipid-modifying agents*, and diuretics;
4) from among medicinal products for metabolic and endocrine disorders: medicinal products for diabetes, medicinal products for thyroid disorders, and corticosteroids;	4) from among medicinal products for metabolic and endocrine disorders: medicinal products for diabetes, medicinal products for thyroid disorders, and corticosteroids;
5) from among analgesics, antirheumatic and antipyretic medicinal products: morphine derivatives and antipyretic analgesics;	5) from among analgesics *and antirheumatic medicinal products: opioids, non-steroidal anti-inflammatory drugs, anilides and gabapentinoids, and medicinal products for rheumatoid arthritis*;
6) medicinal products used in local anaesthesia and general anaesthesia;	6) medicinal products used in local anaesthesia and general anaesthesia;
7) from among antidotes, vaccines, immune sera and immunoglobulins: essential medicinal products used in the treatment of poisoning, immune sera and vaccines used for the treatment and prevention of hepatitis A and B, rabies and tetanus, and normal	7) from among antidotes, vaccines, immune sera and immunoglobulins: essential

Existing Act	*Proposal*
8) from among medicinal products for respiratory diseases: medicinal products for asthma;	8) from among medicinal products for respiratory diseases: medicinal products for asthma;
9) from among medicinal products for gastrointestinal diseases: medicinal products used in the treatment of gastric and duodenal ulcers;	9) from among medicinal products for gastrointestinal diseases: medicinal products used in the treatment of gastric and duodenal ulcers, *medicinal products for inflammatory bowel diseases, and bile acid preparations*;
10) from among psychotropic medicinal products: antipsychotics, anxiolytics and antidepressants;	10) from among psychotropic medicinal products: antipsychotics, *anxiolytics, antidepressants, and mood stabilisers;*
11) from among neurological medicinal products: antiepileptics and medicinal products for Parkinsonism;	11) from among neurological medicinal products: antiepileptics and *medicinal products for Parkinson's disease*;
12) from among ophthalmological medicinal products: medicinal products for glaucoma and antimicrobial medicinal products for ophthalmic use;	12) from among ophthalmological medicinal products: medicinal products for glaucoma, antimicrobial medicinal products *and corticosteroids for ophthalmic use, as well as mydriatic and ophthalmic anaesthetic eye drops*;
13) antineoplastic medicinal products and medicinal products used for the treatment of their adverse effects, immunostimulants, immunosuppressants, antithrombotic agents and haemostatics;	13) antineoplastic medicinal products and medicinal products used for the treatment of their adverse effects, immunostimulants, immunosuppressants, antithrombotic agents and haemostatics;
14) from among veterinary medicinal products: rabies vaccines and medicinal products required for the treatment or prevention of diseases in, and the handling of, food-producing animals.	14) from among veterinary medicinal products: rabies vaccines and medicinal products required for the treatment or prevention of diseases in, and the handling of, food-producing animals.
Where a party subject to the stockpiling obligation maintains stocks of a medicinal substance instead of a medicinal product, it shall also maintain stocks of all excipients, additives and packaging materials required for the manufacture of the corresponding medicinal product in the quantities required to comply with the stockpiling obligation.	Where a party subject to the stockpiling obligation maintains stocks of a medicinal substance instead of a medicinal product, it shall also maintain stocks of all excipients, additives and packaging materials required for the manufacture of the corresponding medicinal product in the quantities required to comply with the stockpiling obligation.
More detailed provisions on the medicinal substances included in the groups of medicinal products referred to in subsection 1 that are subject to the stockpiling obligation shall be laid down by Government decree. Every two years, the Finnish	More detailed provisions on the medicinal substances, *including their pharmaceutical*

Existing Act

Medicines Agency (Fimea) must submit to the Ministry of Social Affairs and Health a report on the need to revise the list of medicinal substances set out in the Government Decree. Where necessary, the Finnish Medicines Agency shall determine, by product designation, which medicinal products contain the medicinal substances specified in the Government Decree and in which those medicinal substances are of primary therapeutic significance. The Finnish Medicines Agency (Fimea) may also decide, for individual medicinal substances and medicinal products, that the stockpiling obligation does not apply to all pharmaceutical forms.

Section 5

Stockpiling obligation of a pharmaceutical factory

A manufacturer of medicinal products shall maintain mandatory reserve supplies of imported medicinal substances and the excipients, additives and packaging materials used in the manufacture of medicinal products from those substances or, instead thereof, of the medicinal products manufactured by the manufacturer, as follows:

1) a quantity corresponding to the average consumption for ten months of the medicinal products referred to in section 4(1)(1) and (2);

2) a quantity corresponding to the average consumption for six months of the medicinal products referred to in section 4(1)(3)–(7); and

3) a quantity corresponding to the average consumption for three months of the medicinal products referred to in section 4(1)(8)–(14).

The average consumption forming the basis

Proposal

forms, included in the groups of medicinal products referred to in subsection 1 that are subject to the stockpiling obligation shall be laid down by Government decree. Every two years, the Finnish Medicines Agency (Fimea) must submit to the Ministry of Social Affairs and Health a report on the need to revise the list of medicinal substances set out in the Government Decree. Where necessary, the Finnish Medicines Agency shall determine, by product designation, which medicinal products contain the medicinal substances specified in the Government Decree and in which those medicinal substances are of primary therapeutic significance. The Finnish Medicines Agency (Fimea) may also decide, for individual medicinal substances and medicinal products, that the stockpiling obligation does not apply to all pharmaceutical forms.

Section 5

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1) a quantity corresponding to the average consumption for ten months of the medicinal products referred to in section 4(1)(1) and (2); *however, in the case of medicinal products for the treatment of HIV infection, only a quantity corresponding to the average consumption for three months;*

2) a quantity corresponding to the average consumption for six months of the medicinal products referred to in section 4(1)(3)–(7); and

3) a quantity corresponding to the average