1.1 Principal impacts

1.1.1 Economic impact

The proposed amendments to the Act on Obligatory Stockpiling are estimated to have some economic impact on public finances and businesses.

As regards public finances, it is unclear whether the proposal will increase or decrease costs overall. Costs may increase, for example, as a result of the proposal to change the review period for compensation paid for obligatory stockpiling from six-month periods to calendar quarters (Section 12) and the proposal to introduce an administrative review procedure (Section 20a). On the other hand, costs may decrease as a result of, among other things, the proposal to introduce an interest rate cap (Section 12), should interest rates rise significantly from their current level, and the proposal to disregard certain acquisitions when calculating the average consumption forming the basis of the stockpiling obligation (Section 8a). No funding has yet been allocated for the proposed amendments.

For businesses, the proposed amendments to the Act on Obligatory Stockpiling are generally expected to reduce costs overall. Costs arising from the obligatory stockpiling of medicinal products are likely to decrease, for example, due to the proposal to reduce the size of importers' obligatory stocks of antimicrobial medicinal products (Section 6), the proposal to disregard certain acquisitions when calculating the average consumption forming the basis of the stockpiling obligation (Section 8a), and the proposal to allow importers and pharmaceutical manufacturers to fall below their stockpiling obligation on their own initiative (Section 15). Conversely, the proposal to introduce an interest rate cap (Section 12) may increase costs for businesses if interest rates rise significantly from their current level. However, the overall magnitude of the economic impacts remains unclear.

1.1.2 Other effects on people and society

1.1.2.1 Impact on public authorities

The proposal is expected to have a significant overall impact on public authorities. In this respect, the impacts concern not only public-sector entities subject to stockpiling obligations, but also the supervisory authorities responsible for enforcing the Act on Obligatory Stockpiling and the Ministry of Social Affairs and Health. The financial impacts on public authorities have been described above.

As regards the bodies maintaining public healthcare operating units, the proposal would mean that municipalities and joint municipal authorities would no longer be included among such bodies. References in the Act on Obligatory Stockpiling to municipalities and joint municipal authorities would be replaced by references to wellbeing services counties, the City of Helsinki and the HUS Group. The amendment would take into account the changes to responsibility for organising health and social services resulting from the health and social services reform. Through this change, the proposal would alter the entities subject to stockpiling obligations. However, the practical impact of the amendment is mitigated by the fact that, following the health and social services reform, wellbeing services counties have already been responsible for the obligatory stockpiling of medicinal products.

In addition, the proposal would expand the right of public healthcare operating units to fall below their stockpiling obligation independently (Section 15). Furthermore, proposals affecting all entities subject to stockpiling obligations, such as the proposal concerning authorisation to fall below the stockpiling obligation on the basis of a significant decrease in consumption (Section 15), would also affect the bodies maintaining public healthcare operating units. The financial impacts on wellbeing services counties have been described above.

As regards the Finnish Institute for Health and Welfare, the proposal would remove the basis for calculating its stockpiling obligation (Section 8). In addition, the Finnish Institute for Health and Welfare would, under the proposal, be permitted to fall below its stockpiling obligation independently in certain situations (Section 15). Amendments applying to all entities subject to stockpiling obligations, such as the proposal to disregard certain consumption when calculating the average consumption forming the basis of the stockpiling obligation (Section 8a), would also affect the Finnish Institute for Health and Welfare.

As regards the Finnish Medicines Agency, the proposal would expand its powers to grant authorisations to fall below the stockpiling obligation (Section 15). In addition, the proposal allowing entities subject to stockpiling obligations to fall below their obligations independently, to a greater extent than at present and without authorisation from the Finnish Medicines Agency (Section 15), is likely to reduce the number of

applications submitted to the Agency for authorisation and, consequently, the resources required for processing such applications. The proposal requiring the Finnish Medicines Agency to notify entities subject to stockpiling obligations of the consumption that is not to be taken into account when calculating the average consumption forming the basis of the stockpiling obligation (Section 8a) is also likely to result in a minor increase in administrative work.

As regards the National Emergency Supply Agency, the proposed interest rate cap and the shortening of the compensation review period from six-month periods to calendar quarters (Section 12) would affect the compensation procedure administered by the Agency.

The proposal to introduce an administrative review procedure (Section 20a) would affect both the Finnish Medicines Agency and the National Emergency Supply Agency, as such a procedure is currently not available for any type of decision. Furthermore, the introduction of an administrative review procedure would also affect parties wishing to appeal decisions issued by the Finnish Medicines Agency and the National Emergency Supply Agency.

As regards the Ministry of Social Affairs and Health, it is proposed that the Ministry would in future be able to decide on the use of obligatory stocks in emergency situations also where such stocks are used for the provision of international assistance (Section 16). In addition, the content of the Ministry's decision is proposed to be clarified with regard to notification and supervisory obligations.

1.1.2.2 Other impacts

Certain proposals contained in the proposal are relevant from the perspective of the protection of property and the freedom to conduct a business of private entities subject to stockpiling obligations. 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.

These include, for example, the proposal to update the groups of medicinal products covered by the stockpiling obligation (Section 4) and the proposal to grant the Ministry of Social Affairs and Health the authority to impose notification and supervisory obligations (Section 16). On the other hand, the fundamental and human rights impacts of the above-mentioned proposals are not solely negative. The purpose of these proposals is to safeguard security of supply with regard to medicinal products, which is closely linked to the duty of the public authorities under section 19(3) of the Constitution to promote the health of the population.

In addition, the proposal contains propositions that would reduce the existing restrictions on the protection of property and the freedom to conduct a business of private entities subject to stockpiling obligations. These include, for example, the proposal to reduce the stockpiling obligation applicable to importers in respect of antimicrobial medicinal products (Section 6) and the proposal to allow pharmaceutical manufacturers and importers to fall below their stockpiling obligation independently in certain situations (Section 15).