

Impact of the Act

The bill extends the right to import medicinal products and active ingredients of medicinal products to hospital pharmacies. The implementation of the amendment may be expected to have an impact in the following areas: social impact, economic impact, impact on regional development and governance. The impact of the amendments proposed by the bill will be assessed by the target groups. The impacts related to the availability and quality of healthcare services and the organisation of work in hospitals and hospital pharmacies have been assessed under the social impact.

Impact target group 1 – patients

The entire population, i.e. the people who have or may have a medical need as of the entry into force of the amendment, is affected by the amendment.

Area of impact: social impact

As a result of the amendment, hospitals will be able to plan their medicinal product supply somewhat better than currently, have up-to-date information on the possible supply of the medicinal product, and thereby ensure a stable supply, which will, in turn, indirectly contribute to ensuring that the need for treatment of patients is satisfied. Granting hospital pharmacies the right to import medicinal products will improve the availability of medicinal products used in hospital care, which will also indirectly have a positive impact on ensuring the quality and continuity of the healthcare service provided to patients.

Impact target group 2 – hospitals and hospital pharmacies

The proposed amendment will affect hospitals in terms of the opportunities and obligations of hospital pharmacies, and therefore, these target groups will be considered together in the impact assessment. As at 1 April 2024, according to the State Agency of Medicines, there are 24 hospital pharmacies in Estonia, in total, two of which are branch pharmacies.¹ Most of them are located in the hospitals of the Hospital Network Development Plan², but not all hospitals of the Hospital Network Development Plan have their own hospital pharmacies. In such cases, the hospital is supplied by the hospital pharmacy of another hospital operator by agreement.

Area of impact: social impact

The amendment of the Medicinal Products Act will improve the availability of medicinal products to hospital pharmacies. The amendment will not have a significant impact on the doctors working in hospitals because, as in the past, decisions on the choice of medicinal products will be made by the health care provider (hospital) and not by the doctor. Compared to the past, the hospital will have more options for this. The amendment will bring about changes in the operation of hospital pharmacies, as the import of medicinal products will have to comply with the requirements for the import of medicinal products, but these will not presumably involve significant adaptation difficulties.

If a hospital pharmacy does not wish to use the opportunity created by the proposed amendment and import medicinal products directly, it will continue its practice of obtaining

¹ Map of pharmacies of the State Agency of Medicines. Available at: <https://apteegid.ravimiamet.ee/>.

² Regulation No. 105 of the Government of the Republic of 2 April 2003 'Hospital Network Development Plan'. Available at: <https://www.riigiteataja.ee/akt/105042023014?leiaKehtiv>.

medicinal products similarly to the current practice and the proposed amendment is not expected to worsen the availability of medicinal products in this case. In Finland, where hospital pharmacies have the right to import medicinal products for the activities of their hospital, hospital district, or health centre, hospital pharmacies use this possibility in nearly 30 cases per year (estimated number of notifications sent to the Finnish Medicines Agency, information received from the Finnish Ministry of Social Affairs and Health). It can therefore be assessed that, this method is, in particular, an exceptional option for improving access to medicinal products in cases where the normal supply chain does not allow the medicinal product to be delivered to the patient quickly enough.

Area of impact: economic impact

Better access to medicinal products for hospitals can lower the prices of medicines for hospitals, enable hospitals to better plan their treatment costs, and also have a positive impact on a more targeted use of health insurance funds. In 2023, according to the statistics on human medicines issued by the State Agency of Medicines³, medicinal products were supplied to hospital pharmacies from pharmaceutical wholesalers for 129 million euros, which represents 28% of the total volume of the market of medicinal products.

The savings resulting from the proposed amendment are difficult to assess. If the importing right could be used to achieve savings of up to 0.1% due to the increase in the number of participants in the procurement, this would mean savings of up to 36,400 euros for the North Estonia Medical Centre and up to 31,700 euros for the Tartu University Hospital (calculated on the basis of the annual report data for 2023). Assuming that both of those major hospitals exercise the right to import the entire range of medicinal products, that the number of participants in the procurement increases, and that at least a minimal price decrease can be achieved, savings in the order of 50,000 euros can be estimated for the two hospitals. It must be taken into account that this estimate is highly uncertain and based on indirect assumptions and calculations.

At the same time, the proposed amendment will enable hospitals to make independent decisions on the choice of medicinal products and will give them the possibility to choose from a wider range of products. However, the expenditure of hospitals on importing medicines may increase somewhat, as they do not yet have established distribution channels or experience. In order to reduce the risk of undesirable effects, hospitals can, for example, cooperate in joint procurements.

Hospitals and hospital pharmacies will not acquire wholesale or retail rights for medicinal products by way of the amendment; in the case of supplying the hospital based on an agreement with another hospital operator, they will not be allowed to continue to apply a mark-up on medicinal products within the limits established by Regulation No. 36 of the Government of the Republic of 21 February 2005 ‘Threshold values for mark-ups in wholesale and retail trade of medicinal products and the procedure for their implementation’⁴. This means that the proposed amendment will not create a business opportunity for hospitals or hospital pharmacies, as they will not be able to increase the price of the medicinal product when supplying another hospital, and the hospitals themselves will not participate in tenders from other hospitals.

³ Statistics on human medicines from the State Agency of Medicines. Available at: <https://www.ravimiamet.ee/en/statistics/statistics-medicines>.

⁴ Regulation No. 36 of the Government of the Republic of 21 February 2005 ‘Threshold values for mark-ups in wholesale and retail trade of medicinal products and the procedure for their implementation’. Available at: <https://www.riigiteataja.ee/en/eli/528032016007/consolide>.

Area of impact: impact on regional development

The proposed amendment will make it easier for hospital pharmacies in larger regions, which generally have more staff resources, to implement the option of importing medicinal products and the related obligations in practice. Thus, the change may have an undesirable effect on smaller and/or rural hospital pharmacies, but they will be able to conduct joint procurements with larger hospital pharmacies to reduce the risk.

Impact target group 3 – pharmaceutical wholesalers

In 2023, according to the statistics on medicinal products for human use from the State Agency of Medicines⁵, 66 companies with a wholesale distribution licence for medicinal products were operating in Estonia. 28 companies were engaged in the distribution of medicinal products for human use to general and hospital pharmacies and other institutions. Approximately 82% of the market volume of human medicinal products was accounted for by the turnover of the two largest wholesalers: Magnum Medical OÜ (48.3%) and Tamro Eesti OÜ (33.4%). They were followed by Baltfarma OÜ (5.7%), the Health Insurance Fund (4.5%), Roche Eesti OÜ (4.2%), and Oribalt Tallinn AS (1.2%). The remaining 22 wholesalers accounted for less than 3% of the market volume.

Area of impact: economic impact

Sales to hospital pharmacies account for 28% (129 million euros) of the total wholesale market of medicinal products, according to the statistics on human medicines from the State Agency of Medicines⁶. As in the current circumstances, pharmaceutical wholesalers will still have the possibility to participate in hospital procurement tenders, where, by offering an appropriate price and range of products, they will retain the opportunity to distribute medicinal products to hospitals. The use of hospital imports will have an impact on the turnover of wholesalers, with the extent of the impact depending, in particular, on the willingness of the hospitals themselves and the possibility of obtaining medicinal products from EU wholesalers more widely, as well as on the willingness of foreign qualified wholesalers or pharmaceutical companies (who must hold GMP or GDP certificates in accordance with the requirements imposed on them) to submit their bids. Given the known distribution channels and experience of wholesalers, the amendment may increase the interest of wholesalers in finding the necessary medicinal product for the hospital as quickly and cheaply as possible.

The proposed amendment will make it possible to increase the competition in the pharmaceutical market by also allowing, in addition to pharmaceutical wholesalers registered in Estonia, eligible EU wholesalers to participate in hospital procurement tenders.

The amendment may have an undesirable effect on wholesalers of medicinal products registered in Estonia. Considering that hospital pharmacies will have the opportunity, not the obligation, to import medicinal products themselves, it may be assumed that hospital pharmacies will, at least initially, use the right to import medicinal products rather modestly; for example, in a situation where it is not possible to obtain medicinal products required for hospital treatment through a wholesaler or if the hospital has experience of delays in

⁵ Statistics on human medicines from the State Agency of Medicines. Available at: <https://www.ravimiamet.ee/en/statistics/statistics-medicines>.

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deliveries, due to which the aim is to ensure the stability and availability of stocks of life-saving or similar medicinal products. It is therefore unlikely that, at least initially, there will be a significant negative impact on the turnover of wholesalers. At the same time, a later increase in the economic impact cannot be ruled out, if hospital pharmacies wish to start importing medicinal products themselves in a larger range and volume.

Impact target group 4 – the State Agency of Medicines

The affected target group among all state authorities is the State Agency of Medicines.

Area of impact: impact on governance

The amendment will establish requirements for the import of medicinal products to hospital pharmacies, including the requirement to notify the State Agency of Medicines of the import of medicinal products, to submit reports to the State Agency of Medicines and, in the case of import of unauthorised medicinal products, to apply for a marketing authorisation for unauthorised medicinal products issued by the State Agency of Medicines. The holder of a wholesale distribution licence still has similar notification and reporting obligations, which is why these are not new tasks for the State Agency of Medicines, but there may be an increase in the workload of the agency, especially initially, when hospital pharmacies are just beginning to exercise the right to import, including in connection with notifying the parties of changes. Upon the entry into force of the amendments, amendments will need to be made to the customer portal and the SamTrack information system of the State Agency of Medicines.

Conclusion on the significance of the impact of the proposed amendment

The extent and frequency of the impact on the stakeholders will, overall, be average, as the implementation of the amendments may require some adjustments in their work processes, but these are not expected to cause adaptation difficulties, and hospital pharmacies may encounter the import of medicinal products regularly, but not daily. The proposed amendment does not impose an obligation on all hospital pharmacies to import medicinal products. Hospitals and hospital pharmacies will have the opportunity to plan their activities and processes intended for the use of the additional option over a longer period of time.

For hospitals, the prices of medicinal products may decrease and medicinal products may become more accessible. The change may have an undesirable impact on hospitals, in particular smaller and/or rural hospitals, in terms of the cost of importing medicinal products, but this can be mitigated by managing work processes (e.g. through joint procurement). The amendment may have an undesirable effect on the turnover of wholesalers of medicinal products, as increased competition will pressure wholesalers to reduce prices, and their market share will decrease depending on the extent to which hospital pharmacies will take advantage of the opportunity to import medicinal products and active ingredients, and foreign wholesalers or manufacturers of medicinal products will submit bids in tenders.