Formation, replenishment and preservation of the stockpile of medicinal products

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Executive Summary

The stockpile of medicinal products forms a part of the emergency preparedness system of the state, which must ensure the life and health of people. The audit in question focused on the formation, preservation and replenishment of the security stockpile and operation stockpile in the area of government of the Ministry of Social Affairs, as well as the procurement of medicinal products for treating HIV/AIDS. The preparedness of the Ministry for using the stockpiles in an emergency was reviewed, as well.

The National Stockpiles Act regulates issues relating to national stockpiles. The Act determines the classes of national stockpiles and the procedure for their administration, and regulates relations that arise from the establishment, storage, replenishment and use of national stockpiles. The same Act establishes particular Ministries in charge for the administration of security reserves. The preparedness of Ministries for emergencies is regulated in the Emergency Preparedness Act.

Security reserve

The Ministry of Social Affairs organised the formation of the security stockpile of medicinal products and medical supplies and has entered into an agreement with the depositary of the stockpile. The depositary stored and replenished the stockpile in compliance with the decisions of the expert commission organising the medicinal security stockpile within national stockpiles. The audit revealed that the stockpile existed physically in the place of storage and that the composition of the stockpile complied with the reports submitted by the depositary of the stockpile. However, the quantity of the stockpile did not comply with the minimum quantity approved by the Government of the Republic, which must ensure the medicinal supply necessary for resolving an emergency lasting for one month in Estonia. If the current financing scheme is continued, the minimum quantity would be achieved no earlier than in some twenty years.

The storage of the security stockpile entailed unjustified additional costs. Out of the storage costs the general and administrative expenses of the depositary were covered. At the same time, the Ministry did not require the depositary of the security stockpile to submit accurate calculations concerning the costs incurred in storing the stockpile. The Ministry seemed to cover the costs on the assumption that the stockpile had been completed to the full extent.

Prices of medicinal products sold for the purpose of replenishment of the security stockpile were lower than the cost of acquisition of the medicinal products. Since the medicinal products were sold through the pharmacy of the depositary, the revaluation was unjustified and it can be deemed as indirect subsidising of the depositary of the security stockpile.

Operation stockpile

The Health Care Board organised the formation and replenishment of the operation stockpile through agreements made with health care providers. While auditing the operation stockpile of medicinal products and medical supplies it was ascertained that the acquired stockpile existed physically in the place of storage and that the composition of the stockpile complied with the list and composition approved by the Health Care Board as well as with the reports submitted by the depositaries of the stockpile. The medicinal products were fit for use, i.e. the expiry dates of the medicinal products had not expired.

As regards the minimum quantity and location of the operation stockpile, the audit revealed a failure to adhere to the relevant Regulation of the Government of the Republic – the quantities of the operation stockpile accounted for merely 7% of these prescribed. Even though all hospitals and emergency medical care providers (a total of 109) were supposed to form stockpiles, only eight of such entities had an operation stockpile. However, the State Audit Office shares the position of the Health Care Board that, considering the large number of health care providers (incl. emergency medical care providers), all of them probably should not be required to form, preserve and replenish an operation stockpile.

The Minister of Social Affairs lacked specific calculations as to why the operation stockpile must be of the quantity as established by the Regulation of the Government of the Republic. Nor has the Ministry applied for amendment of that Regulation.

Preparedness for emergency

The Ministry of Social Affairs lacked clear risk assessments concerning the security stockpile and the operation stockpile, as well as measures for hedging these risks. These problems are being dealt with now.

The Health Care Board has commenced a critical review of the classes and principles of formation of the stockpile for the purpose of more efficient administration thereof.

The changed situation necessitates the need to amend, first of all, the National Stockpiles Act, and other relevant legislation. The Ministry should decide which stockpile of medicinal products is needed and why. In addition to physical storage of the stockpile, other, more flexible ways should be implemented. Thereby it would be reasonable to determine the ordinary capability of health care providers, i.e. the level of their preparedness for crises, following the exhaustion of which the consumption of the stockpile and the state aid would be commenced.

As regards the stockpile of medicinal products procured within the scope of the national HIV/AIDS programme, the Ministry of Social Affairs has performed the tasks established by the programme in acquiring and using the medicinal products.

Main proposals to the Minister of Social Affairs

- To review the existing procedure for formation and storage of the stockpiles of medicinal products and, being based on risk assessments, to decide which stockpiles and which quantities we would need in critical situations and how to ensure the most rational use of the stockpiles when the need arises. Being based on that analysis, to forward suggestions to the Government of the Republic for amendment of legislation.

- To make a decision on whether to plan a material increase of expenditure relating to stockpiles in the near future or to propose to the Government of the Republic that the existing procedure be amended.

- To intensify the supervision of the Ministry of Social Affairs over the formation of the budget for storage of the security stockpile, incl. to require the depositary of the stockpile to submit the principles and calculations applied in forming the prices of storage and, based on these submissions, decide on the amount of actual costs.

- To require the depositary of the security stockpile to transfer the sum of revaluation of medicinal products sold through the pharmacy of the depositary to the security stockpile budget and to increase and replenish the stockpile out of that sum.

- To establish a procedure pursuant to which reports would be submitted to the Ministry on the use and stock of antiretroviral drugs.

Response of the Minister of Social Affairs

The Minister stated that representatives of the Ministry are currently participating in work groups engaged in the elaboration of a new development strategy and risk assessments concerning the national stockpile. As a result of the work of the said work groups, amendments will be made to the legislation that regulates the given sphere, incl. the stockpiles of medicinal products.

The Minister found that requiring the depositary of the stockpile to submit principles and calculations applied in the formation of prices for individual services included in the costs of the depositary would contribute to the improvement of the Ministry’s supervision over the costs of storage of the security stockpile.

The procedure for revaluation and sales of the stockpile of medicinal products, which the depositary of the stockpile was entitled to decide upon at its own discretion, will from now on be incorporated in the agreement to be made with the depositary.

The Ministry will commence the elaboration of a procedure that requires the submission of reports on the use and stock of antiretroviral drugs to the Ministry this year.

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