

Organisation of compensation of medicines

Has the state been successful in guaranteeing the accessibility and optimal use of medicines?

Report of the National Audit Office to the Riigikogu
Tallinn, 6 September 2012

Summary of audit results

The following was assessed in the course of the audit:

- whether the activity of the state in the area of medicines helps achieve the objectives of the area, i.e. whether objectives exist and whether they can be measured;
- whether medicines are accessible in Estonia; and
- whether the use of medicines in Estonia is optimal, i.e. whether doctors issues prescriptions that are based on active ingredients, whether patients buy cheaper medicines and whether patients actually buy the medicines prescribed for them.

As the importance of medicines grows, it is important that patients are able to buy the medicines prescribed for them and that such medicines are right and safe for the patients. 91 million euros was spent on compensation of medicines in 2011. The budget of medicines has grown constantly: its proportion of the budget of health services has increased slightly and, as the experience of other countries suggests, it is likely to continue growing. The significance of medicines in the provision of health services is also increasing in addition to this, which means that the medicines policy, incl. accessibility and compensation, is becoming increasingly important.

The National Audit Office is of the opinion that the state has not been successful in organising compensation of medicines, because a large number of medicines are prescribed on the basis of the medicine's name, medicines are more expensive than in many other countries and the personal contribution of patients in cost-sharing is among the highest in Europe.

The reasons for this situation are insufficient competition on the pharmaceutical market, the reluctance of doctors to prescribe medicines on the basis of active ingredients and the inability of state agencies to guarantee efficient supervision of the activities of doctors and pharmacists. Other reasons include the limited awareness and purchasing power of patients.

■ **The Ministry of Social Affairs has failed to guarantee effective competition.** The pharmaceutical wholesale market in Estonia is dominated by two wholesalers, who hold more than 80% of the market. These two wholesalers are the owners of many (and the suppliers of most) pharmacies, which is why competition on the retail market is poor and it is difficult for third parties to enter. A restriction on the establishment of pharmacies was introduced in 2006 to promote competition on the market and to reduce the closure of country pharmacies. However, this restriction has failed to meet these goals. The minister has been advised of the condition of competition several times, but nothing has been done to improve the situation.

■ **Supervision of doctors and pharmacies has been inefficient and does not guarantee that patients can buy cheap medicines.** Although the Estonian Health Insurance Fund and the State Agency of Medicines supervise both doctors and pharmacies, the situation in the prescribing of medicines has not improved significantly and medicines with reference prices are not being sold in pharmacies. The Health Board has never inspected the activity of doctors in the prescribing of medicines despite being obliged to do so. Implementation of a 'supervision module' of digital prescriptions could increase the

efficiency of supervision.

■ **The proportion of the total cost of medicines that patients have to cover is higher in Estonia than the European average.** Data for 2008 indicate that the average contribution of patients to the cost of medicines or cost-sharing was 18.9% in Europe. In Estonia in 2011, the same figure was 34.5%. Only some countries in the European Economic Area apply cost-sharing that is higher than in Estonia. Large cost-sharing is a result of the reasons described above.

■ **Medicines are expensive and the selection is smaller than on other similar markets.** A comparison of the retail prices of medicines (incl. VAT) in Estonia, Latvia, Lithuania, Finland, Sweden and Slovakia indicated that the prices of packaged medicines in Estonia are similar to those in Latvia. There were some packaged medicines which cost less in Latvia than in Estonia, but prices in Estonia were still 6.9% higher when calculated proportionally. On average, the prices of medicines in Estonia were 17.5% higher than in Lithuania and 32.2% higher than in Slovakia. The prices in Finland were 17.8% and in Sweden 28.7% higher than in Estonia. The number of medicines for which price agreements had been entered into was also higher in the abovementioned countries than in Estonia.

■ **Entering medicines in the list of medicines distributed at a discount takes longer than prescribed.** Processing new medicines took 2.8 times longer than prescribed. Of all of the applications processed by the Committee for Medicinal Products, 30 were entered in the list of medicines distributed at a discount in 2011. Processing these applications took 501 days on average instead of the required 180 days. Generic medicines were included in the list on time.

■ **Only 45% of prescriptions were issued as prescriptions based on active ingredients during the audited period (this increased to 68% during the audit).**

The requirement of issuing prescriptions based on active ingredient has been in force for seven years, but no changes have occurred in this time. This is why many patients are buying expensive medicines. The analysis carried out by the National Audit Office indicated that approximately one-third of medicines with widely used active ingredients that are subject to a 75-100% discount are bought for prices higher than the reference price. As the cost of a medicine is compensated on the basis of the reference price, buying medicines for a higher price increases the costs incurred by patients. Many prescriptions were issued in such a way that patients were unable to buy cheaper medicines, and in addition to this, cheaper medicines were often not even available in pharmacies. The calculations of the National Audit Office showed that patients pay approximately 7 million euros more for medicines distributed at a discount than they should.

■ **The state's medicines policy has no clear goals.** All that the Public Health Development Plan, the Development Plan of the Ministry of Social Affairs and the Principles of Estonian Medicines Policy up to 2010 say about medicines is that their safety, quality and accessibility must be guaranteed. None of these strategic documents specifies how these goals should be achieved.

Main recommendations of the National Audit Office to the Minister of Social Affairs:

■ Initiate a change in law to stipulate that companies engaged in the wholesale of medicines may not own a pharmacy, either directly or indirectly.

■ Set specific goals regarding the proportion of active ingredient-based medicines by the end of 2013 and commission the Health Board to supervise the achievement of this goal.

■ Initiate a change in law to improve the awareness and options of patients by establishing a requirement that pharmacies must show the entire list of medicines with the same active ingredient and their prices, the rate of the discount applied to them and the total cost of each specific medicine to patients when selling medicines to them.

■ The following should be done to improve the procedure for adding medicines to the list of medicines distributed at a discount and increase the speed of these proceedings:

- reject all applications to add medicines to the list of medicines distributed at a discount that are submitted incorrectly or not properly completed;
- establish the exact conditions on which a negative decision or a positive decision subject to certain conditions is made in regard to an application received by the Committee for Medicinal Products; and
- create alternative options in terms of adding a medicine to the list of medicines distributed at a discount. Introduce cost-sharing to pharmaceutical manufacturers as an option whereby the manufacturer bears the cost of the medicine at first, with only the costs of patients who actually benefit from the treatment being covered by health insurance.

Response of the Minister of Social Affairs:

The Minister of Social Affairs said that an analysis that is more thorough than this audit should be carried out before new restrictions regarding the owners of pharmacies are added to the Medicinal Products Act. However, he also admits that the goal of the existing restrictions and the methods established for their performance should be analysed and that the restrictions relating to the ownership of activity licences should be updated.

The Minister of Social Affairs claimed that he had been unable to set goals regarding the proportion of active ingredient-based prescriptions due to the lack of necessary information. The minister does not believe it necessary to make pharmacists show all medicines with their prices to patients, but he agreed that this could be negotiated with organisations that represent patients.

Shortening the time of proceedings is impossible in the opinion of the Minister of Social Affairs, as the time required to process marketing authorisation and applications for compensation of medicines does not depend on the processor alone, but also on the applicant. Although applicants pay a state fee to have their applications processed which should cover the cost of the proceedings, the money is also used to finance the other activities of the State Agency of Medicines. Additional financing for the State Agency of Medicines has been requested so that the state fees can be used solely for processing applications. No fee has been prescribed for processing applications for compensation of medicines. The Minister of Social Affairs sees no other way of shortening the deadlines than finding additional money.

Tarmo Olgo
Director of Audit, Performance Audit Department