VALSTYBĖS KONTROLĖ
PUBLIC AUDIT

AVAILABILITY OF MEDICINES FOR THE POPULATION

1 December 2023

No. VAE-7

SUMMARY

Relevance of the audit

The goal, objectives, directions of development, expected results and evaluation criteria of the medicines policy are defined by the Medicines Policy Guidelines [1]. The implementation of the Guidelines is foreseen for 2027 and the following results are expected: improved availability of medicinal products with added therapeutic benefits that prolong survival, reduce morbidity and/or disease; increased use of generic and biosimilar medicines; reduction of the patient's costs for prescription medicines; increase in the proportion of reimbursable medicines compared to the consumption of all prescription medicines. There is no plan in place for the implementation of the Guidelines.

The responsible authorities must find ways to ensure that patients have access to affordable, effective, and safe medicines and to reduce the costs of medicines and other non-durable medical goods, but in Lithuania, the cost of purchasing medicines was among the highest in the European Union: 24th place among the 27 EU countries that provided data[2]. Research[3] shows that the availability of innovative medicines in Lithuania is one of the worst in the EU. The lengthy evaluation processes of new medicinal products and the state's financial capacity delay the entry of new medicinal products on the market and the transfer of medicinal products from the Reserve list to the lists of reimbursable medicinal products. Supply disruptions also affect the availability of medicines.

[1] Approved by Order No V-1008 of the Minister of Health of 28 August 2017.

[2] Health at a Glance: Europe 2022. Internet access: https://www.oecd-ilibrary.org/social-issues-migration-health/health-at-a-glance-europe-2022_507433b0-en (accessed on 4/10/2023).

[3] W.A.I.T. (Waiting to Access Innovative Therapies), 2022.

Objective and scope of the audit

The objective of the audit is to assess whether the provision of medicinal products to the population is effective and whether the reimbursement system is oriented to the needs of the population and the financial capacities of the state.

Key audit questions: whether the measures taken to increase the availability of medicinal products are effective; whether the system of reimbursement of the prices of medicinal products is geared towards the needs of the population, considering the financial capacities of the State; whether measures are in place to ensure the rational use of medicines.

Audited entities:

- ✓ The Ministry of Health of the Republic of Lithuania, as it formulates the state policy in the field of pharmaceutical and other activities related to pharmaceutical products, organises, coordinates, and monitors its implementation;
- ✓ The National Health Insurance Fund under the Ministry of Health of the Republic of Lithuania, as it reimburses the costs of the reimbursable medicinal products and medical aid equipment, performs the functions of the information system manager in the part of the declaration of prices and Price list of reimbursable medicinal products and reimbursable medical aid equipment;
- ✓ The State Medicines Control Agency under the Ministry of Health of the Republic of Lithuania, as it registers medicinal products, organises and carries out health technology assessment of medicinal products, monitors the presence of medicinal products on the Lithuanian market and, within its remit, takes the necessary measures to eliminate deficiencies in medicinal products.

During the audit, we collected information and cooperated with municipalities, representatives of associations of pharmaceutical manufacturers, assistance for oncological patients, Lithuanian pharmacies, parallel medicines import associations, the Board of Representatives of Lithuanian Patient Organisations, the Lithuanian Physician Managers Union, the Lithuanian Food and Veterinary Service, and the State Data Agency.

The audited period is 2020-2022. To assess trends and developments, we used data from previous years and 2023.

The audit was carried out in accordance with international standards of supreme audit institutions. The scope of the audit and the methods used are described in more detail in Annex 1, ‘Audit Scope and Methods’ (page 36).

Key audit results

The network of pharmacies in Lithuania is one of the largest in Europe, but the means of obtaining medicines in other ways are not effective enough. There is a lack of more effective measures to promote the rational use of medicines. The entry of medicinal products in the reimbursement system is non-operative in the case of disruptions in the supply of medicines, lack of interchangeability, and the unmet need to reimburse new medicines or medicines to treat very rare diseases.

1. Measures were taken on the supply of medicines, but measures to obtain medicines outside pharmacies could be more effective

- ✓ The Ministry of Health and the State Medicines Control Agency have implemented measures to increase the supply of medicines. In 2022, two times more parallel imports of medicinal products were available on the domestic market than in 2018. Lithuania's role as the reference country and the zero-day procedure resulted in an annual increase in the proportion of medicines registered and a reduction in persistent supply disruptions. In 2022, around 70 % of medicines registered in the Register of Medicinal Products of the Republic of Lithuania were supplied on the market. (Subsection 1.1, pages 12-14).
- ✓ The measures of obtaining medicinal products by other means (other than physical acquisition in pharmacies) are not effective: on average, patients purchase by distance selling about 0.07 % (1.1 thousand of 1.46 million per month) of prescription medicines compared to those purchased in pharmacies; 18 of the 24 municipalities surveyed had no contracts with pharmacies in primary health care facilities in rural areas; foreign purchases of medicines subject to e-prescription in Lithuania will be available at the end of 2023 and were planned for 2022. Alternative means of physical access to medicines should be possible in the most convenient way (Subsection 1.2, pages 14-16).

2. The reimbursement system for pharmaceutical costs is not sufficiently geared towards the needs of the population

- ✓ The entry of medicines on the lists of reimbursable medicinal products is not ensured within the time limit set: 92 % (55 out of 60) decisions on applications for the entry on the lists of reimbursable medicinal products took more than 180 days (from 206 to 911). On 12 September 2023, 44 % (66 out of 150) of unassessed applications remained, and on 17 November 2023 - 38 % (63 out of 165) applications remained. The process was delayed due to the lack of human and financial resources of the State Medicines Control Agency in 2020-2021. As a result, decisions on the entry of medicinal products on the lists of reimbursable medicinal products are delayed. (Subsection 2.1, pages 16-17).
- ✓ The administration of the Price list of reimbursable medicinal products should be improved.
    - The price lists on average included 30 % (252 out of 840) of groups of medicines with one supplier and these were not suppliers of the reference (original) medicinal product. In the first half of 2022, the supply of 9 % (47 out of 505) of medicines in the Price list with a single supplier in the group was interrupted for more than 3 weeks. As a result of a Price list for the second half of 2023, prepared following the new requirements, compared to the first half, the number of groups of medicines decreased from 850 to 841, the number of medicinal products decreased from 2130 to 2033, the number of rejected cardiological (group C) applications doubled, in the single supplier groups the number of groups of bearer prescription medicinal products increased almost twofold from 11 to 23, in 17 days after the entry into force of the Price list for the second half of 2023, the number of supply disruptions per supplier groups was twice as high as in the whole of the first half of 2023 (Subsection 2.2, pages 17-23).

- The information provided by the MAHs is relevant for the preparation of the draft price list, but the MAHs notify any disruption of the supply of the medicinal product shortly before or after the entry into force of the price list. As a result, the State Medicines Control Agency is not able to properly assess the draft price list due to supply disruptions. It is not foreseen how the demand for a new group of medicines or medicinal products that have not been purchased during the relevant period of the previous year should be calculated. The supply of medicines in foreign packaging, which is low in demand in the country, requires a record of shortages, which artificially increases the number of supply disruptions. The Agency does not have information on parallel exports of medicinal products and does not assess the volume of medicines exported in parallel from Lithuania (Subsection 2.2, pages 17-23).

- Having received information on supply disruptions, the National Health Insurance Fund did not exclude 43 % (15 out of 35) of medicinal products from the draft price list for the first half of 2023, of which 6 have not been available for the entire lifetime of the price list. It did not delete 55 % (21 out of 38) of medicinal products from the price list valid for the first half of 2022, 9 of which belonged to the single supplier group. Without excluding potentially disrupted supplies of medicinal products from the draft price list and medicinal products whose supply is disrupted from the current price list, medicinal products shall not be replaced with other medicinal products (Subsection 2.2, pages 17-23).

- 46 % (23 out of 50) of the Minister's orders on price list changes from 2020 to 25 August 2023 entered into force faster than 3 working days after their publication in the Register of Legal Acts – in breach of the minimum time limit provided for in the description of procedure, 22 % (11 out of 50) –after 1 working day. For 40 % (17 out of 43) of cases, the National Health Insurance Fund confirmed the data less than a day before the entry into force of the Minister's Order on price changes. As a result, doctors and pharmacies are unable to get acquainted with the revised price lists and update the data in the information systems (Subsection 2.2, pages 17-23).

- If the supply of a medicinal product is disrupted, patients and doctors are confronted with the problem of the purchase of medicines. In 2024, the Electronic Health Services and Cooperation Infrastructure (EHSI) information system is planned to introduce a function to inform the healthcare professional issuing the e-prescription about possible disruptions in the supply of a medicinal product (Subsection 2.2, pages 17-23).

Without eliminating the shortcomings in the administration of the price list, patients are not able to purchase the necessary medicines on time.

✓ The expenditure of the Compulsory Health Insurance Fund for the purchase of reimbursable medicines is increasing, but the need is not ensured.

- On average, between 2021 and 2023, the allocations for the transfer of medicines from the Reserve List to the List of Reimbursable Medicinal Products were 76 % lower than the estimated need (around EUR 20 million). Due to the lack of funds, the National Health Insurance Fund was unable to transfer the medicinal products included in the Reserve list to the List of reimbursable medicinal products during the calendar year: in 2020, EUR 8.8 million was missing for nine medicines in the first year; EUR 0.3 million for the transfer of two medicines in 2021; EUR 0.2 million

for one medicine in 2022. In total 36 % (10 out of 28) of medicinal products included in the Reserve list for 2020-2022 have been on the list for more than 6 months (around a year). This leads to prolonged inaccessibility for patients (Subsection 2.3, pages 23-28).

- The expenditure of the Compulsory Health Insurance Fund for the treatment of very rare diseases increased by a higher percentage between 2020 and 2022 than the total expenditure on medicines (in 2020, pharmaceutical expenditure increased by 4 %, very rare diseases by 14.6 %, in 2021 by 9 % and 16.8 % respectively, in 2022 by 23 % and 35 %). Due to the lack of funds, 43 % (26 out of 60) of 2022 decisions not to allocate funds for 28 new patients in the current year were accepted. (Subsection 2.3, pages 23-28).
- In Lithuania, the values of cost-effectiveness thresholds relative to GDP per capita are 1, 3 or 5 and are among the highest in the EU (Latvia 3, Poland 2.6). They were due to be revised in February 2023, but this was not done (Subsection 2.3, pages 23-28).

3. Measures in place to ensure rational use of medicines are insufficient

- ✓ Information on the rational use of medicinal products is provided to the public by different institutions: Ministry of Health, State Medicines Control Agency, National Health Insurance Fund, Territorial Health Insurance Funds, Institute of Hygiene, Municipal Public Health Bureaus, Antimicrobial Resistance Management Groups, Šiauliai Territorial Patient Fund Medicines Committee. The fragmented presentation of information does not allow the user to conveniently find the necessary information on the rational use of medicinal products in one place (Section 3, pages 28-30).
- ✓ The only pharmaceutical care service (for patients taking inhaled medicines) regulated in 2016 is provided by 0.5 % (6 out of 1322) pharmacies. No new pharmaceutical services were regulated between 2020 and 2022. Of the 5 planned services, only one (re-dispensing of prescription medicines in a pharmacy) is planned to be regulated by the end of this year. The sluggish development of pharmaceutical services does not make it possible to ensure the proper use of medicinal products (Section 3, pages 28-30).
- ✓ Expenditure per capita on medicines and other non-durable medical goods purchased with own funds amounted to EUR 155.51 in Lithuania with EUR 129.39 on the EU average. According to the OECD, Lithuania's share of self-paying pharmaceutical expenditure (54 %) was above the EU average in 2020. In Lithuania, the total costs are calculated without distinction between prescription and non-prescription medicines and cover the purchase of non-durable medical goods (supplements, vitamins). In the absence of these data, it is difficult to select measures to ensure a more rational use of medicinal products (Section 3, pages 28-30).
- ✓ When issuing e-prescriptions through the Electronic Health Services and Collaborative Infrastructure Information System (ESPBI IS), the compatibility of medicines with other medicinal products for the patient is checked. 17 % (29 out of 175) of personal healthcare institutions that issue prescriptions via their internal systems reported that they did not see information on the compatibility of medicines. The Ministry indicated that, as early as 2000, personal health care institutions had been invited in writing to introduce functionalities for checking medicine interactions in their institution's internal information systems. In the absence of information on the compatibility of

prescription medicinal products with other medicinal products intended for use by the patient, an irrational prescription may be carried out (Section 3, pages 28-30).

Recommendations

Ministry of Health

1. To increase the availability of medicinal products to the population, especially in the regions (Key audit result 1):

    1.1. having assessed, together with social security specialists, experts, and social partners, the need for alternative means of physical access to medicines, to improve existing and/or provide for new measures;

    1.2. raise awareness of alternative means of physical access to medicines.

2. To ensure faster availability of reimbursable medicines (Key audit result 2):

    2.1. take measures to enable the State Medicines Control Agency to assess all applications for the entry of medicinal products in the lists of reimbursable medicinal products within a specified time limit;

    2.2. revise the methodology of the National Health Insurance Fund for the need of the Compulsory Health Insurance Fund – to include a requirement to indicate the need for funds for the reimbursement of medicinal products, so that the medicinal products are transferred from the Reserve list of medicinal products to the List of reimbursable medicinal products within a period not exceeding 6 months.

3. To avoid disruptions in the supply of medicines (Key audit result 2):

    3.1. impose obligations on applicants applying for the entry of medicinal products in the Price list of reimbursable medicinal products to indicate the date and quantity of the first consignment if the medicinal product has not previously been placed on the Lithuanian market (or has not been supplied in the last year);

    3.2. improve the legal regulation relating to the placing on the market of medicinal products bearing packs and package leaflets in the language of another state of the European Economic Area in the Republic of Lithuania, considering the needs of patients.

4. To respond on time and to make reasonable decisions on the impact of price changes on the availability of medicines, monitor the effects of pricing, including the assessment of monitoring indicators (Key audit result 2).

5. To promote the rational use of medicines (Key audit result 3):

    5.1. regulate pharmaceutical care services that pharmacies can provide;

    5.2. assess the need and possibilities of financing pharmaceutical services and adopt and/or revise legislation accordingly;

5.3. publicise information about regulated pharmaceutical care services for health care, pharmaceutical professionals, and patients.

6. To ensure that information published by the responsible authorities on the rational use of medicinal products is made available as a one-stop shop to provide better information to the public on the rational use of medicinal products.

The measures and timelines for the implementation of the recommendations, the expected impact of the audit, and the indicators for assessing changes are presented in the report under the heading 'Recommendations Implementation Plan' (page 31). Relevant information on the state of implementation of recommendations, results, and changes that have taken place is published in open data on the website of the National Audit Office https://www.valstybeskontrole.lt/LT/AtviriDuomenys.