Executive summary of the public audit report

IS ACCESS ENSURED TO REIMBURSABLE GENERIC MEDICATION?

20 May 2016, No. VA-P-10-1-8

Full audit report in Lithuanian available on website
of the National Audit Office
: www.vkontrole.lt

DEFINITIONS AND ABBREVIATIONS

Administrative measures: the regulation and supervision of activity related to reimbursable medication.

The insured: individuals insured with compulsory health insurance who pay compulsory health insurance payments[1] or for who compulsory health insurance are paid by others in compliance with the Law on Health Insurance.

ATC: Anatomical Therapeutic Chemical (ATC) Classification System for drugs approved by the World Health Organisation. The system attributes 7-symbol codes to drugs based on their active ingredient (general name).

Base price: the part of a drug's retail price based on which the Compulsory Health Insurance Fund reimburses drug purchasing costs or a part thereof[2].

Declared price: the price applied by the manufacturer for the Lithuanian market for a given medication and declared to the responsible institution of the Republic of Lithuania based on an established procedure (excluding VAT)[3].

Generic drug: a drug that is manufactured and distributed without applying patent protection. The qualitative and quantitative composition of the drug's active ingredients and its pharmaceutical form is much like the original drug. The generic drug is the bioequivalent of the original medication and this has been proven through biological absorption studies.

Reimbursable drugs: drugs that are included on the Price List of Reimbursable Medications. The full or partial cost of purchasing these drugs is reimbursed from the Compulsory Health Insurance Fund to individuals insured with compulsory health insurance[4].

Price List of Reimbursable Medications: a price list approved by the Minister of Health for medications prescribed on an outpatient basis and reimbursed from the Compulsory Health Insurance Fund.

List of Reimbursable Medications: a list of diseases and reimbursable medicinal preparations for their treatment, list A.

Retail price: the price of a drug calculated by adding VAT costs and the wholesale and retail mark-up to the declared price of a drug. Mark-ups are established by the Minister of Health[5].

Original (patented) drug: a new medication the intellectual property of which is protected by patent law up to the expiry of its patent (can be called a patented drug while the period of data exclusivity or market exclusivity applies)[6].

[1] Law No. I-1343 of the Republic of Lithuania on Health Insurance, 21/05/2006, Art. 2.

[2] Description for the calculation procedure of the base price of drugs and medical aids prescribed in outpatient treatment, which are reimbursed by the Compulsory Health Insurance Fund, approved by resolution No. 994 of the Government of Lithuania of 13/09/2005.

[3] Ibid.

[4] The Law of the Republic of Lithuania on Pharmaceutical Activities, 22/06/2006. No. X-70. Art. 2, p. 23.

[5] Description for the calculation procedure of the base price of drugs and medical aids prescribed in outpatient treatment, which are reimbursed by the Compulsory Health Insurance Fund, approved by resolution No. 994 of the Government of Lithuania of 13/09/2005.

[6] Final Report on the Assessment of the Impact of European Pharmaceutical Policy on Access to Drugs in Lithuania, 2011.

Original drug not covered by patent protection: an original drug for which the intellectual property protection period (patent validity, data exclusivity or market exclusivity period) has expired. Original drugs are also referred to as ethical drugs.

Patient co-payment, co-payment: a sum established in the Price List of Reimbursable Medications that the patient must pay for out-of-pocket as they purchase a reimbursable drug[7].

WHO (PSO): World Health Organisation.

Sveidra: Compulsory Health Insurance information system.

Reference states: Eight EU member states established by the Government of the Republic of Lithuania (Bulgaria, the Czech Republic, Estonia, Latvia, Poland, Romania, Slovakia and Hungary)[8].

CHIF (PSDF): Compulsory Health Insurance Fund.

TIF (TLK): territorial insurance fund.

Drug (medication): a drug or combination of drugs manufactured and distributed for consumption because it meets at least one of the following criteria: 1) has properties that are suitable for treating or preventing human diseases; 2) can be consumed or prescribed for restoring, correcting or modifying a person's physiological functions or diagnosing illness due to its pharmacological, immunological or metabolic effect[9].

Name of drug: the made-up name (one that cannot be confused with a general name) or general/scientific name of a drug that also indicates the manufacturer's brand and name.

Pharmacy: a public pharmacy that stores, controls and sells (issues) medication to residents and legal entities that are not licensed for healthcare or pharmaceutical activity, fulfils the mandatory obligations assigned by the Minister of Health to provide the public with medication, and offer student traineeships[10].

NHIF (VLK): National Health Insurance Fund under the Ministry of Health.

SMCA (VVKT): State Medicines Control Agency of Lithuania under the Ministry of Health.

[7] Description for the calculation procedure of the base price of drugs and medical aids prescribed in outpatient treatment, which are reimbursed by the Compulsory Health Insurance Fund, approved by resolution No. 994 of the Government of Lithuania of 13/09/2005.

[8] Approved by resolution No. 256 of the Government of the Republic of Lithuania of 10/03/2010.

[9] Law No. X-709 of the Republic of Lithuania on Pharmaceutical Activity, 22/06/2006, Art. 2, p. 50.

[10] Ibid, Art. 35, p. 3.

SUMMARY

In Lithuania, reimbursable drugs are used by 1.2 million residents (40.5%). The majority of costs (80%) for purchasing these drugs are reimbursed for the residents of Lithuania from the Compulsory Health Insurance Fund. The costs incurred by the fund for reimbursing medication has increased, rising from 176 million euros in 2012 to 198 million euros in 2015.

The pharmaceutical market is regulated in Lithuania in compliance with EC directives, which establish regulatory procedures for reimbursing drugs, regulating drug prices, etc. One of the measures designed to reduce the price of drugs and increase access to drugs for residents is the inclusion of generic medication in the reimbursable drug system. Once the patent protection for an original drug expires, other manufacturers are allowed to manufacture drugs with the same active ingredients, i.e., generic drugs, as well, which is why the government can regulate them the most.

According to data form the National Health Insurance Fund, the public spent 54 million euros in co-payments as they purchased reimbursable drugs, i.e., a fifth of the total price of all reimbursable drugs. Calculations show that purchases of less expensive generic medication would lead to a 50% smaller co-payment amount – 27 million euros. The use of generic drugs makes it possible to provide quality treatment at a lower cost, ensure the sustainable treatment of a larger portion of the patient population with fewer financial resources and use the resulting savings for new medications[11]. Therefore, as we audited this area, we chose to assess whether sufficient access to reimbursable generic drugs is ensured for the public and analysed the following questions:

- is a sufficient supply/affordability ensured for patients?
- does the national drug policy set goals and measures for improving access to generic drugs?
- are any measures implemented to promote the use of less expensive drugs in the country?

The audited entity was the Ministry of Health, which shapes national policy in the pharmaceutical field, organises and coordinates the provision of medication to the Lithuanian public, and sets requirements for pharmaceutical activity within the limits of its competence[12].

We analysed European and national laws regulating the reimbursement of drugs (the inclusion of drugs in the reimbursement system, price regulation, selling (issuing) drugs to the public, etc.) as well as the measures planned and implemented by the ministry and other responsible institutions. We considered various studies conducted by EU institutions and WHO documents as well as their recommendations in order to research international experience in ensuring public access to drugs. We based our conclusions on data from the Pharmaceutical Department and the National Health Insurance Fund. We analysed reimbursable drug price lists and the changes of generic drug prices in them (manufacturer declared prices, base prices and patient

[11] The European Commission's *Pharmaceutical Sector Inquiry, Final Report (*adoption Date: 8 July 2009); *Study of Pharmaceutical Product Prices and Differences in Possibilities for Purchasing Them in the European Union*, 2011.

[12] Provisions of the Lithuanian Ministry of Health, approved by resolution No. 926 (amended version No. 1443 of 13/10/2010) of the Government of the Republic of Lithuania of 24/07/1998, parts 9.3 and 10.3.

co-payments); the discounts applied by manufacturers to patient co-payments[13]; Sveidra data about drugs issued (sold) from pharmacies and co-payments paid by patients. We monitored the issuance of reimbursable drugs in pharmacies.

The audit covers the period from 2013 to 2014, however, data from 2015 and previous years is also used in order to assess trends and changes.

We determined that from 2012 to 2015, the Ministry of Health implemented various measures in order to improve access to reimbursable drugs: it approved criteria for establishing the therapeutic and pharmaeconomic value of drugs proposed for inclusion in the List of Reimbursable Medications; set time frames for deliberating on requests and announcing information related to the deliberation; established a procedure for including drugs in the Reserve List of Medications; provided clearer regulation for the activity of commissions[14]; and expanded the List of Reimbursable Medications by including new drugs for treating cancerous and viral diseases as well as other illnesses. In order to ensure better access to drugs in Lithuania based on best drug prescription practices recommended by EU institutions and the WHO, authorities should follow an established procedure and indicate drugs by their general names on prescriptions[15]. With the aim of reducing the cost of generic medication, the Price List for Reimbursable Medications groups certain drugs together and sets a limit for entering the market (in the 2014 price list, 50% lower prices were applied to newly introduced first generic drugs and 15% to supplementary drugs in the same group (i.e., the second, third drug, etc.))[16].

We discovered that the offering of generic drugs in reimbursable medication price lists has increased: new medication groups have been added and drugs produced by other manufacturers have also been added to existing groups. National regulation of the prices of reimbursable drugs enabled the reduction of base prices. When a new drug with a lower declared price (based on which the base price is calculated for the entire group) is included in a group of generic drugs, the patient co-payment decreases for that specific drug, but increases for other drugs in the group. This is why access to generic drugs did not improve for users in terms of price: as the base prices for generic drugs decreased in the price lists, calculated patient co-payments increased. A better offering of drugs was ensured for users by the manufacturer discounts applied to patient co-payments. However, the application of such discounts lost its initial effect in the long run: only a few manufacturers were inclined to apply the discounts in the first place, manufacturers gradually decreased discount sizes relative to increasing patient co-payments. In Lithuania, there is a list of reimbursable drugs that pharmacies must have on offer[17], and pharmacies are obliged to have and offer patients the least expensive reimbursable medication under the same general name. However, these requirements are not always adhered

[13] Drug manufacturers that apply discounts to predetermined patient co-payments submit requests to the National Health Insurance Fund, which then recalculates co-payments and publishes this information on the Classifier for Reimbursable Medications.

[14] Commission for Reimbursing Drugs and Medical Aid Tools for Treating Disease and the Appeals Commission.

[15] Rules for issuing subscriptions and issuing (selling) drugs and reimbursable medical aids to the public, approved by order No. 112 of the Minister of Health of 08/03/2002 (version No. V-409 of 07/05/2010 which expired on 01/06/2015, p. 13.2.1, and amended version No. V-669 of 28/05/2015), p. 20.

[16] Description for the calculation procedure of the base price of drugs and medical aids prescribed in outpatient treatment, which are reimbursed by the Compulsory Health Insurance Fund, approved by resolution No. 994 of the Government of Lithuania of 13/09/2005 (version No. 99 of 05/02/2014), p. 7.

[17] Description for the procedure of issuing (selling) reimbursable drugs and medical aids that pharmacies must have in stock on a mandatory basis, approved by order No 1K-40 of the Head of the National Health Insurance Fund under the Ministry of Health of 02/03/2010, Annex 1.

to. Based on a survey carried out by the NHIF[18], only a fourth (26%) of respondents claimed to have been offered the least expensive drug as they purchased medication in pharmacies. As the auditors monitored how reimbursable drugs are issued in pharmacies, only in one of 14 cases did the pharmacist inform the patient about other drugs under the same general name and their prices or offer to buy the least expensive drug. An analysis of reimbursable generic drugs issued by pharmacies in 2015[19] showed that drugs which require larger patient co-payments were issued more frequently. Because pharmacies do not issue less expensive generic drugs to users, market conditions favour the survival of more expensive drugs over cheaper ones.

The drug policy of the Ministry of Health is not sufficiently oriented towards the use of generic drugs and measure implemented by the ministry were not comprehensive: users receive insufficient information about generic drugs, no measures for targeting healthcare specialists, pharmaceutical specialists or pharmacies have been planned.

With a view to improving access to medication and promoting the use of generic drugs, we have issued the following recommendations to the Ministry of Health: to plan and implement specific measures in order to ensure the user's right to receive full information and purchase reimbursable generic drugs for the lowest price; to improve the supervision of pharmaceutical services (by way of regulation and monitoring the issuance of drugs); to plan and implement on-going comprehensive measures to ensure that the financial burden on users does not increase and that they are provided with and have access to information about generic drugs, their use, and reimbursement; to ensure that representatives of healthcare establishments and the pharmaceutical sector (pharmacies, distributors, manufacturers) participate in promoting the choice of generic drugs.

The following public audit conclusions and recommendations were drawn upon the assessment of the audit findings.

CONCLUSIONS

The range of reimbursable generic drugs is increasing in Lithuania, however, better access to drugs is prevented by the following:

1. There is no clear national policy for the use of generic drugs – the issue is only addressed by individual measures:
    1.1. no indicators have been established for monitoring and assessing these drugs, and monitoring efforts are inconsistent and insufficient (Section 2.1.2);
    1.2. Strategic planning documents do not establish goals, objectives and measures for promoting the use of generic drugs or improving their accessibility (Section 2.1.1);
    1.3. regulation and supervision of how drugs are issued in pharmacies is not sufficient for promoting the use of less expensive generic drugs (Sections 1.5, 2.2 and 2.3).
2. User access to generic drugs has not improved in terms of pricing, and the financial burden that falls upon users purchasing generic drugs has increased:

[18] Survey commissioned by the National Health Insurance Fund in 2015, carried out by Baltijos Tyrimai UAB, report available at www.vlk.lt published on 03/11/2015.
[19] Data was analysed for 10 groups covering 122 reimbursable drugs issued to patients in pharmacies.

2.1. as the number of generic drugs in the price list for reimbursable medications increased, declared drug prices did not decrease (prices did not fall for 82% of reimbursable drugs in 2013, and 93% in 2015) (subsections 1.1 and 1.2);

2.2. the number of drugs for which calculated patient co-payments increased on the price list of reimbursable medications also grew (in analysed drug groups, they increased for 75% of drugs in 2014, and for 81% of drugs in 2015) (Subsection 1.3);

2.3. the application of discounts to drugs lost its initial effect (in 2015, there were fewer generic drugs for which co-payment discounts were applied, and the average patient co-payment for which discounts were applied in the assessed drug groups also increased: EUR 1.81 in 2013, EUR 2.61 in 2015) (Subsection 1.4);

2.4. pharmacies do not always adhere to established procedures when issuing reimbursable drugs to users or offer the least expensive option (only one in four survey respondents claimed to always receive such offers, whereas during the monitoring process, only in 1 of 14 cases did pharmacists inform users about other drugs under the same general name and their prices, patients were typically offered more expensive drugs (Subsection 1.5)..

3. No comprehensive measures have been implemented in order to promote the use of less expensive generic drugs, thus market conditions have been created in which only the most expensive drugs can survive.

3.1. users are not provided with sufficient information about their right to choose medication and about other prices and co-payments (only one in four users claimed that they always received the necessary information in pharmacies) as well as about generic drugs (over half of respondents claimed that they had not encountered information about such drugs) (subsections 1.4 and 2.2);

3.2. no targeted measures were implemented for healthcare and pharmaceutical specialists, and the Plan for Promoting the More Rational Use of Medication for 2015–2017 approved by the minister only applies individual measures to promote the use of generic drugs, and implementation of these measures only began at the end of 2015 (Subsection 2.3).

RECOMMENDATIONS

To the Ministry of Health of the Republic of Lithuania

With a view to improving access to reimbursable drugs and promoting the use of generic drugs, we recommend:

1. Establish goals, objectives and measures in the national policy for the promotion of reimbursable generic drugs and set indicator values for measuring the use of reimbursable generic drugs (Conclusion 1.2).
2. Plan for and evaluate generic drug indicators when monitoring the drug market and drug use (Conclusion 1.1).

3. Plan for and implement ongoing comprehensive measures to ensure that
    3.1. the financial burden on users does not increase (conclusions 2.1, 2.2, 2.3);
    3.2. users are provided with and always have access to information about generic drugs, their use, reimbursement, etc. (Conclusion 3.1);
    3.3. allow representatives of healthcare establishments and the pharmaceutical sector (pharmacies, distributors, manufacturers) to participate in the promotion of generic drug use (Conclusion 3.2).
4. In order to ensure the user's right to receive full information and purchase reimbursable generic drugs for the lowest prices pharmaceutical services should be supervised more effectively: plan for and implement specific measures for improving the supervision of pharmaceutical services, and the regulation of control purchases (Conclusion 1.3).