

Experience of the Latvian medicines reimbursement system



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In Latvia, the drug reimbursement system for outpatient treatment develops under limited resources. The reimbursement is performed against the degree of severity of certain diseases.

The largest part of the health care budget recourses for the reimbursement system is allocated for groups of diagnoses 'Diseases of the circulatory system' (21.48% of total expenditures in 2012), 'Endocrine, nutritional und metabolic diseases' (20.44% of total expenditures in 2012) and 'Neoplasms' (14.60% of total expenditures in 2012). Taking into account the rapid growth of the reimbursement expenditures in 2011 as well as the patients' co-payment for non-reference medicinal products certain measures have been implemented such as refund, depending on the exceeded market share, which was implemented for the period of 2011-2012 and amounted to LVL 3.7million in 2011 and LVL 2million in 2012. The two-level tender system has been implemented since September 2011 for interchangeable medicinal products and for newly diagnosed patients only reference medicine is reimbursed by the NHS at the time of the first treatment. As the result of these activities with the increased number of pa-

tients an average price per prescription was reduced from LVL 15.30 in 2011 to LVL 14.43 in 2012 the expenditures per patient were reduced from LVL 157.38 in 2011 to LVL 145.63 in 2012. With the strictly limited state budget, a necessity to use additional possibilities to optimise the resource allocation for the health care program and prevention activities remain topical.

The current Latvian drug reimbursement system for outpatient treatment has been developed since the 1990s. The procedures for the reimbursement are a set of measures which provides a patient with an opportunity to acquire medicinal products and medical devices the expenditures for the acquisition of which are completely or partially covered by the state budget funds in accordance with the Regulation No 899 of the Cabinet of Ministers of the Republic of Latvia "Procedures for the Reimbursement of Expenditures for the Acquisition of Medicinal Products and Medicinal Devices Intended for Out-patient Medical Treatment" (hereinafter – Regulation No 899). Expenditures for the acquisition of medicinal products and medical devices for nineteen groups of diagnoses (classified by the ICD-10) are reimbursed applying the following reimbursement categories ¹:

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- Category I – reimbursement in the amount of 100% provided it has been determined that a patient has a chronic, life-threatening disease or a disease, which causes serious irreversible disability and the medical treatment of which requires the use of the respective medicinal products in order to maintain the patient’s vital functions;
 - Category II – reimbursement in the amount of 75% provided it has been determined that a patient has a chronic disease in the medical treatment of which the maintenance of the patient’s vital functions is made difficult or which causes serious disability without the use of the respective medicinal products;
- and
- Category III – reimbursement in the amount of 50% provided it has been determined that a patient has a chronic or acute disease in the medical treatment of which the use of the respective medicinal products is necessary in order to maintain or improve the patient’s state of health or in case where vaccines are paid for from the funds granted for reimbursement. Approximately 60% of the total state budget funds allocated for the reimbursement system are spent for Category I, 32% – for Category II and 8% – for the reimbursement Category III². The largest portion of the health care budget recurses for the reimbursement system is allocated for group of diagnoses ‘Diseases of the circulatory system’ (21.48% of total expenditures in 2012),

Table 1. State budget expenditures for reimbursement of outpatient treatment at the seven largest diagnoses groups (by amount of expenditures) in Latvia, 2010-2012 (prepared by the author, the source of the data of^{2,3})

EDUCATIONAL INSTITUTION	2010		2011		2012	
	ACTUAL EXPENDITURES		ACTUAL EXPENDITURES		ACTUAL EXPENDITURES	
	MILLION LVL	% OF TOTAL	MILLION LVL	% OF TOTAL	MILLION LVL	% OF TOTAL
ENDOCRINE, NUTRITIONAL AND METABOLIC DISEASES	16,04	21,57%	16,72	20,27%	16,67	20,44%
DISEASES OF THE CIRCULATORY SYSTEM	14,39	19,35%	18,12	21,96%	17,52	21,48%
NEOPLASMS	10,17	13,68%	11,84	14,35%	11,91	14,60%
DISEASES OF THE NERVOUS SYSTEM	5,85	7,87%	5,89	7,14%	6,02	7,38%
DISEASES OF THE RESPIRATORY SYSTEM	4,28	5,76%	4,54	5,50%	4,62	5,67%
MENTAL AND BEHAVIOURAL DISORDERS	4,24	5,70%	4,23	5,13%	3,56	4,37%
INFECTIONS AND PARASITIC DISEASES	3,85	5,18%	5,32	6,45%	4,90	6,01%

'Endocrine, nutritional und metabolic diseases' (20.44% of total expenditures in 2012) and 'Neoplasms' (14.60% of total expenditures in 2012) (Table 1)³.

The list of reimbursable medicinal products consists of three parts – List A, List B and List C. The list of reimbursable medicinal products is drawn up according to the following basic principles ¹:

- List A includes medicinal products of equal therapeutic efficiency within the scope of the common name of the medicinal products or the pharmacotherapeutic group of the medicinal products and medical devices of the same type of the use (reference price system);
 - List B includes such medicinal products and medical devices, which are not interchangeable;
- and
- List C includes such medicinal products and medical devices, costs of which for medical treatment of one patient exceed 3 000 LVL per year and pharmaceutical companies have to provide patients with medicinal products for at least 10% of the amount payable from state funds.

In order to include medicinal products and medical devices into the list of reimbursable medicinal products, the marketing authorisation holder (MAH) submits a written application to the National Health Service (NHS) containing clinical information (a summary of clinical trials, indications, target groups of patients etc.) pharmacoeconomic information (pharmacoeconomic calculations in accordance with the Baltic guidelines for the economic evaluation of the medicinal products (Estonia, Latvia, Lithuania) which came into force in 2002, information regarding the sales prices, calculation of the anticipated consumption of funds granted for reimbursement, including the comparative therapy and the number of patients as well as the calculation regarding the probable quantity and the estimated turnover of the medicinal products to be sold in Latvia in ac-

cordance with the procedures of reimbursement).

While examining an application regarding the inclusion of medicinal products or medical devices into the list of reimbursable medicinal products, the NHS performs a medical assessment and economic assessment. The economic assessment includes the following evaluation¹:

1. treatment expenses, in using the relevant medicinal products or medical devices, and their effects upon the funds granted for the health care including reimbursement (including the effects of possible adverse reactions caused by the use of the medicinal products or medical devices during the course of treatment and the treatment costs);
 2. therapeutic efficiency and costs of the new common medicinal product names in comparison with another type of available treatment in accordance with the Baltic guidelines for economic evaluation of the medicinal products
- and
3. prices of medicinal products and medical devices in comparison with prices of the respective medicinal products and medical devices in certain European Union Member States.

Prices of reimbursed medicines are negotiated between the NHS and the MAHs. A general principle in accordance with the Regulation No 899 is that prices should not exceed the prices in Estonia and Lithuania and the third lower price in the Czech Republic, Denmark, Hungary, Rumania and Slovak Republic. The limited mark-ups for wholesalers and pharmacies are applied. The number of patients treated through the reimbursement system rises every year. The biggest number of patients is treated through the reimbursement system in the group of diagnoses for 'Diseases of the cir-

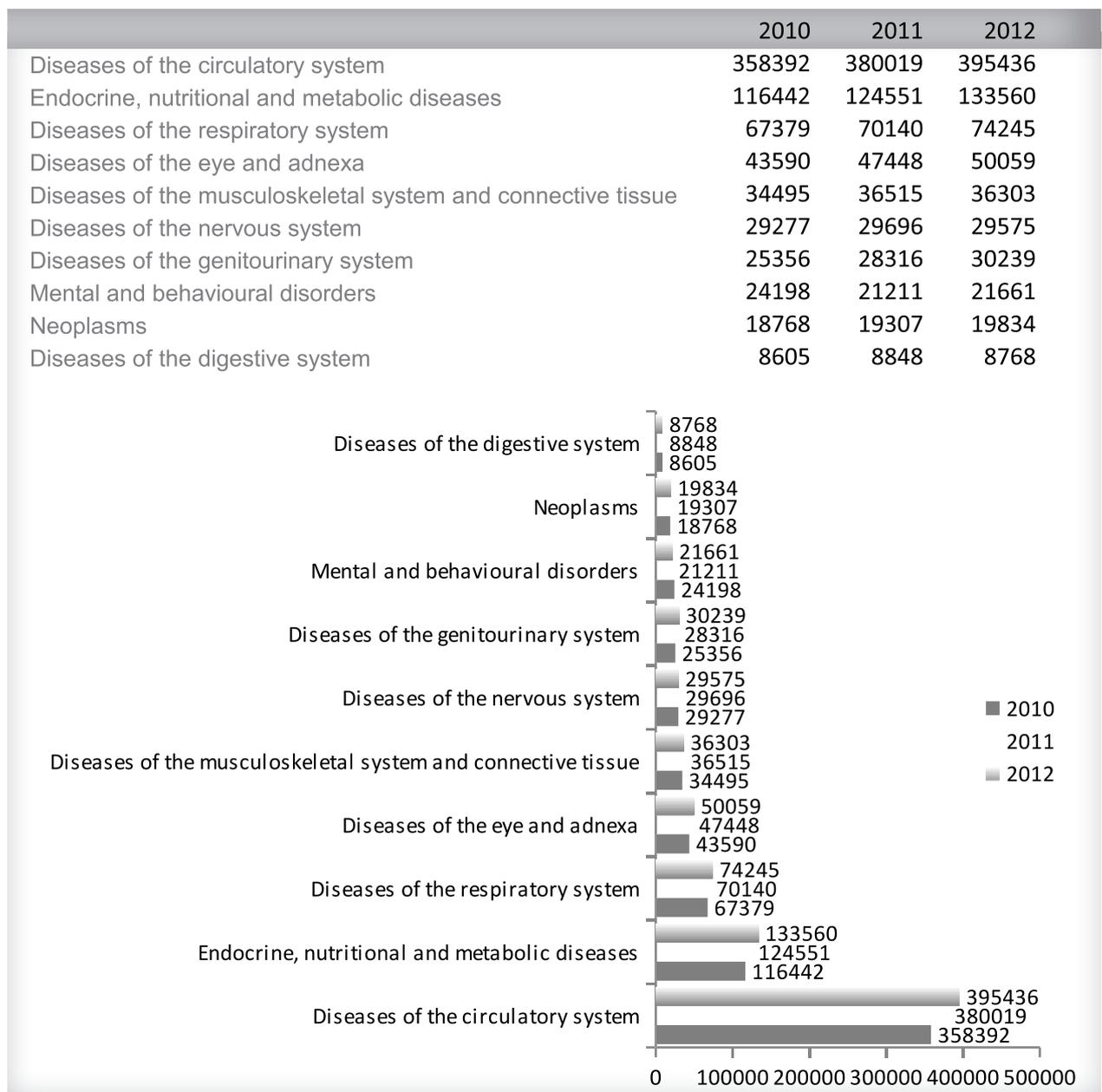


Figure 1. Number of patients treated in reimbursement system for outpatient treatment at ten largest diagnoses groups (by number of patients) in Latvia, 2010-2012 (prepared by author, using the data of^{2,3})

Table 2. Total state budget expenditures for reimbursement of outpatient treatment and number of patients treated in Latvia, 2010-2012 (prepared by author, using the data of^{2,3})

YEAR	NUMBER OF PATIENTS TREATED	STATE BUDGET EXPENDITURES, LVL	EXPENDITURES PER PATIENT, LVL	EXPENDITURES PER PRESCRIPTION, LVL
2010	505773	74358648	147,02	14,39
2011	524282	82513870	157,38	15,30
2012	559978	81551251	145,63	14,43

culatory system', 'Endocrine, nutritional and metabolic diseases' and 'Diseases of the respiratory system' (Figure 1).

Taking into account the rapid growth of the reimbursement expenditures in 2011 (Table 2), as well as the increased patients' co-payment for non-reference medicinal products (Figure 2) the certain measures have been implemented^{1,3}:

- Pay-back system has been implemented for the period of 2011-2012, in accordance with that the MAHs, depending on their market share, had to compensate to the NHS a certain degree if the annual medicines budget is exceeded. This pay-back system amounted to LVL 3.7 million in 2011 and LVL 2 million in 2012.

- The two-level tender system has been implemented for medicinal products of List A, as well as for newly diagnosed patients only a reference medicine is reimbursed by the NHS at the first time of treatment since September 2011. As the result of these activities in circumstances of the increased number of patients (Table 2), the average price per prescription was reduced from LVL 15.30 in 2011 to LVL 14.43 in 2012, as well as the expenditures per patient were reduced from LVL 157.38 in 2011 to LVL 145.63 in 2012.

The National Health Service, on the basis of the decision of the doctors' council of the relevant treatment field, is entitled to take a decision regarding the reimbursement of expenditures for the acquisition

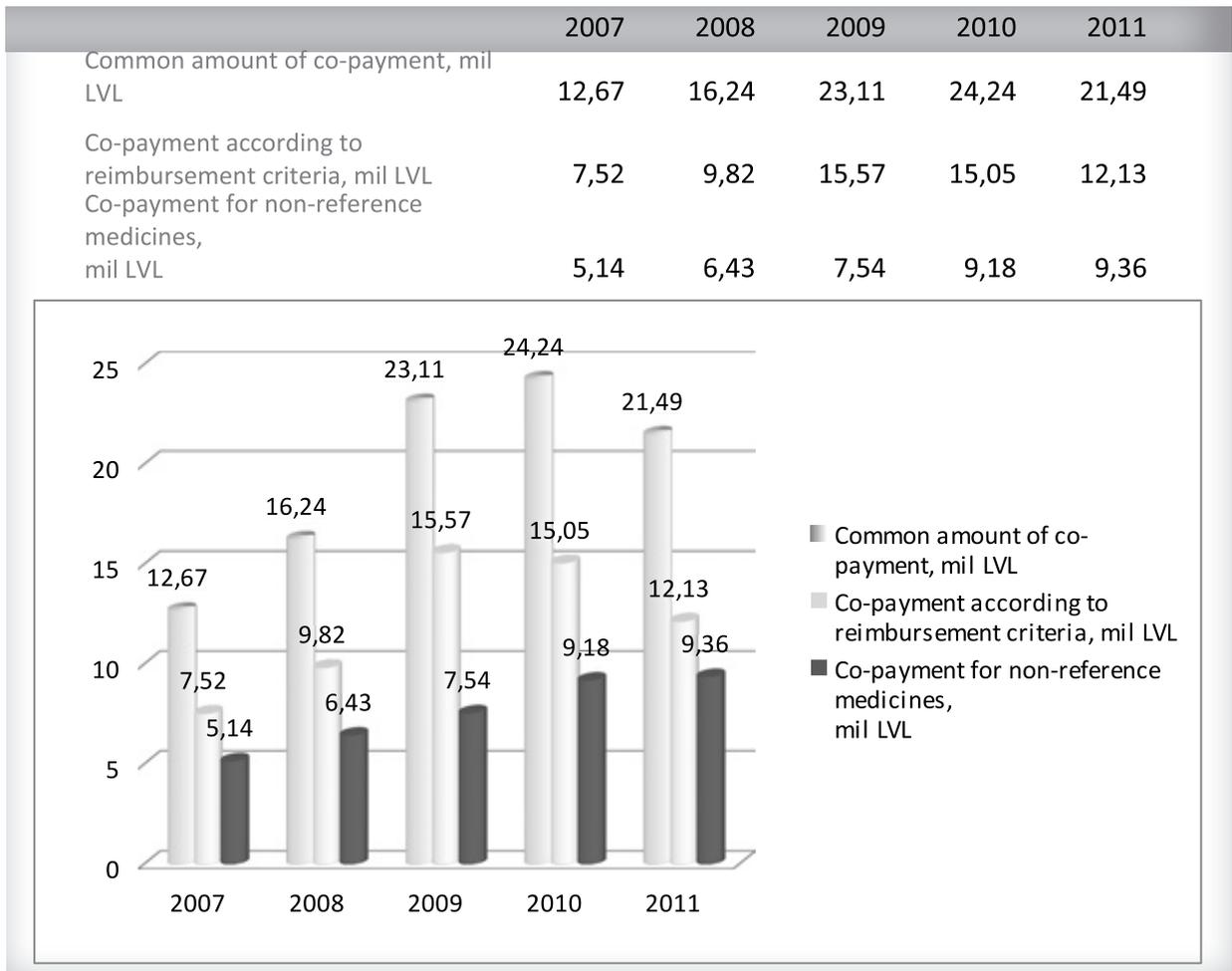


Figure 2. Patients' co-payment tendencies in reimbursement system for outpatient treatment in Latvia, 2007-2011³

of medicinal products and medical devices for individual patients. In 2012 the NHS provided the individual compensation for 554 patients including patients of the rare diseases which are not entered into the common list of the reimbursed diagnoses. The individual agreements between the NHS and MAHs, such as price-volume agreements as well as possibilities to cover the co-payment of the patients those receive reimbursement through individual compensation have been introduced since October 2011. Additionally since 1st September 2012 the expenditures of all prescription medicines have been reimbursed in the amount of 50% for treatment of children under 2 years of age and in the amount of 25% for the treatment of pregnant women.

The implemented measures have insured the significant improvement and optimisation of resources management but in the circumstances of the strictly limited state budget a necessity to use additional possibilities to optimise the resources allocation to the health care programs and prevention activities remain topical. ■

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