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Drug Policy in Latvia

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ABSTRACT

We present a general overview of the health care system as well as the pricing and reimbursement environment in Latvia. Overall, the pharmaceutical sector in Latvia, including pricing and reimbursement, is strictly regulated. The main Latvian stakeholder in the pharmaceutical sector is the Ministry of Health. The State Agency of Medicines and the National Health Service (NHS) are also important institutions for regulation of pharmaceuticals, including pricing and reimbursement. The NHS is the most important institution for regulation of reimbursement of pharmaceuticals. It is responsible for health technology assessment and also for implementing decisions regarding the reimbursement of pharmaceuticals by including medicines in the positive reimbursement lists for outpatient care and defining positive lists of medicinal products for inpatient use. The reimbursement of expenditures for medicinal products and medicinal

devices for outpatient care is a main part of drug funding in Latvia. Reference pricing is in place and prices are revised 4 times a year. The positive reimbursement list for outpatient care consists of three parts: list A, list B, and list C. All the medicines in the positive list are classified into one of three reimbursement categories (100%, 75%, or 50%) depending on the illnesses for which they have been approved. Pharmaceuticals used for inpatient care are included in the cost of inpatient services and are provided free of charge to patients. Inpatient drugs are purchased by health service providers.

Keywords: health care system, Latvia, pharmaceutical system, pricing, reimbursement.

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Introduction

A number of factors could influence or support decisions in the health care sector, for example, use of real-world data as additional information, social aspects, and patients' insurance and co-payments.

Being aware of this and taking into account its interest in the health care area, the International Society for Pharmacoeconomics and Outcomes Research Central and Eastern European Publication Network working group initiated a multinational project to review and describe the drug policies in several countries.

Different aspects were analyzed. Starting with a general overview of the health care system, special attention was paid to the pricing of medicinal products, reimbursement decision-making process and the factors influencing it, as well as the impact on patients' access.

This study aimed to present an overview of the health care system and the pricing and reimbursement environment in Latvia. This article was prepared as part of a project conducted by the working group under the International Society for Pharmacoeconomics and Outcomes Research Central and Eastern European Publication Network.

Methods

The project was conducted in parallel in several countries in 2016 to 2017. The information was collected in a structured way to

allow for a fast and relatively simple search to obtain answers, in our opinion, to key questions defining drug policy issues and to facilitate further comparisons across countries. In alignment with the other countries participating in the project, in Latvia we used the same predefined questionnaire to address the issues of interest.

Country Background

The population of Latvia in 2015 was 1.99 million people [1]. The life expectancy at birth has increased by 3 years since 2000 to 74 years in 2010 (69 years for males and 78 years for females). It, however, still remains the lowest among the Baltic countries and substantially lower than the average in the European Union (EU) [2]. The total health expenditure as a share of gross domestic product (GDP) was 5.5% in 2014, being one of the lowest shares of GDP spent on health in Europe [3]. General taxation by the central government is the source for the resources for health.

Health Care System

General information

Since becoming independent in 1991, Latvia has put substantial effort in creating the National Health Service (NHS). The final NHS was established in 2011. The constant changes occurring in Latvia have taken place against a backdrop of relatively poor health and limited funding. It is important to note that Latvia has one of the

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highest rates of out-of-pocket (OOP) expenditure on health in the EU [2].

According to the Medical Treatment Law (paragraph 16), everyone has the right to receive emergency medical care in Latvia in accordance with regulations. Paragraph 17 of the law specifies who is covered by the statutory health care system: 1) citizens of Latvia; 2) noncitizens of Latvia (individuals who are not citizens of Latvia or any other country, but who, in accordance with the Latvian law "Regarding the status of citizens of the former USSR who possess neither Latvian nor other citizenship," have the right to a noncitizen passport issued by the Latvian government as well as other specific rights); 3) citizens of the member states of the EU, the countries of the European Economic Area, and the Swiss Confederation who reside in Latvia as a result of employment or being self-employed, as well as members of their families; 4) third-country nationals who have a permanent residence permit in Latvia; 5) refugees and persons who have been granted an alternative status; and 6) persons detained, arrested, and those sentenced with deprivation of liberty [4].

The Latvian statutory health care system is based on general tax-financed health care provision. General taxation by the central government is used to secure resources for health care; nevertheless, patient co-payment is still significant. Health care spending in Latvia is among the lowest when compared with member countries of the Organisation for Economic Co-operation and Development (5.5% vs. 9.0% of the GDP in 2014) [5]. Funding by the public sector is also far lower than the organization's average, because OOP payments account for 40.1% of the spending [5].

Public health care funding flows from the Ministry of Finance through the Treasury to the NHS, a state-run organization under the Ministry of Health (MoH), acting as the central statutory purchasing organization.

The MoH is responsible for the national health policy and the overall organization and functioning of the health system. It is also responsible for the implementation of state health policies and ensures the availability of health care services in Latvia.

The statutory health care system covers services provided by physicians and institutions on the basis of agreements with the NHS. The range of health services covered by the state is regulated according to the Regulation of the Cabinet of Ministers of Latvia No. 1529: "Regulations on organization and financing of health care." According to the regulation, the Latvian benefits basket is determined by a number of explicit inclusion and exclusion lists as well as by certain implicit criteria.

Health care in Latvia is provided by the state- and local government-owned institutions, private clinics and hospitals, and individuals. All service providers within the statutory system have to comply with the regulations defined by the MoH and are financed by the NHS. The state is the owner of national multi-specialty hospitals (i.e., the university hospitals) as well as all specialized hospitals. Rehabilitation care is provided by dedicated rehabilitation hospitals and rehabilitation centers. Only a very small part of the hospital sector is privately owned.

In relation to outpatient services (both general practitioners and specialists), about 70% to 80% of health centers are private, with the remaining being owned by municipalities. Most of the small hospitals and some regional hospitals are owned by municipalities, whereas larger hospitals (e.g., university hospitals) and specialized hospitals (e.g., psychiatric hospitals) are owned by the MoH. Some outpatient clinics are organized as public-private partnerships (municipalities, along with private owners) [2].

The government has initiated a health care reform to improve public health indicators. The main objectives of the reform are improving the health care provider network, promoting the

quality of health care services, solving human resource issues, and developing a strategic approach for procurement of health care services when ensuring the optimal public funding of the health sector.

Pricing of medicinal products

To commence the distribution of a medicinal product in the territory of Latvia, marketing authorization holders (MAHs) must submit the exfactory price of the product to the State Agency of Medicines.

Pricing of pharmaceuticals is regulated in Latvia according to Regulation No. 803: "Regulation on pricing principles for medicinal products." For nonreimbursable medicines, prices are based on the manufacturer's price of the product defined by the MAH. Limited markup for wholesalers and pharmacies is applied according to defined formulas:

1. The price for which a drug wholesaler sells a medicinal product is determined by multiplying the manufacturer's price by the correction factor and adding the correction sum and the value-added tax (VAT). The VAT for medicines in Latvia is 12%. The correction factor and the correction sum are determined on the basis of the manufacturer's price. To determine the wholesaler's price, the following formula is used:

$$LC = RC \times k + X + V,$$

where LC is the wholesaler's price, RC is the manufacturer's price, k is the correction factor, X is the correction sum, and V is the VAT. In accordance with Annex 1 of Regulation No. 803, the correction factors and correction sums are applied on the basis of the manufacturer's price (see Table 1). The wholesaler's price is the maximum price for the wholesaler, regardless of the number of wholesalers involved in a particular drug distribution.

2. The price for which a pharmacy sells a medicinal product is determined by multiplying the price for which the pharmacy procures the product from the drug manufacturer or the drug wholesaler without VAT with the correction factor and adding the correction sum and the VAT. The correction factor and the correction sum are determined on the basis of the procurement price. To determine the pharmacy price, the following formula is used:

$$AC = IC \times n + Y + V,$$

where AC is the pharmacy price, IC is the procurement price, n is the correction factor, Y is the correction sum, and V is the VAT. In accordance with Annex 2 of Regulation No. 803, the correction factors and correction sums are applied on the basis of the procurement price (see Table 2). This pharmacy price is the maximum price for pharmacies, regardless of the number of pharmacies involved in the distribution process. Pharmacies can also apply lower markups.

For pharmaceuticals included in the positive list, prices are negotiated between the NHS and the MAHs. Limited markup for

Table 1 – Level of correction factors and correction sums applied on the basis of the manufacturer's price.

Manufacturer's price (€)	Correction factor	Correction sum (€)
0–4.26	1.18	–
4.27–14.22	1.15	0.13
14.23 and higher	1.10	0.84

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