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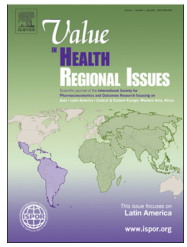

Drug Policy in Estonia

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ABSTRACT

The aim of this article was to present a general overview of the health care system as well as pricing and reimbursement environment in Estonia. In Estonia the main stakeholders in the pharmaceutical sector are the Ministry of Social Affairs, the State Agency of Medicine, and the Estonian Health Insurance Fund. The national health insurance scheme is public, and approximately 95% of the population is covered by it. It is a social insurance, and universal and equal access to health care based on national health insurance is granted. The Estonian Health Insurance Fund is financed from social taxes and state budget and is responsible for the reimbursement of pharmaceuticals in the hospital setting. It acts as an advisory body to the Ministry of Social Affairs on the process of reimbursement regarding cost effectiveness. Pharmaceutical products' reimbursement dossiers submission and decisions are dealt with on the state level. Health technology assessment analyses are required by the authorities and the Baltic Guidelines for Economic Evaluations of Pharmaceuticals have to be followed. The reimbursement lists are positive lists only, and the criteria upon which reimbursement decisions are based are officially defined. Revisions of reimbursement are performed depending on the need and they are based on the prices of reference countries.

Keywords: reimbursement, pricing, Estonia, health care systems.

Introduction

There are several areas of special interest when looking at the health care systems and at what the basis for reimbursement decisions is. That includes factors influencing decisions such as the use of real-world data as additional information, the social aspects, patients insurance, and co-payments. Observing the changing environment and the complexity of decisions taken within the health care systems in Europe, the International Society for Pharmacoeconomics and Outcomes Research (ISPOR) Central and Eastern European (CEE) Publication Network working group initiated a multinational project. The project focuses on reviewing and describing the drug policy in several CEE countries.

Objectives

The article was prepared as part of the project conducted by the working group under the ISPOR CEE Publication Network. Our aim was to present an overview of the health care system, pricing, and reimbursement environment in Estonia.

Methods

The information used for this article was collected in a structured way to allow for fast and relatively simple analysis to obtain answers to key questions defining drug policy issues and to facilitate further comparisons across countries. In alignment to other countries participating in the project, we used the same predefined questionnaire to address the issues of interest in Estonia.

Country Background

Estonia has a population of 1.3 million (January 2015) and had a life expectancy at birth of 72.3 years for males and 81.5 years for females in 2014 [1]. In recent years, some positive trends have been visible in the economic environment; for example, according to Statistics Estonia, in 2015 the unemployment rate was 6.2%, the employment rate was 65.2%, and the labor force participation rate was 69.4%. The unemployment level was significantly lower and the employment rate and labor force participation rate were higher than in 2014 [2].

According to the Organisation for Economic Co-operation and Development report, health expenditure in 2014 was 6.0% of gross domestic product [3,4]. The health insurance system is public, and private expenditures comprise approximately a quarter of all health expenditure, mostly in the form of patient co-payments [5].

Conflict of interest: The authors have indicated that they have no conflicts of interest with regard to the content of this article.

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Health Care System

General Information

The main stakeholders in the pharmaceutical sector are the Ministry of Social Affairs (MoSA), the State Agency of Medicine (SAM), and the Estonian Health Insurance Fund (EHIF).

The national health insurance scheme is public, and it covers approximately 95% of the population. It is a social insurance and relies on the solidarity principle of providing universal and equal access to health care based on national health insurance, which covers emergency care, primary health care (general practitioners [GPs]), and specialized health care (excluding dental care).

Health insurance in Estonia is organized by the EHIF, which is financed from social taxes and state budgets. Employers pay social tax (33% of the income) for all employees and 13% of this goes to the EHIF. The EHIF is responsible for the reimbursement of pharmaceuticals in the hospital setting and acts as an advisory body to the MoSA on the process of reimbursement based on the results of cost-effectiveness analysis.

The MoSA is responsible for strategic planning in terms of pharmaceuticals, as well as pricing and reimbursement decisions in the outpatient setting.

The SAM is responsible for controlling all pharmaceutical activities. It acts as a supervising body and advises the MoSA on the process of reimbursement regarding clinical efficacy.

Primary Care

Outpatient care is organized as the first level of contact with the health care system. It is provided by independent GPs contracted by the EHIF and the maximum and minimum number of individuals on a practice list is defined by a regulation of MoSA and cannot exceed 2000 patients per GP.

GPs are the first patient contact; thereafter, patients are referred to specialist care. Patients are free to access directly the following specialists: ophthalmologists, dermato-venerologists, gynecologists, psychiatrists, dentists, and pulmonologists. For all other kinds of special care, a referral is needed from the GP. In case a patient consults one of these specialists without a referral from the GP, the patients have to pay the full cost themselves.

Access and quality of primary care are monitored by the EHIF. Health services/hospitals are financed according to the contract concluded between the EHIF and the hospitals, on the basis of the service prices (such as diagnosis-related group) and volume of the service.

For prescription (Rx) reimbursement (outpatients), the funds are legally limited to a maximum of 20% of the total health care budget.

Decision-Making Process

The submission of pharmaceutical products' reimbursement dossiers and the decisions made on their basis come from the state level.

To obtain reimbursement for pharmaceutical products, health economic modeling and health technology assessment (HTA) analyses are required by the authorities. For that purpose, the Baltic Guidelines for Economic Evaluation of Pharmaceuticals have to be followed [6].

In Estonia, there is no officially defined incremental cost-effectiveness ratio (ICER) threshold. However, in reality, to receive reimbursement, the ICER/quality-adjusted life-year (QALY) has to be less than €40,000.

During the reimbursement decision-making process, it is mandatory for the marketing authorization holder (MAH) to provide information about a pharmaceutical product's prices for all European Union (EU) countries where it is marketed. Commercial arrangements are possible and the price-volume agreements typically stand for 12 months.

Medicines reimbursement process in the outpatient setting

The process is illustrated in Figure 1. The process starts when the MAH applies for reimbursement by submitting a dossier that includes the health economic evaluation of a product. The SAM and the EHIF provide expert opinion. The Drug Committee in the MoSA is responsible for dossier evaluation and the decision. The Minister of Health & Labor takes the final decision and confirms final reimbursement.

Reimbursement applications can be submitted throughout the year. If the decision is positive, it is followed by negotiations for price-volume agreements between the MAH and the MoSA. For a new product's reimbursement, it is mandatory to propose the lowest price in the EU.

The official evaluation period is 180 days; however, in practice, the timelines are often exceeded. For already reimbursed products, prices are evaluated at least once a year and they are compared with the prices in the reference countries Latvia and Lithuania. The final price should not be higher than those of the reference countries.

Medicines reimbursement process in the hospital setting

The process, as illustrated in Figure 2, begins with a submission of a reimbursement dossier, which is done by the Specialists' Society by December 31 each year. Evaluation takes place during the full following year and it is a process in which the stakeholder is the society and the MAH has no responsibilities to be directly involved in the application process or in the discussion for next year's submission priorities.

However, the MAH is allowed to proactively propose innovative cost-sharing solutions. The reimbursed product is included in the weighted average hospital service fee list once a year and the public funds are divided annually by the EHIF between hospitals in Estonia.

The Role of HTA in the Decision-Making Process

The Department of Public Health at the University of Tartu is responsible for HTA in Estonia. The department was commissioned by the MoSA and the results of its assessments are used

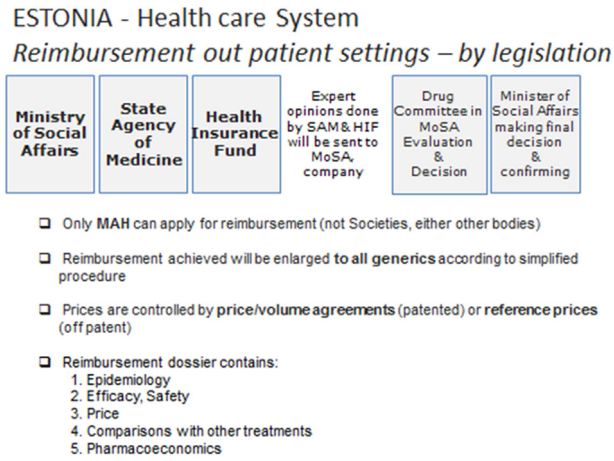

Fig. 1 – Medicines reimbursement process in the outpatient setting in Estonia. HIF, Health Insurance Fund; MAH, marketing authorization holder; MoSA, Ministry of Social Affairs; SAM, State Agency of Medicine.