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## Drug Policy in Poland

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### ABSTRACT

We presented a general overview of the health care system as well as the pricing and reimbursement environment in Poland. Poland aims to ensure proper access to safe and effective medicines while reducing patients' share in treatment costs. Nevertheless, the co-payment for pharmacotherapy is still high (more than 60%). The key policymaker and regulator in the system is the Ministry of Health, which is supported by the Polish Agency for Health Technology Assessment and Tariff System (Agencja Oceny Technologii Medycznych i Taryfikacji), responsible for evaluating applicant drugs, and the Economic Commission, responsible for negotiating the official sales prices and conditions for reimbursement with pharmaceutical companies (e.g., level of reimbursement and risk-sharing scheme agreements). The Agency for Health Technology Assessment and Tariff System dossier is obligatory for reimbursement application and includes the analysis of clinical effectiveness, economic analysis (with the threshold of quality-adjusted life-year established as no more than 3 times the

gross domestic product per capita), and the analysis of budget impact. In Poland, only a positive list of reimbursed drugs is published and it is updated every 2 months. The following levels of reimbursement are in use: 100%, 70%, 50%, and lump sum (about €0.8). The first reimbursement decision is given for a period of 2 years only, the second for 3 years, and the third for 5 years. There is no separate budget or special legal regulations for orphan drugs. Generic substitution of drugs is desired but not mandatory. Physicians are not assigned with pharmaceutical budgets. The access to real-world data is limited; the only registers available are for drugs used in drug programs.

**Keywords:** health care system, pharmaceutical system, Poland, pricing, reimbursement.

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### Introduction

This article was written as part of a project conducted by the working group under the International Society for Pharmacoeconomics and Outcomes Research, Central and Eastern Europe Network. We present a general overview of the health care system as well as the pricing and reimbursement environment in Poland, focusing mostly on the national pharmaceutical pricing and reimbursement policies.

### Health Care System

Poland is a parliamentary representative democratic republic with a multiparty system and free elections. It is the largest country in Central and Eastern Europe in terms of both population (38.1 million) and area (312,685 km<sup>2</sup>). Since the successful transition to a freely elected parliament and a market economy

after 1989, Poland has been a stable democracy with constant economic growth and is well established in Europe and worldwide. It has been a full member of the European Union since 2004 [1].

The country has a mixed public-private health care financing system; the health care services are financed from compulsory health insurance contributions, taxes, and out-of-pocket payments. The public health care system includes both outpatient care (primary and specialist) and inpatient care (hospitals, sanatoriums, and hospices). Medical staff is well trained and health care in Poland is available to all citizens as guaranteed by the Constitution of Poland adopted on April 2, 1997. The Ministry of Health (MoH) is in charge of policy and regulation of the health care system, and the National Health Fund (NHF) manages the health care insurance scheme. The sector is financed mostly from contributors paid by each employed individual to the (National Health Fund NHF; *Narodowy Fundusz Zdrowia* [NFZ]) almost 100% of the population is covered. Private health care is also available

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in the country and many citizens choose it to avoid the long queues imposed by the public insurance system [2,3].

The MoH is the key policymaker and regulator in the health insurance system [2]. There is a clear separation of health care financing and provision: the NHF—the main payer in the system—is in charge of health care financing and contracts with public and nonpublic health care providers. Health insurance contributions, paid entirely by employees, are collected by intermediary institutions and are pooled by the NHF and distributed between the 16 regional NHF branches [3]. Public authorities provide equal access to health care services financed from public funds for citizens, regardless of their financial situation. The basic element of the system is the general practitioner, who, most often, is a specialist in family or internal medicine. The co-payment is high; more than 60% of total cost of pharmacotherapy is covered by patients [2]; reimbursed inpatient drugs are covered by the NHF with no co-payment.

The health expenditure in 2013 was 6.7% of the gross domestic product (GDP) [1], and 70.6% of health care expenditures came from the public resources, whereas the private expenditure accounted for 29.2% of the total health care coverage [4]. Health care expenditure in 2014 was as high as €25,980 million [5]. According to data from the Organisation for Economic Co-operation and Development, pharmaceutical spending was 1.3% of GDP and 20.9% of total health care spending in 2015; US \$339 (€306) per patient was spent for pharmaceuticals in 2014 [6].

## Pricing Policy

The Act of 12 May 2011 on Reimbursement of Medicines, Foodstuffs Intended for Particular Nutritional Uses and Medical Devices (the Reimbursement Act) [7] was drafted by the MoH to rationalize the activity of the public payer, the NFZ, in the field of reimbursement policy and to rationalize its budget. Another objective was to set fixed prices and fixed margins (both wholesale 5% and regressive retail margin) for reimbursed drugs, to have the same prices for patients in all pharmacies in Poland, and to implement the new way of calculating them, which should be in accordance with the accounting standards (The Commission of the European Communities Regulation, 2008) and the European Union legislation, mainly the Council Directive 89/105/EEC of December 21, 1988 [8], relating to the transparency of measures regulating the prices of medicinal products. This directive recommends making reimbursement decisions on the basis of data from best available clinical trials and the assessment of clinical effectiveness, and stated that all reimbursement decisions must be based on credible assessment, and in addition experts' opinions can be taken into account.

External reference pricing and internal reference pricing are valid in Poland, but value-based pricing (linked to threshold prices in the economic analysis) is also considered and influences the price of a reimbursed drug. For internal reference pricing, the general applied rule is that the maximum price of a generic product cannot exceed 75% of the price of reimbursed drug with the same substance as the applicant drug [7]. In one reimbursement limit group, there are drugs with the same international name, or different international names but similar therapeutic effect and mechanism of action, if they have similar effectiveness and indications for use and so the current rules of internal reference pricing in Poland led to the creation of jumbo groups. Often, different active ingredients are grouped, as long as they have the same reimbursement indication and similar efficacy. On top of that, all doses are usually placed within the same group, as well as different drug formulations or different mechanisms of action. The same applies to both branded and generic drugs. The reimbursement limit is currently set at the cheapest drug whose

cumulative share (expressed in daily defined doses [DDD]) is 15% of the sales in the group [7].

The number of reference countries considered for external (international) reference pricing is 31 and the lowest price for the same product is a base for a reference; in other words, the same product should not be cheaper in any reference country than in Poland.

For reimbursed products, fixed wholesale margins (5%) for retail reimbursed products are in use, whereas for nonreimbursed products the margin is not regulated [7]. A pharmacy margin for reimbursed ambulatory drugs is regressive and is strictly regulated in the Reimbursement Act [7], whereas for nonreimbursed products the margin is not regulated and is usually about 25%. Regressive margins are decreasing, and expensive products have lower margins than do the cheaper ones [7].

## Stakeholders

The Polish Agency for Health Technology Assessment and Tariff System (Agencja Oceny Technologii Medycznych i Taryfikacji (AOTMiT)), which was established in 2005, is an independent public organization providing statements and recommendations on technologies applying for public fund, most of which are drugs. The other important entity within the AOTMiT is the Transparency Board, established in 2012 (previously, it was the Consultative Council of the AOTMiT, founded in 2007), which is an independent advisory body consisting of twenty scientists and clinical experts; the members are appointed by the MoH, the NFZ, and the National Drug Registration Agency; and by the Commissioner for Patients' Rights. Since 2009, the AOTMiT is defined as an independent legal entity. The role of the AOTMiT in the decision-making process involves assessment and appraisal of all medical technologies claiming public money coverage. The stage of assessment of medical technology is based on a specially designed objective methodology carried out in accordance with guidelines and published requirements, without subjective opinions. The appraisal stage is a subjective valuation of medical technology that takes into consideration ethical, social, and organizational aspects [9,10].

## Procedures for Including Pharmaceuticals in the Positive List

In the reimbursement process in Poland, the marketing authorization holder (MAH) who initiates the process has to provide the MoH with a completed application form accompanied by a number of attachments, including the full HTA dossier. Subsequently, the MoH provides the AOTMiT with the HTA documentation, and the agency has no more than 60 days to assess the documentation. The MAH is required to complete any missing data in documentation within 14 days from the announcement, and during this period the whole process is on hold. An outcome of an assessment stage is a verification analysis (published on the Website of AOTMiT for public consultations for 7 days) which is based on the HTA dossier submitted by the MAH. Verification analysis is established by the analytic team of the AOTMiT, and is used to formulate the reimbursement statement made by the Transparency Board in the next step (appraisal stage); verification analysis is one of the aspects considered by the Transparency Board during the appraisal process; statement of the Transparency Board and afterwards the recommendation of the President of the AOTMiT finalize the appraisal stage [9,10].

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