Health Policy 120 (2016) 356–361

Contents lists available at ScienceDirect

Health Policy

journal homepage: www.elsevier.com/locate/healthpol

Health Reform Monitor

# Implementation of the 2011 Reimbursement Act in Poland: Desired and undesired effects of the changes in reimbursement policy☆

Paweł Kawalec[a,*], Anna Sagan[b], Ewa Stawowczyk[c], Iwona Kowalska-Bobko[a], Anna Mokrzycka[a]

[a] Jagiellonian University Medical College, Faculty of Health Science, Institute of Public Health, Poland
[b] European Observatory on Health Systems and Policies, United Kingdom
[c] StatSoft Polska Sp. z o.o., Poland

ARTICLE INFO

*Article history:*
Received 28 July 2015
Received in revised form 9 February 2016
Accepted 12 February 2016

*Keywords:*
Reimbursement policy
Drug policy
Reimbursement system
Pharmaceuticals

ABSTRACT

The Act of 12 May 2011 on the Reimbursement of Medicines, Foodstuffs Intended for Particular Nutritional Uses and Medical Devices constitutes a major change of the reimbursement policy in Poland. The main aims of this Act were to rationalize the reimbursement policy and to reduce spending on reimbursed drugs. The Act seems to have met these goals: reimbursement policy (including pricing of reimbursed drugs) was overhauled and the expenditure of the National Health Fund on reimbursed drugs saw a significant decrease in the year following the Act's introduction. The annual savings achieved since then (mainly due to the introduction of risk sharing schemes), have made it possible to include new drugs into the reimbursement list and improve access to innovative drugs. However, at the same time, the decrease in prices of reimbursed drugs, that the Act brought about, led to an uncontrolled outflow of some of these drugs abroad and shortages in Poland. This paper analyses the main changes introduced by the Reimbursement Act and their implications. Since the Act came into force relatively recently, its full impact on the reimbursement policy is not yet possible to assess.


## 1. Introduction

There is no homogeneous reimbursement policy in the European Union (EU). EU Member States are free to set their own lists of reimbursed drugs, their prices and reimbursement levels, as long as they comply with the overall EU regulations, such as the Transparency Directive [1,2]. The growth in public pharmaceutical expenditure (76% in the outpatient sector in the EU countries on average between 2000 and 2009) forced many European countries to introduce new pricing and reimbursement regulations aimed at reducing spending on drugs [2]. In Poland, spending on drug reimbursement by the public payer, the National Health Fund (NHF), saw a 12% growth in 2009 compared to 2008, which was the highest annual growth rate in the 2000–2011 period [3].

The Act on the Reimbursement of Medicines, Foodstuffs Intended for Particular Nutritional Uses and Medical Devices [4] (hereinafter referred to as "the Reimbursement Act" or "the Act") was drafted by the Ministry of Health in order to rationalize the activity of the NHF in the field

☆ Open Access for this article is made possible by a collaboration between Health Policy and The European Observatory on Health Systems and Policies.

* Corresponding author. Tel.: +48 12 43 32 801
*E-mail address:* pawel.kawalec@uj.edu.pl (P. Kawalec).

http://dx.doi.org/10.1016/j.healthpol.2016.02.010

of reimbursement policy and to rationalize its budget (i.e. reduce its spending on reimbursed drugs). Another objective was to make prices of reimbursed drugs uniform across the country by introducing fixed prices and fixed wholesale and retail margins and to implement a new way of calculating them, which would comply with the EU accounting standards (Commission Regulation (EC) No 1126/2008 of 3 November 2008) and EU transparency regulations (mainly Council Directive 89/105/EEC of 21 December 1988 relating to the transparency of measures regulating the prices of medicinal products for human use and their inclusion in the scope of national health insurance systems [5] which recommends that reimbursement decisions are made on the basis of a credible assessment of data from the best available clinical trials and an assessment of clinical effectiveness and allows for experts' opinions to be additionally taken into account).

## 2. Policy content and process

The Reimbursement Act came into force on 1 January 2012 as part of a package of healthcare acts that also included: the Act on the Information Systems in Health Care, the Act on Patient Rights and the Patient Rights Ombudsman, the Act on the Professions of Physician and Dentist, and the Act on Therapeutic Activity. It laid down, in one legal act, the rules for the reimbursement of medicines, foodstuffs intended for particular nutritional uses, and medical devices. The key changes introduced by this Act are summarized in Table 1.

### 2.1. Pharmaceutical cost containment measures

In order to alleviate budgetary pressures, the Act introduced several mechanisms to decrease expenditure on reimbursed drugs: (1) the Act defined a percentage of the total funds for guaranteed benefits that can be used for drug reimbursement–this percentage was set at 17% (it used to be 18% or more); (2) when the amount spent on drug reimbursement exceeds 17%, all Marketing Authorisation Holders (MAHs) of the reimbursed drugs will have to cover the extra expenditure (a pay-back mechanism); (3) the Act made statutory prices based on mandatory negotiations, set price limits for generic drugs (set at 75% of the original drug price) and introduced adjusted fixed wholesale and retail margins (the pricing process for reimbursed drugs is depicted in Fig. 1). Before the introduction of the Act, there were no fixed prices for reimbursed drugs, which meant that access to reimbursed drugs was unequal. Prices had a character of maximum prices and pharmacies could charge lower prices to attract customers and increase sales. Pricing of generics was not regulated. The wholesale margin was relatively high compared to other European countries (8.91% in Poland compared to less than 5% in the Czech Republic, Greece, Spain, Finland, Italy, Sweden, and Latvia [6]) but manufacturers could offer rebates to pharmacies and this practice was widespread. There were also no fixed retail margins. The Reimbursement Act brought the wholesale margin down to 5% (from 2014 onwards), prohibited the use of rebates (pharmacies may now face financial penalties if they obtain rebates from the manufacturers), and made retail margin dependent on the wholesale price. The Act also prohibited advertising and other marketing of reimbursed drugs, which was previously not restricted (Table 1).

Another improvement introduced by the Reimbursement Act was the establishment of the Economic Committee, which is attached to the Ministry of Health and is responsible for negotiating with pharmaceutical companies the official sales prices for reimbursed drugs, levels of patient co-payments, and indications for reimbursement. The Economic Committee makes recommendations regarding: (1) the level of reimbursement (this can either be (a) 100% reimbursement with no patient co-payment, i.e. free of charge; (b) a flat fee; or (c) partial reimbursement – 70% or 50%), depending on the cost and duration of treatment; (2) differences in the reimbursement level, e.g. lower drug prices for certain population groups; and (3) reimbursement period (2, 3 or 5 years). According to the Act, reimbursement decision has to be made on the basis of scientific evidence. To have the drug reimbursed, the MAH has to prove its cost-effectiveness compared to the alternative therapeutic substance which is already reimbursed from public funds.

Another novelty of the Act in the area of reimbursement is the introduction of a negative reimbursement criterion, whereby reimbursement is waived when a health condition can be avoided by a change in lifestyle. This can lead to the exclusion of certain drugs, which could improve the quality of life for the patients, from reimbursement.

Under the provision of the Act, physicians were given additional obligations in terms of writing detailed prescriptions for reimbursed drugs, including specifying the reimbursement category. The NHF may impose heavy financial penalties if irregularities in prescribing (e.g. wrong level of reimbursement indicated on the prescription or writing a prescription for a reimbursed drug to a person not entitled for reimbursement) are detected.

### 2.2. Access to innovative high-cost drugs

The Reimbursement Act also introduced risk-sharing schemes (RSSs), which constitute a relatively novel mechanism for financing innovative medicines that are high-cost [7]. RSSs are mostly used when there is uncertainty about the cost-effectiveness of expensive, innovative drugs. During the health technology assessment (HTA) process a "threshold price" is calculated, i.e. the price at which the Incremental Cost-Effectiveness/Utility Ratio (ICER/ICUR) (the result of Cost-Effectiveness/Utility Analysis) does not exceed the threshold of three times per capita GDP. The MAH of the expensive drug may reduce the ICER/ICUR by proposing a risk-sharing scheme (RSS). It allows the distribution of financial and/or health outcomes risk between the MAH and the public payer [7]. In accordance with the Reimbursement Act [4] the proposed RSSs can (1) make the MAH's revenue dependent on the health outcomes (i.e. focus on the health effects); (2) make the official sales price dependent on the MAH assuring the supply of the drug at lower negotiated price (price discount); (3) make the official sales price dependent on the drug's turnover (price-volume agreement); (4) make the official sales price