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Drug Policy in Greece

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ABSTRACT

Objectives: To provide a detailed overview of the recent reforms in pharmaceutical pricing and reimbursement processes as well as in other important areas of the pharmaceutical policy in Greece. **Methods:** Information was collected via a structured questionnaire. The study used publicly available resources, such as publications, relevant legislation, and statistical data, while health experts were also consulted. **Results:** Recent pharmaceutical reforms included significant price cuts, increased copayments and some provisions for vulnerable groups, rebates/clawbacks, mandatory electronic prescribing and prescription by international nonproprietary name, generics substitution, prescription limits and detailed auditing, centralized procurement, as well as changes in the pricing and reimbursement processes, with the introduction of positive and negative lists and an internal price referencing system. Price lists are compiled by the National Organization for Medicines and are issued by the Ministry of Health (MoH). An advisory pricing committee comprising representatives of stakeholder groups was abolished in early 2018. Nevertheless, under the new provisions, a health technology assessment body for the economic evaluation of reimbursed drugs is to be established for the first time in Greece. The committee is to be staffed by experts appointed by a ministerial decision of the MoH. The specific features of the process are yet to be determined. **Conclusions:** The pricing and reimbursement decision-making processes are centralized under the competence of the MoH. Despite the good intentions of the reformers, there are still some aspects of transparency, equity, and long-term sustainability that remain under question in Greece.

Keywords: Central Eastern European countries, drug policy, economic crisis, Greece, HTA reimbursement system.

Introduction

The economic crisis that has troubled Europe since 2008 was felt the strongest in Greece, with severe social, economic, and health repercussions. Its gross domestic product (GDP) has dropped by about 30%, unemployment rates have skyrocketed (27.5% in 2013), wages and household consumption have both declined by more than 40%, and 35.6% of Greece's population was at risk of poverty and social exclusion in 2016 [1,2]. Because of the severe fiscal problems, the Greek government was forced to sign three bailout programs (memorandums of understanding [MoUs]) in 2010, 2012, and 2015 [3]. The health sector was considered as one of the major culprits of the financial derailment, and several waves of reforms as part of the economic adjustment programs have hit Greece like a tsunami [4].

Although there are several articles that describe aspects of the recent reforms [4–8], to our knowledge, literature still lacks a comprehensive overview of the current framework in the Greek pharmaceutical sector after all these policy changes, especially considering the recent critical passage of Law 4512 on January 17, 2018. Furthermore, a project was conducted recently by the Central Eastern European (CEE) Publication Network Working Group of the International Society for Pharmacoeconomics and Outcomes Research, which provided a review of the different national approaches to pricing and reimbursement policies in the CEE region as well as variations in the use of health technology assessment (HTA) [9–16]. This research was carried out within the working group framework and represents the Greek contribution to the aforementioned project undertaken in the CEE countries.

Methods

Information concerning the various aspects of the drug policy was collected via the same questionnaire and presented in a structured way similar to that of the previous work that has been undertaken by the CEE Publication Network working group so as to facilitate comparisons between countries. The study used publicly available resources, such as publications, relevant laws and ministerial decisions, and statistical data, while interviews with health experts were also conducted.

Context of the Health System

Country Background

Greece is a Southeast European country. In 2016, it had a population of 10.8 million, a low fertility rate (1.3), and a high proportion

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of elderly population (21.3%) [2]. Furthermore, the GDP per capita in nominal terms was €16,154 and the unemployment rate was 23.6% for the same year [2]. Greece follows the epidemiological profile and health trends of Southern Europe. However, evidence is accruing concerning the deleterious health effects of the economic crisis, in the form of increases in infant mortality, psychological problems and suicide rates, and worsening general health and health-related quality of life [1,4,17–20].

Short Overview of the Health System

At the onset of the crisis, total current health expenditure in Greece was among the highest in the European Union (EU) as a share of the GDP (i.e., 9.5%), which was mainly financed through public schemes (estimated at 68.5% of total health expenditure) [2]. The chronic problems and the failure to constrain health expenses growth that predated the crisis placed the health sector under pressure for deep reforming and at the heart of the economic adjustment programs. As a result of the cost-containment measures, total current health expenditure decreased by 34.5% (from €22.5 to €14.7 billion) between 2009 and 2015, and the share of public financing dropped to 59.1% [2].

The Greek health system presents the basic features of both the CEE and the Southern European health models. It is a mixture of public integrated, public contract, and public reimbursement systems, since the tax-funded National Health System (ESY) introduced in 1983 operates along with a Bismarckian compulsory social health insurance system and an overdeveloped private delivery sector [21].

The decision-making process remains mainly centralized under the competence of the Ministry of Health (MoH) [21,22]. The MoH provides goods and emergency prehospital, primary and secondary health services to the residents and citizens of Greece through the ESY. The existence of an integrated health system as has been proposed and implemented in several other countries of the EU and the Organisation for Economic Co-operation and Development (OECD) is still lacking [23]. The private sector consists of profit-making hospitals, diagnostic centers, and private practices, which are mainly funded from out-of-pocket (OOP) payments, and private insurance usually serves as supplementary to the social health insurance [21,24].

As per the requirements of the MoUs, the health insurance branches were separated from the administration of pensions, and all health-related activities were brought under the authority of the MoH in 2010 [5]. In the subsequent year, all major social insurance organizations were unified under a self-managed health insurance organization called the National Organization for the Provision of Health Services (EOPYY), now covering more than 98% of the Greek insured population with a standardized benefits package [3,25]. The EOPYY acts as a unique buyer of pharmaceutical, ambulatory and hospital services for its insurers from both public and health care suppliers.

A series of other policy reforms have been implemented in the Greek health sector in recent years with the purpose of improving efficiency and cost containment, among which the most important include [4,5,21,26] : mandatory all-day functioning of public hospitals (2010), reduction in public health care personnel remuneration and hiring restrictions (2010), centralized procurement of health supplies (2010), reduction in entitlements (2011–2012), increased user charges (2011), introduction of a diagnosis-related group hospital payment system (2011), obligatory electronic prescription (e-prescription) for all medical activities (2012), enhanced internal auditing and cost accounting procedures (2012), and restructuring of primary health care and placing it under the jurisdiction of the ESY (2014), which was further decentralized with the recent institution of a two-level primary health services system (2017).

Pharmaceutical Policies

Pharmaceutical Expenditure

Pharmaceutical expenditure increased at a much faster rate than the GDP in Greece during the 1990s and early 2000s. In the 2000s, Greece adopted expansionary pharmaceutical policies with limited budget control, resulting in a considerable rise in pharmaceutical spending. More specifically, the accumulated growth of pharmaceutical expenditure in Greece between 2000 and 2007 was 3 times the EU average (i.e., 146% vs. 58% in the EU), thereby becoming one of the biggest pharmaceutical spenders in the European region toward the end of the 2000s [3]. Greece was associated with the highest rate of average annual pharmaceutical growth per capita in real terms among the OECD countries before the crisis estimated at 11% (2.3% was the OECD average) and also with the largest negative growth of −6.5% (−0.32% was the OECD average) during the crisis (Fig. 1) [27]. Between 2009 and 2015, pharmaceutical expenditure in Greece dropped from 2.6% to 2.1% as a share of GDP (from €6.1 to €3.8 billion) [28]. Most countries, particularly those under economic adjustment programs (such as Portugal and Ireland), are associated with an effort to curtail pharmaceutical expenditure in the recent years.

As per the MoUs, the European institutions suggested the implementation of a wide range of cost-control pharmaceutical policies aiming at lowering the share of pharmaceutical expenditure in GDP to less than 1% by the year 2014. By applying a simple linear extrapolation technique, we estimate that in the absence of these policies, public pharmaceutical expenditure would have reached the level of €8.3 billion by the year 2016 (Fig. 2). Nevertheless, the implementation of a series of price controls, increases in co-payments, rebates and clawbacks, and e-prescribing policies actually reduced public pharmaceutical expenditure to the level of €1.95 billion.

Marketing Authorization

The market authorization, pricing and reimbursement processes in the Greek pharmaceutical sector are outlined in Figure 3.

There are four procedures whereby a medicinal product is granted market authorization in Greece [30]: the centralized procedure of the European Medicines Agency, the mutual recognition and decentralized procedures with other EU member states (national application to more than one country), and the national procedure. The National Organization for Medicines (EOF) is the competent authority for issuing a marketing authorization for medicinal products in Greece, following an application accompanied by supporting documents. The EOF may import any product in special cases of life-threatening diseases and the compassionate use program [31] or in situations of public health concerns [32].

Pricing

Since 2012, the responsibility of the pricing of pharmaceuticals has been transferred from the Ministry of Development to the EOF to improve the efficiency of the decision-making process and administration [4]. Price lists are first submitted to the MoH and are then issued by a ministerial decision in a price bulletin [33]. Till recently, a pricing committee, comprising representatives from stakeholder groups, was also involved in the process by reviewing the price lists and providing its recommendations to the MoH. This committee was, however, abolished in early 2018 [34]. Hence, the process has become more centralized, since the MoH not only issues the price lists compiled by the EOF but also decides on any objections against the approved price bulletins.