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## Why do generic drugs fail to achieve an adequate market share in Greece? Empirical findings and policy suggestions



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#### ABSTRACT

Objectives: Since 2010, the memoranda of understanding were implemented in Greece as a measure of fiscal adjustment. Public pharmaceutical expenditure was one of the main focuses of this implementation. Numerous policies, targeted on pharma spending, reduced the pharmaceutical budget by 60.5%. Yet, generics' penetration in Greece remained among the lowest among OECD countries. This study aims to highlight the factors that affect the perceptions of the population on generic drugs and to suggest effective policy measures. Methodology: The empirical analysis is based on a national cross-sectional survey that was conducted through a sample of 2003 individuals, representative of the general population. Two ordinal logistic regression models were constructed in order to identify the determinants that affect the respondents' beliefs on the safety and the effectiveness of generic drugs.

Findings: The empirical findings presented a positive and statistically significant correlation with income, bill payment difficulties, safety and effectiveness of drugs, prescription and dispensing preferences and the views toward pharmaceutical companies. Also, age and trust toward medical community have a positive and statistically significant correlation with the perception on the safety of generic drugs. Policy interventions are suggested on the bases of the empirical results on 3 major categories; (a) information campaigns, (b) incentives to doctors and pharmacists and (c) to strengthen the bioequivalence control framework and the dissemination of results.

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#### 1. Introduction

The memoranda of understanding (MoU), which have been implemented since 2010 as a measure of reconstructing the Greek economy and fiscal adjustment had a major focus on the pharmaceutical market [1–3]. Among the measures targeted to the healthcare sector, the fiscal adjustment programs aimed to contain the public pharmaceutical expenditure, as, in the years prior to crisis, the Greek governments had failed to do so [4] resulting to its

significant increase as a share of public health expenditure [5]. Furthermore, the expected improvements in health indicators were not achieved [6–12]. A series of policies were introduced in order to reduce the public pharmaceutical expenditure through pharmaceutical price reductions, while aiming at increasing generic drugs penetration up to 50% [13,14]. The former policy was implemented successfully, but the latter has not met the desirable goal up to date [6]. Thus, it still remains crucial to achieve a high penetration of generics.

As part of the agreement with the Troika (i.e. a committee composed by the European Commission, the European Central Bank and the International Monetary Fund which

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co-ordinates and supervises the application of the memoranda), the following measures had to be implemented: price cuts, introduction of a positive list for the reimbursed drugs, changes in the profit margins of pharmacies, clawback and rebate policies [5]. Meanwhile, the incentives toward doctors and pharmacists for the creation of positive attitude toward the promotion of generic drugs did not meet the expected results in terms of the market share of generic drugs. In order to introduce barriers to the consumption of on/off patent branded originator drugs, the government introduced co-payments. The generic drug, if available, was free of charge (most of the times) based on a reference pricing system [2].

The memoranda related the reforms to gross domestic product (GDP), but they did not foresee its potential large reduction [15] attributable to austerity measures and negative growth of the economy. Despite the lack of a safety net mechanism for securing minimum funding of health care services in case of a significant decrease of GDP, the measures were on the right path as the Greek Health System was characterized by vast expenses, structural distortions, institutional weaknesses and organizational arrhythmias [16–18].

As a result of the MoU I (May 2010) and MoU II (March 2012), the public pharmaceutical budget was reduced by 60.5% between 2009 (€5.1 bn) and 2014 (€2.0 bn) [19]. According to the MoU III (August 2015), the budget for the period 2016–2018 is set at €1.945 bn [3]. Still, the proportion of generic drugs in Greece has remained among the lowest in OECD countries. Specifically, in Greece generic drugs as a proportion of the outpatient pharmaceutical market amounted to 17% in 2009 in terms of volume, and 22% in 2014. [19]. Based on the available OECD data, in 2013 the relevant OECD average was 48% [20]. Although it is obvious that the use of generics can be beneficial for both patients' (in terms of health and their purchasing power) and public expenditure [21,22], the pertaining views on the use of generic drugs are negative among the Greek population - a view also shared by doctors in some instances

The drug market in Greece is regulated and monitored by the government. As a result, the existing environment can be described in economic terms as a monopsony where supply can be universally monitored. In contrast, consumers' demand has to be reinforced in order to achieve a high penetration of generics. In order to create a policy suggestion which will be effective and efficient for the optimal result of the generics' market share increase, a mix of interventions has to be introduced. The economic importance of generics use as well as the failure of Greece to implement their penetration strategy has been highlighted by various researches [4,20,23,24]. However, none of them tried to investigate the specific factors (variables) which affect the beliefs of the population. Neither have they tried to examine whether the said strategy should not be limited only to monetary factors, but it should also attempt to alter population perceptions (e.g. information campaign interventions as it has happened in other European countries) [25]. The present paper aims to identify the population's beliefs on generic drugs, the inefficient strategies which have been implemented in the past and also attempts to

suggest efficient policy measures/campaigns which can be introduced after the examination of the Greek healthcare market characteristics, while investigating the preferences and beliefs of the population.

## 1.1. The Greek pharmaceutical market reforms. A short overview from 2010 to 2015

The implemented reforms of the Greek pharmaceutical market concerned mainly the control of the supply side. The first implemented policy focused on the pricing system of the on-patent branded originator, off-patent branded originator and generic drugs. On-patent branded originator drugs' price was estimated as the average of the three lowest prices among the European Union countries. Offpatent branded originator drugs' price was the same as the on-patent originators or reduced by 50% based on the on-patent price. Generics' prices were set at 65% of the referred on-patent branded originators. In order for the agreed target between the Troika and the Greek government to be achieved, rebates and clawbacks were imposed on pharmaceutical companies, and hospitals had to proceed to tendering procedures in order to achieve discounts [4,5,26,27].

Regarding the demand side, a positive list for drugs to be reimbursed was introduced, as well as an e-prescribing system in conjunction with International Nonproprietary Name (INN) prescribing, both aiming to control doctor prescription behavior and reinforce generics' penetration. INN prescription of the active substance (as opposed to drugs' commercial brand name) was first made obligatory for doctors. However, from April 2015 to September 2015 a ministerial decision was in place which allowed doctors to additionally recommend a specific drug by its brand name (on condition that it was included in the list of drugs with the certain active substance). Further regulations were also introduced in this direction, setting a minimum share of all prescriptions issued by a doctor to be generics' or off-patents [5,26,28].

#### 1.2. Methodology

This present study is a part of a series of national health interview surveys, which have been conducted since 2002 by the National School of Public Health, Athens, Greece. These cross-sectional surveys were carried out in 2002, 2006, 2011 and 2015. The 2015 survey is composed of four waves, starting in January 2015 and expecting to be finalized by the end of 2016. The surveys are not longitudinal.

The present analysis is based on the data collected during the cross-sectional survey which took place between 22nd of July and the 2nd of September 2015. The national sample consisted of 2003 respondents aged 18-years and over. Proportional stratified sampling methodology was employed. Based on the latest Greek population census in 2011 and the NUTS (Nomenclature of Territorial Units for Statistics) administrative division of the country, Representative Sampling Units by geographic region, urbanization, sex and age were identified. For each Representative Sampling Unit, all registered telephone numbers were recorded, of which a random selection was carried

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