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Generics market in Greece: The pharmaceutical industry's beliefs

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Abstract

The aim of this study was to investigate the beliefs and perspectives of the pharmaceutical industry on generic medication in Greece. Questionnaires were mailed to all 58 members of the Hellenic Association of Pharmaceutical Companies from November 2002 to February 2003. The response rate was 52%, namely 30 questionnaires were completed and returned. The questionnaire requested information on companies' involvement in generics, their opinion on generics' characteristics and on public policies affecting the demand and supply of generic medication. A descriptive analysis of the outcomes, that is percentage comparison through binomial tests and Fisher tests, was performed. According to our findings, 43% of the respondents were involved in the production and distribution of generics and the mean period of their involvement was 12 years. The majority of the respondents were in favor of their companies' involvement in generics, despite the relatively small market share of generics in Greece; 9.7% of total pharmaceutical market in 2003. Bearing in mind that in Greece the promotion of generics is not encouraged, pharmaceutical companies believe that the mandatory introduction of bioequivalence studies is an indirect promotional strategy towards generics. Additionally, the majority declared that their main competitive advantages are their safety, efficacy and effectiveness as well as their economic benefit to the society. Finally, the respondents expressed their preference for the introduction of pharmacoeconomic submissions for drugs' reimbursement by social insurance funds.

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1. Introduction

The drugs market is governed internationally by plenty of regulatory interventions, which attempt to counterbalance the economic benefits of pharmaceutical industry with the direct and indirect social benefits of the consumers. The reinforcement of innovation with patent protection in the pharmaceutical industry as well as the protection of public health, equal access of patients to safe and effective drugs and the control of pharmaceutical expenditure constitute the most important drug policy issues in all developed countries [1–4].

International experience has to demonstrate various policies aiming at the control of pharmaceutical expenditure. Most regulatory interventions are primarily focused on drugs' pricing and reimbursement

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decision-making. The introduction of positive or negative lists, reference or negotiated prices [5–9] as well as economic evaluation submissions are primarily used for reimbursement purposes but can also be used as a complementary instrument to control pricing [2,5,6]. Moreover, generic drugs substitution leads to competitive prices and thus to increasing market share [5,6,10–12]. A 'generic drug' is bioequivalent to a brand name drug with respect to pharmacokinetic and pharmacodynamic properties, but it is sold at a lower price and after the patent expiration of the original drug [13]. The term 'generic drug' in this paper refers to both off-patent branded and non-branded generics.

Price regulation of generics both in the EU and the USA, aiming at the creation of a competitive environment between brand name and generic drugs producers, is set, since the last decade, among the priorities of health policy [7,14–17]. However, the effectiveness of the measures mentioned above has been questioned in some cases, given that, although they succeeded in controlling pharmaceutical expenditure to a point, they did not manage to limit consumption volume [6,8,10,18–20].

Taking into consideration the international experience on drug policy issues, in the present study we aimed to investigate the generics market in Greece, by reporting the perspectives, opinions and beliefs of the pharmaceutical companies.

2. Generics policy in Greece

The increase in pharmaceutical expenditure and public health spending, in general, are issues of major concern in Greece [21,22]. Although generics promotion has not been officially placed among the priorities of drug policy, empirical evidence shows that generics have a small but growing share in the Greek pharmaceutical market [21,23,24]. In 1999, the market share of generics in values accounted for 10.4% of the total sales of both generics and originals and it fell to 9.7% in 2003. However, this corresponds to an increase in the sales of generics from €114 million in 1999 to €230 million in 2003 [25]. In Fig. 1, the market share of both originals and generics is presented in values.

According to data from the Institute of Pharmaceutical Research and Technology [26], it is evident that



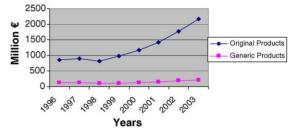


Fig. 1. Original products vs. generic sales in Greece (in values).

domestic production is losing ground over imports, resulting in a complete share inversion over the last 15 years. More specifically, while in 1987 local production represented 75% of total sales, in 2003 it was reduced to 19% of total sales (Fig. 2). In contrast, the imported pharmaceutical products accounted for 18% of total sales in 1987, reaching almost 70% in 2003 [26].

The reduction of the locally produced and packaged medicinal products is due to the medicinal pricing policy which was introduced in 1997 and was based on the lowest EU ex-factory price [21,24]. Until then, the average of the three lowest prices was in effect. The new regulations, in combination with the abolishment of third party taxes, led to a reduction in the prices of many medicinal products, as well as to inversion from production to importation. Despite the fact that the main representatives of the generic market are companies of Greek interest, a small number of large multinational companies is also involved in the Greek market with small shares of sales. For example, in 2002, among the 20 companies with the largest sales of drugs in Greece, 9 were involved in the generic market with percentages ranging between 0.35 and 67% of total generics sales in values [25].

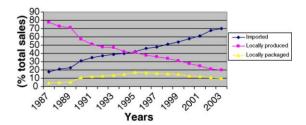


Fig. 2. Sales of medicinal products by origin in values.

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