

Chapter 57

Generic Drugs in the Pharmaceutical Market: A European Perspective

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ABSTRACT

Over the past three decades, marketing has increased its interest in studying the role of generic products in the pharmaceutical sector, one that has only recently incorporated the concept of “generic” products, compared to others such as the mass market. Since the emergence of generic products as one of national brands’ main competitors, these have shown significant growth in both their market share, as well as in new product categories. Initially, the concept of generic products was limited to categories of packaged foods and later extended to categories such as medicine. Pharmaceutical market presents an opportunity to analyze the expansion of the “generic” concept, in a strongly regulated framework. In Europe, different policies have resulted in a varying development of generic market shares. Today, the sustainability of health system is a matter of increasing concern to European governments. Generic drugs offer an opportunity to contain pharmaceutical expenditures, since generic price are lower than their original brand equivalent. Developing this market is the main objective.

INTRODUCTION

What are generic drugs or generic medicines? Generic drugs are medicines that are identical, or bio-equivalent to brand name medication, which offer the same dosage, form, safety, strength, administration route, quality, performance characteristics and intended use (Generic Pharmaceutical Association, 2015). Generic and brand name medicines share the same active pharmaceutical ingredient (API). They are exact replicas of the branded drugs (also known as copycat drugs) and typically go by their chemical name—the generic for amoxicillin is Amoxil, for example. As a mass market product, generic drugs may be classified in branded generics (generics with a specific trade name) and unbranded generics (which use the international non-proprietary name and the name of the company¹) (Organisation for Economic Co-operation and Development, 2014b).

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Once government agencies of each countries have approved a branded drug, it is given a 20-year patent. Nevertheless, the patent for a given drug is typically granted before the drug is approved. So, the drug tends to have market exclusivity for an average of 12 years. For the remaining time, clinical trials and registration is performed. The legislation restricts the exclusive right of use which normally accompanies the patent grant by permitting generic competitors to use the product for testing and developing the generic alternative while the patent is still in effect. This permits a generic products are available once the patent protections afforded to the original developer have expired. Instead of clinical trials, bioequivalence studies are obligatory to be registered as generic product and launched onto the market. Thus, as there is no need for expensive preclinical and clinical trials, generic drugs are much cheaper than their brand name counterparts.

Generic prices are generally 10%-80% lower than their original brand equivalent, reducing the cost of pharmaceutical care. For example, in 2013 alone, generic drugs saved the healthcare systems and consumers over \$239 billion (U.S. market) while for the EU market, the savings was €40 billion (European Generic and Biosimilar Association, 2010; IMS, 2013; Lewek, Smigielski, & Kardas, 2014).

In summary, generic drugs are an alternative to brand name drugs. It is medicine with proven therapeutic values, available at affordable prices, which consequently translate into savings for both healthcare systems and patients. Generic drugs provide one of the clearest value propositions in healthcare today. Developing the generic drugs market contributes significantly to maintaining the sustainability of healthcare delivery, a matter of increasing concern for governments worldwide. (European Generic and Biosimilar Association, 2009).

The main objectives of this chapter are to:

1. **Highlight the Interest of European Governments:** This market, contributes significantly to maintaining the sustainability of healthcare. Pharmaceutical expenditures are a significant component of total healthcare costs. Thus, the search for less expensive therapeutic alternatives has proven the importance of generic medicines when striving to lower these costs. The European Generic Medicines Associations (EGA) argues that sustainable healthcare systems can only be achieved through the increased use of generic medicines. Generic medicines are well-known medicines with proven therapeutic value available at affordable prices. This is consequently translated into savings for both healthcare systems and patients. Moreover, generic medicines stimulate market competition thus driving the development of new medicines for illnesses, diseases and conditions for which treatment may not yet be available. (European Generic Medicines, 2009).

In this chapter, we analyze the situation of this market in numerous European countries. The industrialized countries provide evidence about to the results of policy tools used to encourage the use of generic medicines. Such evidences points out the importance of strategies to facilitate easy market entry as well as policies seeking to influence market demand. It should be noted that the European pharmaceutical sector is heavily impacted by the various regulatory systems operating in European markets. For example, Northern European markets, where generic medicines have the highest penetration rates, are characterized by consistent, long-term generic medicine policies and fewer obstacles to entry, such as price barriers.

2. **Show the Specific Situation of Spanish Market:** Spanish pharmaceutical market has traditionally been dominated by brand medicines with little presence of generic products. Compared with other UE Member States, the entry of generics in Spain has been late. However, competition is

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