

# New product development process and time-to-market in the generic pharmaceutical industry

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## Abstract

Generic pharmaceutical companies tend to improve their market position by being first in the market when a patent on an original product elapses. The time-to-market of new products is an important source of their comparative advantages. In our study we investigate the organizational and managerial factors lying behind time-to-market in four generic pharmaceutical companies in Central and Eastern Europe. Our research also supports some results found in other studies on the lead-time of new product development. However, we find some factors specific to generic pharmaceutical companies. Our findings are incorporated into a diagnostic model of new product development in generic pharmaceutical companies, which is an important practical result of our research.

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## 1. Introduction

According to the [Scrip Reports \(2002\)](#) in the same period between 2000 and 2005 pharmaceuticals are expected to grow in value from USD 362 billion to USD 561 billion in constant prices — a rise of some 55%. In the same period around USD 100 billion worth of products face patent expiry ([Cap Gemini Ernst & Young, 2002](#)). This along with the severe budgetary problems of many governments represents an immense opportunity for generic companies, whose global market is today estimated at about USD 20 billion per annum. Moreover, the prevailing strategy is that generic companies with first to market products capture the market, enjoy a high market share, create barriers to entry for the competition and create brand awareness for their products

([Thomas, 1988](#); [Scrip Reports, 2002](#)). The timing of introducing a new product and therefore the speed to market is a key issue for all manufacturers in this industry ([Henderson, 2000](#)).

The formation of a generic company generally depends on its proximity to major markets and local prevailing conditions inviting generic production. For example, Canada's governmental support favoring generics and its geographical proximity to the US — the world's largest generics market — has dictated Canadian involvement. Germany, the largest European generics market, with government action actively favoring generics, expects German generic companies to dominate Europe. Teva from Israel is a unique example of a successful local company targeting the world in an aggressive fashion and thereby achieving its position as a top generics producer by acquisition ([Scrip Reports, 2002](#)).

Despite the importance of the efficiency of new product development in the generic pharmaceutical industry and even though time-to-market has been extensively discussed in the literature, there is very little research directly relating to the generic pharmaceutical industry. Our research is the

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first in this area. For this we have collected data from four generic pharmaceutical companies from Central and Eastern Europe,<sup>2</sup> where 34 new product development projects launched in 2002 have been included.

This article presents some important factors impacting on the lead-time of new products, which can also be found in researches of other industries. In particular, we find a negative relationship between the incorporation of organizational tools and techniques, such as concurrent activities' management and time-to-market. Further, there is an appropriate negative relationship between the integration of new product development departments in particular phases of the new product development process and the cycle-time of those phases. Appropriate capacity management and project management also contribute to a shorter lead-time of a new product. However, there are also some particularities of generic pharmaceutical companies. We find that retargeted products (where an existing product is launched in a new market) have longer time-to-market than completely new products. The generic pharmaceutical industry depends very much on local market conditions and it is often easier to launch new products in already existing markets than to launch existing products in new markets. Further, we find that if the active pharmaceutical ingredient is sourced externally the time-to-market is shorter. The same is true of the external sourcing of the pharmaceutical formulation. Since generic companies often build their competencies in the market rather than on the technology used, strategic alliances and early supplier involvement in the new product development are important factors of their market success.

## 2. Definition of a generic pharmaceutical product and a new product, phases of the new product development process, research hypothesis and data

### 2.1. Definition of a generic pharmaceutical product

A product enters the pool of available substances when its originator loses its exclusivity through the expiry of a patent. Consequently, generics are generally accepted as products that are no longer patent-protected and which are therefore available in an 'unbranded' version<sup>3</sup> These types of generic products are called 'pure generics'.

However, even this categorization has become distorted over the passage of time with the introduction of products being referred to as 'branded generics'. This term refers to products not issued by the originator but those that may be allied to the name of the producer. There is also a relatively new area of activity concerned

with patent-expired molecules. They are 're-invented' by reformulation and sometimes also allied with new drug delivery methods.

### 2.2. A new product in the generic pharmaceutical industry

In studying generic pharmaceutical products no standard categorization as described in the literature can be used since it does not cover the specifics of this industry.<sup>4</sup> We will define new products as:

- *Line extensions*. Similar to the definitions of Booz, Allen, and Hamilton (1982) and Cooper (1994) we define line extensions as small adaptations of an existing product, which is normally already available in the market.
- *Retargeting*. With the term retargeting we understand that an existing product is registered, launched and marketed in a new market, as described by Cooper (1994).
- *New product*. With the term new product we understand a completely new product for the company and for the market in the generics segment. Based on the level of innovativeness, this category is divided into the following subcategories: a) ordinary generic products without active patent protection; b) generic products with active patent protection; c) products with a new delivery system (proof of the concept of the technological platform); and d) bio generics, products which have gene-recombinant drug technology (genetic engineering).

### 2.3. Phases in new product development in the generic pharmaceutical industry

The new product development process differs very much from industry to industry and there is no general or standard process that can be applied to all industries and companies. Based on the extensive literature regarding development phases in the new product development process (Booz, Allen, & Hammilton, 1969; Cooper, 1979, 1994, 2000; Rosenthal, 2002; Koufteros, Vonderembse, et al., 2002; Thomas, 1993) and based on interviews we conducted with several generic pharmaceutical companies, we have defined the new product development process as shown in Fig. 1.

*Phase 0* covers the *broad generation of ideas* or potential drug candidates. A dedicated expert team decides which ideas/candidates should be selected to proceed to the preliminary assessment phase.

*Phase 1* is the *rough assessment of the drug candidates*. This is only desk research or AN assessment 'on paper' which usually covers the marketing potential, the production possibilities, the R and D and registration strategy as well as the purchasing strategy.

<sup>2</sup> Besides Lek, which became part of the Novartis Group, other companies from Central and Eastern Europe (e.g., Pliva, Krka, Richter Gedeon, Slovafarma) also belong to the biggest generic pharmaceutical companies.

<sup>3</sup> See Scrip Reports (2002).

<sup>4</sup> See Booz et al. (1982), Cooper (1994), Crawford (1980).

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