NEW PRODUCT DEVELOPMENT PROCESS IN GENERIC PHARMACEUTICAL COMPANIES: DETERMINANTS OF THE TIME-TO-MARKET

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ABSTRACT

Despite the importance of the efficiency of new product development, there is very little research in this area directly relating to the **generic** pharmaceutical industry. In our study we analyse four generic pharmaceutical companies from the Central and Eastern Europe, where 34 new product development projects launched in 2002 have been included. We have found that the more strategic alliances the company enters for the new product development process, the shorter the time-to-market. Furthermore, there is a positive relationship between the incorporation of organizational tools and techniques, such as concurrent activities' management and appropriate resource planning and project management, and the time-to-market. Additionally, there is a 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. We have also found that retargeted products (existing product is launched on a new market) have longer time-to-market than completely new products. Moreover, if the active pharmaceutical ingredient is sourced externally, the time-to-market is shorter. The same is true for the external sourcing of the pharmaceutical formulation. Our findings have been incorporated into a diagnostic model of new product development in generic pharmaceutical companies, which is an important practical result of our research.

Key Words: R&D and Technology Management, Supply Chain Management, Technology Management.

1. INTRODUCTION

In the years between 2000 and 2005, according to the IMS, the pharmaceuticals are expected to rise in value from $362 billion to $561 billion in constant prices – a rise of some 55%. Estimations show that $100 billion of products face patent expiry by 2004 (Cap Gemini Ernst & Young, 2002). This represents an immense opportunity for generic companies, whose global market is worth $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 (Scrip Reports, 2002). Timing of the new product introduction and therefore the speed to market become a key issue for all manufacturers in this industry.

Despite the importance of the efficiency of the new product development in the generic pharmaceutical industry and despite the fact that time-to-market has been extensively discussed in the literature, there is very little research in this area directly relating to the generic pharmaceutical industry. Our research is the first in this area. For that we have collected data from four generic pharmaceutical companies from the Central and Eastern Europe, where 34 new product development projects launched in 2002 have been included.

In the article we present some important factors impacting the lead-time of new products, which can also be found in researches of other industries. In particular, we have found that the more strategic alliances the company enters for the new product development process, the shorter the time-to-market. Further, there is a positive relationship between the incorporation of organizational tools and techniques, such as concurrent activities' management, appropriate resource planning and project management, and the time-to-market. Additionally, there is also a 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. However, there exist also some particularities for the generic pharmaceutical companies. We have found that retargeted products (existing product is launched on a new market) have longer time-to-market than completely new products. Furthermore, we have found that if the active pharmaceutical ingredient is sourced externally, the time-to-market is shorter. The same is also true for an external sourcing of the pharmaceutical formulation. Our findings have been incorporated into a diagnostic model of new product development in generic pharmaceutical companies, which is an important practical result of our research.

The paper is organized as follows. The next section provides definitions of a generic pharmaceutical product and a new product in generic pharmaceutical industry, the phases of the new product development process in this industry, the main hypothesis and data. The third section presents our main results. First we describe managerial practices in the new product development process of generic pharmaceutical producers and then we show the factors affecting the new product development time. The fourth chapter discusses and summarises our findings. The paper concludes with a presentation of implications of our findings for the managerial practice.

2. DEFINITION OF A GENERIC PHARMACEUTICAL PRODUCT AND A NEW PRODUCT, PHASES OF 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 patent expiry. Consequently, generics are generally accepted as products that are no longer patent-protected, and are therefore available in an "unbranded" version (see Script Reports, 2002). These types of generic products are called "**pure generics**".

However, even this categorization has become distorted through the passage of time, with the introduction of products referred to as "**branded generics**". This term refers to products not issued by the originator, but those that may have been allied to the name of the producer. There is 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 (Booz et.al, 1982, Cooper, 1994, Crawford, 1980). We will define new products as:

- **Line extensions.** Similar to Booz et al. (1982) and Cooper (1994) definitions we define line extensions as small adaptations of an existing product, which is normally already available on the market.
- **Retargeting.** With the term retargeting we understand that an existing product is registered, launched and marketed on 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 value added; b) generic products with value added, which have an active patent protection; c) products with new delivery system (proof of concept of technological platform); d) bio generics, products which have gene-recombinant drug technology (genetic engineering).

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

The new product development process differs very much from industry to industry and there is no general or standard process that could be applied for all industries and companies. Based on the extensive literature regarding development phases in the new product development process (Booz et al. (1969), Cooper (1979), Rosenthal (1992)) and based on the interviews conducted with several generic pharmaceutical companies, we have defined the new product development process with the following phases:

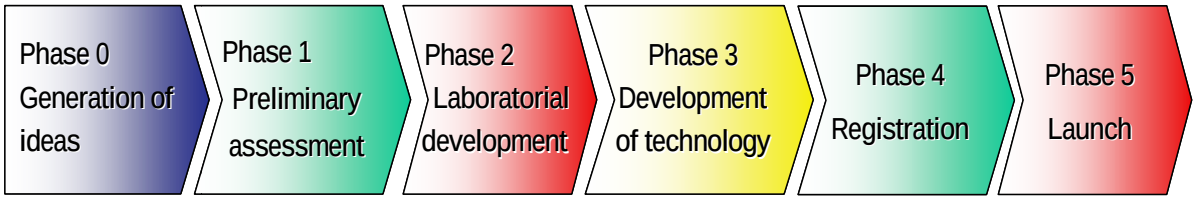

Figure 1. New product development process for generic pharmaceutical companies

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 into the preliminary assessment phase.

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

Phase 2 is the *laboratorial development*. This phase starts with experimental and accelerated stability study work, the development based on a laboratorial scale, including the (pilot) bio-equivalent-study and development of the primary packaging. The scale-up from the laboratorial to the semi-industrial scale is done.

Phase 3 is the *development of the technology*. This phase includes the 1st test, the transfer to the industry measure and the preparation of registration documentation. It includes clinical studies, toxicological studies, bio-equivalent studies and completed stability studies. This phase finishes with the production of three registration batches.

Phase 4 is the *registration* itself. This is the filing of registration dossiers at regulatory authorities. It finishes when the product is registered and the registration documentation and marketing authorization is obtained.

Phase 5 includes all *final pre-launch activities* (e.g. production of launch stock, ordering of raw materials, packaging materials, etc.) including the launch of the product on the selected market (product on shelf available).

2.4. Hypothesis

As mentioned, there is a wide literature (Stalk, 1988, Cohen et. al, 1996, Datar et. al, 1997, Gupta and Souder, 1998) on factors that influence the length of time to market in the new product development (NPD). Based on this literature we develop the following hypothesis, in our view important also in the pharmaceutical generic industry.

Strategic alliances in pharmaceutical industry include joint R&D projects, licensing agreements, cross-licensing agreements (swaps of know-how), equity investments (which are also often linked with know-how transfers) and marketing alliances (which are concerned with the marketing of products that have already been developed and have received the FDA approval). The basic proposition is that a firm's rate of NPD is a positive function of the number of strategic alliances that is has entered. However, as described by Deeds et al. (1996) the relationship between strategic alliances and the rate of NPD may be non-linear.

Hypothesis 1: *There will be a positive relationship between the number of strategic alliances a generic pharmaceutical company enters and its rate of new product development.*

A review of the recent literature on accelerated product development shows a lengthy list of tools and techniques aimed to reduce NPD cycle time (Gonzales *et al.* (2002), Bonner *et al.* (2002), Cordero (1991), Griffin (1997), Ittner *et al.* (1997), Langerak *et al.* (1999), Datar *et al.* (1997)). If we consider all possible versions and modifications of these techniques, over 600 different types can be identified (Nijseen et al., 1995). These new approaches include techniques as Quality function deployment (QFD), Design for manufacture (DFM) and product data management (PDM). They can be classified into 4 different groups: They can be classified into 4 different groups: design techniques (e.g. QFD, DFM, quick product specification, design optimization, etc.), organizational techniques (e.g. stage-gate process, concurrent activities management, etc.), manufacturing techniques (e.g. manufacturing resource planning – MRP, just in time, etc.) and information technologies (e.g. computer aided design – CAD, computer aided manufacturing – CAM, product data management – PDM, etc.).

Hypothesis 2: *There will be a positive relationship between incorporation of NPD tools and techniques (e.g. design techniques, organizational techniques, manufacturing techniques and information technologies) and the time-to-market in the generic pharmaceutical industry.*

Droege et al. (2000), Cooper et al. (1995), Spaulding (2002), Nijssen et al. (2002) and Kessler et al. (1999) show that the management of the supply chain is a strategic activity that must be conducted across the entire enterprise, from marketing and product design groups all the way through to the accounts receivable department. Supply chain management must be conducted between enterprises, since optimizing entire supply chains will require a level of information sharing and collaboration among enterprises previously unknown in most businesses. This is especially important in the pharmaceutical industry. Its supply chain is vitally important to the industry, the patients and physicians it serves and is undergoing more change than it has ever experienced.

Hypothesis 3: *There will be a positive relationship between integration of new product development departments in generic companies and the time-to-market. Similar is true also for the integration with their customers and suppliers.*

Technologic familiarity is one of the well-studied criteria in the literature (Yeoh, 1994; Spaulding, 2002). This variable can also be defined as a prior experience. It is measured by

the number of drugs a pharmaceutical firm has developed in particular therapeutic markets. One angle to analyze the technological familiarity of the products is based on the product type, grouped into completely new products and retargeted products, meaning that an existing product is launched on a new market.

Hypothesis 4: *Retargeted products are faster to market than completely new products.*

2.5. Data

For the purpose of this study the population was defined as generic pharmaceutical companies in the Central and Eastern Europe who are manufacturers and have also a research and development department. We believe that because of the proximity of these companies it will be easier to obtain the data that are needed to fulfil the goals of this research. Based on this we selected the most advanced, most export-oriented and the biggest generic pharmaceutical companies in the Central and Eastern Europe. The pharmaceutical industry is a highly regulated, highly competitive and highly innovative industry, which all results in a general unwillingness to uncover business information. Only through personal contact with the companies, which was achieved through the Deloitte & Touche client base in the generic pharmaceutical industry it was possible to motivate the companies to participate.

After the initial contact with the selected companies, a personal presentation in 6 generic pharmaceutical companies has been conducted. In this presentation it was also stated that it is an academic, free-of-charge research whereby the Deloitte & Touche network will be used to ensure region-wide coverage and participation. Finally, four companies have decided to cooperate in this research and to contribute their data. With each of the participating generic pharmaceutical companies a confidentiality letter has been signed by Deloitte & Touche to ensure that all the data, information and documentation are confidential during the course of this project and 10 years thereafter.

3. DATA ANALYSIS

3.1. New product development managerial practices in generic pharmaceutical companies

Out of a total of 972 projects/products, which represent the total number of projects/products in all phases (phase 0 to phase 5), 26 projects have been in phase 5 in 2002, which is the so called (pre-) launch phase. As seen in Table 1, an existing product, but on a new market (50%) was the most observed type of product launched by the responding manufacturers, followed by ordinary generic new products (35%).

Table 1. Number of new product introductions by product type in 2002

Product type	**No. launched in 2002**	**%**
Line-extensions	1	4%
Existing product, new market	13	50%
New product - Ordinary generics	9	35%
New product - VA generics	1	4%
New product - NDS generics	1	4%
New product - Bio generics	1	4%
TOTAL	**26**	**100%**

If we compare the structure of launches in 2002 on the one hand and the structure of the total new product pipeline in 2002 (which includes all phases) on the other, we can see that there is a shift towards more innovative new products. The percentage of retargeted products is decreasing (26% of total new product pipeline), whereas the percentage of completely new products – ordinary generics as well as generic products with value added – is increasing (66% of total new product pipeline). This shift in the structure of new products towards more innovative new products is aligned with the cross-industry study of Booz, Allen and Hamilton (1982) and Griffin (1997), if compared respectively.

With the questionnaire we have also analyzed the managerial practices generic pharmaceutical companies use within their new product development processes. We can group them into three main building blocks: process related, organization related and measurement related. Below we will present some results of the analysis of the questionnaire. A more detailed analysis can be seen in Škerlj (2004).

All generic pharmaceutical benchmarking partners use a formal new product development process, with clearly defined phases and cut-off points between phases. Some companies still have a functional, sequential process, while some have migrated to some form of multi-functional stage gate approach. The mortality curve of generic pharmaceuticals is very similar to the cross-industry mortality curve analyzed by Griffin (1997), but substantially different from a similar earlier study done by Booz, Allen and Hamilton (1982). For the benchmarking partners the average commercialization rate is 36,6%, if we take into consideration all phases, including phase 0, which is the idea generation phase. This means that almost 65% of the preliminary assessed generic pharmaceutical products do not make it to the market. While more or less the same number of ideas are creating one success, today projects are eliminated much earlier in the new product development process, where less time and money is being spent on any particular idea (see also Page, 1993 and Sounder, 1987).

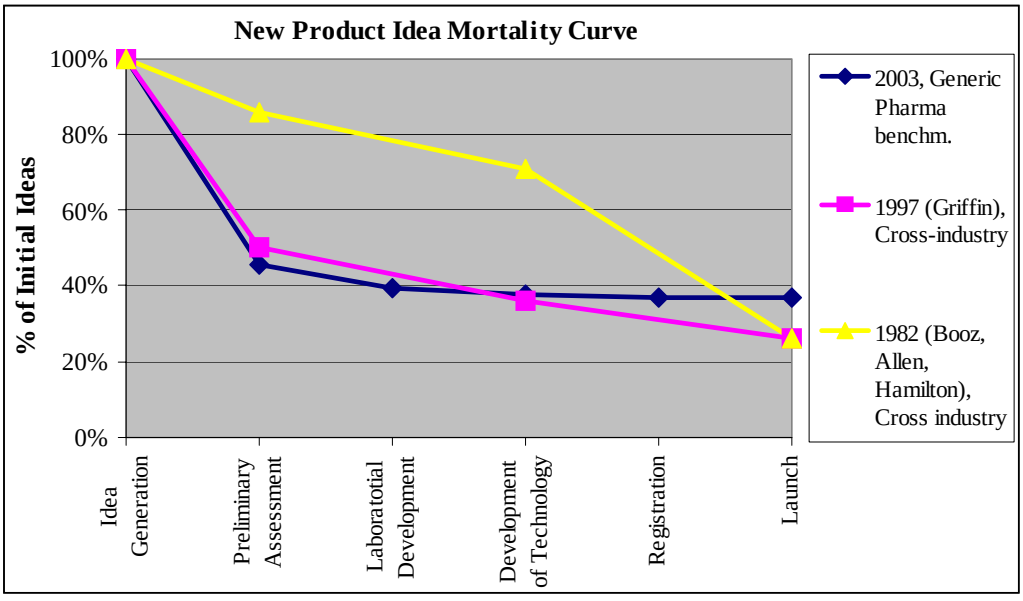

Figure 2. New product idea mortality curve.

The involvement of suppliers in the new product development process has been relatively weak in the analyzed generic pharmaceutical companies, since in only 15% of the analyzed projects suppliers have been involved already in the preliminary assessment phase (phase 1).

Regarding the organizational structure of the new product development process, responsibilities and project management, the results show that none of the companies has an

end-to-end process owner. All companies have multi-functional organizational structure with defined project managers for each particular phase.

The main drivers of phase 0 are marketing and business development (strategic marketing). The input for this "creative" phase is often coming from subsidiaries in different countries and their country managers, who are mostly sales oriented people with a deep knowledge of customer needs. Phase 0 is usually lead and managed by a person from the business development department; in very rare cases it is lead by research and development.

Phase 1, where a thorough analysis of the drug candidates is made, is a multi-functional task. Several aspects need to be analyzed for each drug candidate, from purchasing strategy, research and development and production capabilities, registration and patent situation, as well as sales potential and competitive situation. From our analysis follows that several departments are involved in conducting this preliminary assessment. In addition, a person from business development department usually conducts the project management in phase 1.

Phases 2 and 3, which are the real development phases, are mainly carried out by the research and development department, which is extensively supported by the production and purchasing departments. During this time, the registration is also starting with their activities, which include the preparation of registration dossiers for the registration authorities. Overlapping of the activities of phases 2, 3 and preparations for phase 4 is crucial in the light of shortening of the total time-to-market. A person from the research and development department usually leads phases 2 and 3, in very rare cases a person from production.

The registration department, with a strong support of the research and development department, mainly conducts phase 4, the registration itself. Inputs for the preparation of registration dossiers are obtained from several different departments, such as purchasing, production, marketing, etc. In some generic pharmaceutical companies this phase is lead by a person from the research and development department and in some by a person from the registration department.

Phase 5, the launch phase, where all the final pre-launch activities are finalized, is a multi-functional organization. Usually a marketing person leads this phase, although in some companies the research and development department is also project managing this phase.

Without measuring the speed, costs, flexibility and quality of the new product development process the success and efficiency cannot be managed. All participating companies measure the lead-time (defined as the lapsed time for a particular phase and product). However, cost efficiency is not measured by all companies and in all phases. It is not measured at all phase 2, and even at that point in time only 2 companies out of 4 measure it. Additionally, no participating company is measuring the number of drug candidates (number of projects) in phase 0, which is the "generation of ideas/candidates" phase.

The results of the analysis show that the generic pharmaceutical companies always measure market shares, product sales and shares of the new product revenue in the total company's revenue. But customer satisfaction (focused mainly on doctors, pharmacists, etc.) is seldom measured. Also surprisingly, key figures like internal rate of return and net present value are not always calculated.

The observed generic pharmaceutical companies do focus on lead-time improvements mainly in phases 2, 3, 4 and partly in phase 5. Three out of four have quantified goals for lead-time improvement for the two development phases (phase 2 and 3) as well as for the registration phase (phase 4). For the launch phase (phase 5) only two companies have reported that they have set these goals and none of them has quantified goals for lead-time improvements for phases 0 and 1.

To motivate the most successful new product development employees, the companies do primarily use cash bonuses and rights from intellectual property. Common are also salary raises, promotions and company awards. This is somewhat in contradiction with the findings

of Booz et al. (1982) and Feldman (1996), who found that performance-based financial incentives in general play a minor role in compensating new product development employees.

3.2. Determinants of the new product development time

3.2.1. Overview of the new product development time by phases

Total new product development time on average for all product types for the 4 analyzed benchmarking partners is 59.2 months. As can be seen in the table below, the phases that "consume" most time are phases 2, 3 and 4. And even more important, these three phases have the highest standard deviation. Also phase 5, which is the pre-launch phase, has an important impact on the total time, whereas phase 0 (idea generation) and phase 1 (preliminary assessment) are the shortest phases that do not extensively impact the total time-to-market.

Table 2. Average time of each phase of the new product development phase and standard deviation

	Months (average)	**Standard deviation**	**Months (minimum)**	**Months (maximum)**
Time phase 0 (Generation of ideas)	3.3	4.3	0.1	2
Time phase 1 (Preliminary assessment)	1.7	1.1	2	2
Time phase 2 (Laboratorial development)	15.3	19.3	9	72
Time phase 3 (Development of technology)	12.6	10	6	10
Time phase 4 (Registration)	19.5	13.3	6	15,5
Time phase 5 (Launch)	8.9	6	5	12
TOTAL TIME	**59.2**	**24.7**	**26**	**113.5**

3.2.2. Factors affecting total new product development time

In the three figures below we present discrepancies between the time-to-market for completely new products and retargeted products (figure 3), for different types of sourcing of the active pharmaceutical ingredient (figure 4) and for different types of sourcing of the pharmaceutical formulation (figure 5).

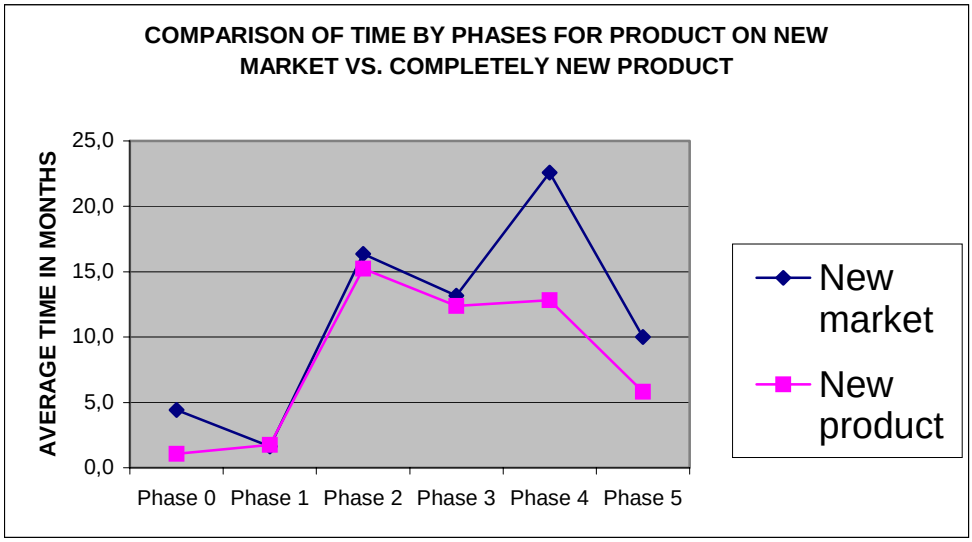

Figure 3. Comparison of time by phases for retargeted product and completely new product

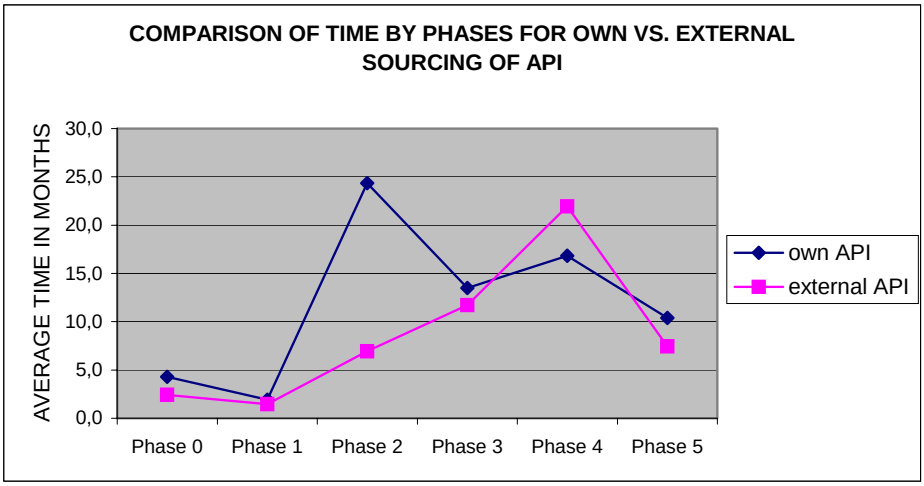

Figure 4. Comparison of time by phases for different types of sourcing of active pharmaceutical ingredient (API)

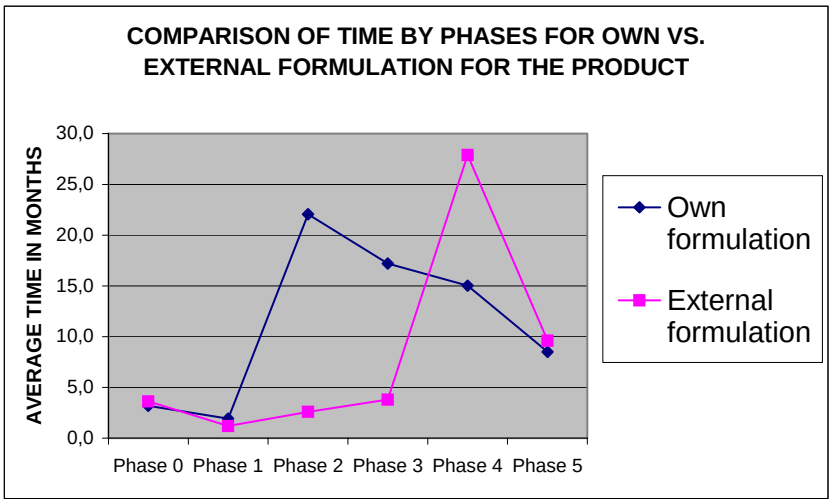

Figure 5. Comparison of time by phases for different types of sourcing of pharmaceutical formulation

From the figures above we can conclude the following: 1) time-to-market for retargeted products is longer than time-to-market for completely new products (Figure 3). Herewith our study differs from the cross-functional studies (Kuzmarcki (1994) and Griffin (1997)), which have found the opposite. Reasons could lie in better project management and higher new product development efficiency of completely new products than retargeted products. Our results show that in case of the development of a completely new product more departments are involved in phases 3, 4 and 5, while the frequency of meeting conducted by the involved departments is also higher. The contribution to the company's revenue is usually higher for a new product than it is for a retargeted product. Additionally, in case the generic pharmaceutical company is overloaded in its new product development capacities, new products usually get higher priority than just retargeted products do. 2) In case that the active pharmaceutical ingredient (API) is internally developed, the total time-to-market is significantly longer than if it is externally sourced (Figure 4). The total new product development time in case of an internally developed API is 68.6 months, whereas it is only 50.4 months when it is externally sourced. The main difference in the time-span comes from phase 2, which is the laboratorial development phase. The only exception is phase 4, the registration phase, which is on average shorter if the API is developed internally. The data also confirms that the involvement of suppliers is significantly stronger if the API is externally sourced. Furthermore, the number of deficiency letters received in the registration phase is higher in case of internally developed API. This can lead to the conclusion that phase 4 takes on average longer in case of internally developed API. 3) If we compare the time-to-market of a finished generic pharmaceutical product where on the one hand the formulation for this product has been developed internally while on the other had it has been externally sourced (e.g. complete formulation licensed in or only technology bought), big discrepancies exist (Figure 5). This has no effect on phases 0, 1 and 5, but significant differences exist for phases 2 and 3, which are substantially longer if the formulation is developed internally. Phase 4, on the other hand, is significantly shorter in this case. The main reason for the differences in phases 2 and 3 is that when the formulation for the product is externally sourced, it is usually also the active pharmaceutical ingredient that is externally sourced. This of course significantly reduces the required internal resources for its development, in particular production and research and development capacities.

An overview of the main variables, which are significantly impacting the total time-to-market, is shown in the Table 3. The correlation coefficients have the expected sign.

Table 3. Correlation coefficients between the individual variables and the total time-to-market

VARIABLE	SIGN	SIGNIFICANCE	EXPLANATION
Source of API	-	*	If the API is sourced externally, the time-to-market tends to be shorter.
Source of formulation	-	*	If the formulation is sourced externally, the time-to-market tends to be shorter.
Start preparation of registration dossier	+	(*)	The earlier in the process the registration dossiers are started to being prepared, the shorter the time-to-market.
Revenue in first 3 years	-	*	The higher the contribution of the new product to the revenue of the first 3 years, the shorter the time-to-market.
NPD pipeline overload	+	(*)	The more the NPD pipeline is overloaded the longer the time-to-market.
Calculation of NPV	-	*	The calculation of NPD measures (e.g. NPV) contributes to shorter time-to-market.
Nr. of FTE's involved	+	**	The more FTE's involved in phase 2, 3 and 4, the longer the time-to-market.
Involvement of suppliers	-	** for phase 3 and 4; * for phase 1 and 2	The more suppliers are involved in phase 1-4, the shorter the time-to-market.
Product type	-	(*)	The time-to-market of retargeted products tends to be longer than it is for completely new products.

** $\alpha \leq 1\%$

* $\alpha \leq 5\%$

(*) $\alpha \leq 10\%$

As already mentioned, the phases, which have the biggest impact on the total time-to-market, are in particular phases 2, 3, 4 and partially also phase 5. In the following we will more specifically analyse the variables affecting each individual phase of the new product development process, focussing mainly on phases 2, 3 and 5. We will not analyse in more detail phase 4, the registration phase, since many external factors (e.g. regulation of selected country, government policies, etc.) are affecting the cycle-time of the registration of a generic pharmaceutical product in a particular country.

3.2.3. Factors affecting the new product development time in phase 2

Table 4 summarizes the main variables, which statistically significant impact the cycle time of phase 2.

Table 4. Main variables impacting the cycle time in phase 2

VARIABLE	SIGN	SIGNIFICANCE	EXPLANATION
Nr. of FTE's involved in phase 2	+	(*)	The more FTE's involved in phase 2, the longer the phase 2 of the new product development proces.
Involvement of suppliers in phase 2	-	**	The more suppliers are involved in phase 2, the shorter the phase 2.
NPD pipeline overload	+	**	The more the NPD pipeline is overloaded the longer the phase 2.
Source of API	-	*	If the API is sourced externally, the phase 2 tends to be shorter.

** $\alpha \leq 1\%$
* $\alpha \leq 5\%$
(*) $\alpha \leq 10\%$

The signs of the correlation coefficients between the analysed variables and the cycle time of phase 2 are within expectations. More full-time equivalents result in longer cycle time of phase 2, while early involvement of suppliers shortens it. If the active pharmaceutical ingredient is sourced externally, the cycle time of phase 2 is shorter. And the more the new product development pipeline is overloaded, the longer the cycle-time of phase 2.

3.2.4. Factors affecting the new product development time in phase 3

The table below presents the main variables impacting the cycle time of phase 3, the laboratorial development phase.

Table 5. Main variables impacting the cycle time in phase 3

VARIABLE	SIGN	SIGNIFICANCE	EXPLANATION
Nr. of departements involved in phase 3	-	*	The more departements involved in phase 3, the shorter the phase 3 of the new product development process.
Nr. of FTE's involved in phase 3	+	**	The more FTE's involved in phase 3, the longer the phase 3 of the new product development proces.
NPD pipeline overload	+	**	The more the NPD pipeline is overloaded the longer the phase 3.
Start preparation of registration dossiers	+	**	The earlier the preparation of registration dossiers is being started, the shorter the phase 3.
Source of formulation	-	**	If the formulation is sourced externally, the phase 3 tends to be shorter.

** $\alpha \leq 1\%$
* $\alpha \leq 5\%$

The results in this case are also indicative. The more department are involved in phase 3, the shorter is the cycle-time of phase 3. This shows the importance of supply-chain integration throughout the entire company. The number of full time equivalents involved in phase 3 has, similar as in phase 2, a negative impact on its cycle-time. Again, the variable “overload of new product development pipeline” is having the expected impact on the cycle-time of phase 3 as it did have on the cycle-time of phase 2. The fact that the formulation is sourced externally also has an impact on the shortening of the cycle time of phase 3.

Interesting is the positive relationship between the cycle time and the start of the preparation of the registration dossier. The argumentation could be reciprocal: the shorter the phase 3, the earlier the company starts with the preparation of the registration dossier.

3.2.5. Factors affecting the new product development time of phase 5

Phase 5, the launching phase, which includes all final pre-launch activities (e.g. ordering of materials, production of launch stock, etc.) including the launch of the product on the relevant market, takes on average almost 9 months. On average 235 days are spent from the registration until the launch day. This is a very high number, since the goal of every pharmaceutical company is that this number is as close to 0 as possible. On average, 51 days before the marketing authorization for a certain product, the analyzed generic pharmaceutical companies start with their launch activities. The correlation of this variable with the lead-time from registration until the launch of the product is negative (- 0.27, $\alpha = 0.16$). This means that overlapping activities (concurrent activities) from phase 5 with those of phase 4 is an important factor in reducing the time-to-market.

4. DISCUSSION OF THE RESULTS

Hypothesis 1**,** which states that there will be a positive relationship between the number of strategic alliances a generic pharmaceutical company enters and its rate of new product development, can be analyzed by two main findings. First, if the active pharmaceutical ingredient (API) is internally developed, then the total time-to-market is significantly longer than if the API is externally sourced. Second, if the formulation for the generic pharmaceutical product is developed internally, then the total time-to-market is significantly longer than if the formulation is externally sourced. The main differences are in phases 2 and 3, which are the real development phases. If the company has many strategic alliances, the time-to-market is shorter.

In general we can classify different tools and techniques into 4 different groups: design techniques, organizational techniques, manufacturing techniques and information techniques. In our research we have focused on organizational techniques, which comprise concurrent activities management, clear stage-gate new product development processes, project management techniques, performance measurement and others. Hypothesis 2 that there is a positive relationship between the incorporation of new development tools and techniques and the time-to-market could be therefore only partially confirmed. The data of the generic pharmaceutical benchmarking shows that at some stages activities are managed and performed concurrently. In particular, this has been measured through the variable “at which phase the company has started the preparation of registration dossiers” that have to be submitted to registration authorities at phase 4. One additional variable analyzed to measure concurrent activities was the question “How many days before the marketing authorization has been obtained did you start with the launch activities”. The results show that the earlier the company starts with its launch activities, the shorter the cycle time of phase 5 (pre-launch activities) and the faster the product is launched on the market. Another variable resulting in longer time-to-market is bad or inappropriate planning of resources. The data of the generic pharmaceutical benchmarking shows, that the more the new product development pipeline is overloaded, the longer the cycle time of phases 2 and 3 as well as the total time-to-market. Additionally, the data also suggests that the more full time equivalents are involved in phases 2, 3 and 4, the longer the cycle time of those phases as well as the total time-to-market.

Hypothesis 3, which states that there is a positive relationship between the integration of new product development departments and the time-to-market, has been analyzed with two variables. The first variable defines the number of departments that are involved in each phase of the new product development process. The second variable defines the cooperation with

the suppliers in each phase. The data shows that there is a significant impact of the involvement of several different new product development departments and the cycle time of phase 3 (technological development). The more departments are involved in phase 3 of the development of a specific new product, the shorter its cycle time. This relationship between the number of departments involved in a particular phase and its cycle time is statistically significant only for phase 3. Furthermore, the data also shows that there is a positive correlation between the involvement of suppliers in the new product development process and the time-to-market.

Hypothesis 4 is not confirmed with our data. The result is surprising and shows that completely new products have a shorter total time-to-market. Although in case of retargeted products prior experience exists for the product itself, it takes longer for that product to bring it to the market. There might be several reasons for this, from the fact that the revenue proportion of a completely new product is usually higher and therefore these products have a higher priority, to the fact that completely new products are first launched on domestic markets which are usually also most known to the company.

Some limitations to this research should be kept in mind when applying the results. First, only four generic pharmaceutical companies participated in this research and only 34 new products have been analyzed. A second limitation is that the analysis has been conducted on a sample of Central European generic pharmaceutical companies. Although some efforts have been done to involve also generic pharmaceutical companies from the US, Israel and India, without an extensive local support from those countries it was not possible to involve a broader sample. Because management practices, cultures and norms differ around the world, these findings are likely to be less applicable to companies managing new product development outside the Central European region. Differences in new product development practices for the generic pharmaceutical companies around the world, although extensive to determine, would be a fascinating piece of future research. Third, the study adopted a cross-sectional design of study (i.e. time specific) and utilized retrospective, questionnaire responses. Future research may pursue a real-time strategy of data collection to explore the nuances of projects or a longitudinal strategy of data collection to explore relationships to test for any time-lag effects.

5. MANAGERIAL IMPLICATIONS

Based on the results of our study we have developed a diagnostic model for the management of new product development process. The appendix shows what could, for example, company B do to improve the performance of the new product development process. Here we will summarise the main steps in the decision-making process: 1) New product development performance can be viewed as an integrated system of five fundamental building blocks: a) product and portfolio strategy; b) lean and disciplined new product development process; c) organization and resource management; d) performance measures; e) information systems and technologies; 2) Since the questionnaire that we have used for data gathering from the generic pharmaceutical companies has mainly emphasized the areas of process excellence, organizational excellence and performance measures, we will mainly focus on these three building blocks; 3) Based on gathered information from different sources for each building block we can define certain characteristics, which are specific to “winning” companies (see appendix, Figure 6); 4) With the definition of key capabilities and performance for each building block we can assess each company relative to the “winning” company (scale 1-9) (Figure 7); 5) The actual performance of the new product development process in each company can be analyzed based on different measures (in our case we have used financial performance measures and time-to-market performance measures) (Figures 8 and 9); 6) Each building block can be presented with a summarized assessment of the performance, which in

our case is the arithmetical average of the key performances of each building block (Figure 10); 7) We analyze each company in view of its relative capabilities and achieved financial performance of the new product development process; 8) The analysis enables the company: a) an overview of the current performance and capabilities in the new product development process relative to "winning" companies; b) identification of potential improvement opportunities; c) definition of actions and the way of implementation (Figure 11).

Figure 6. Characteristics of "winning" companies

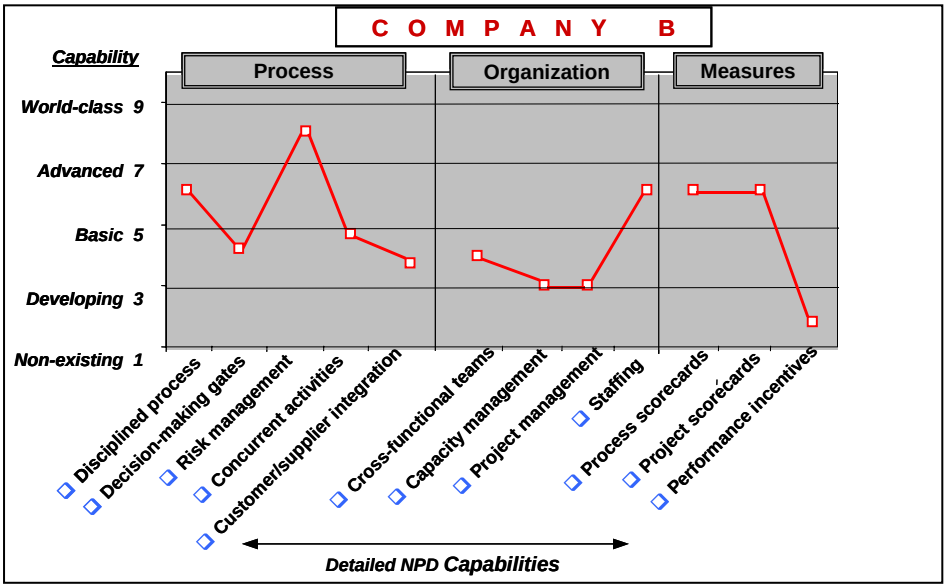

Figure 7. Assessment of key capabilities for company B

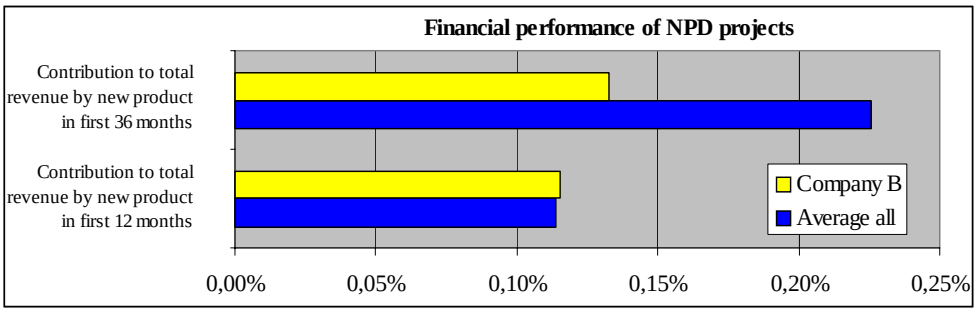

Figure 8. Financial performance of new product development projects for company B

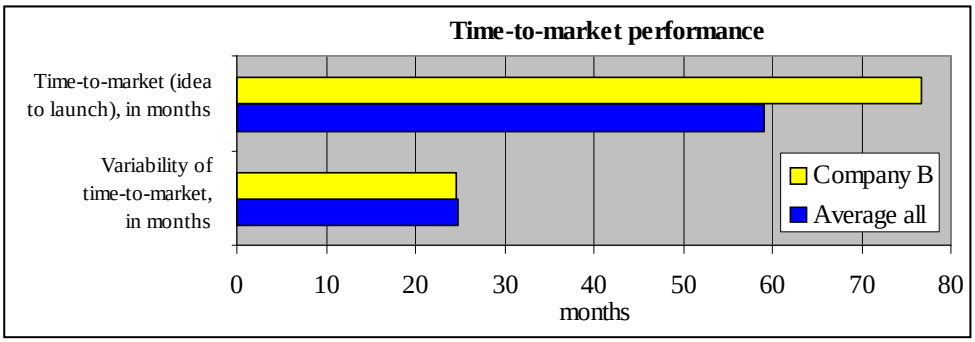

Figure 9. Time-to-market performance of new product development projects for company B

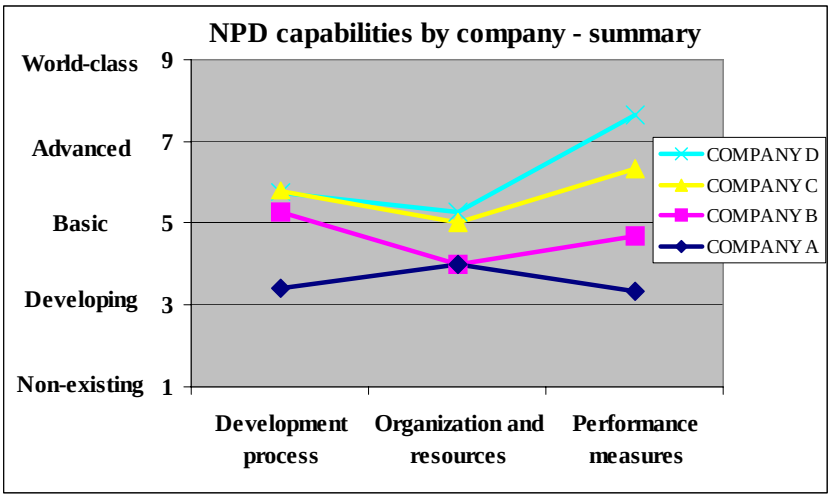

Figure 10. Summarized assessment of new product development performance for each building block

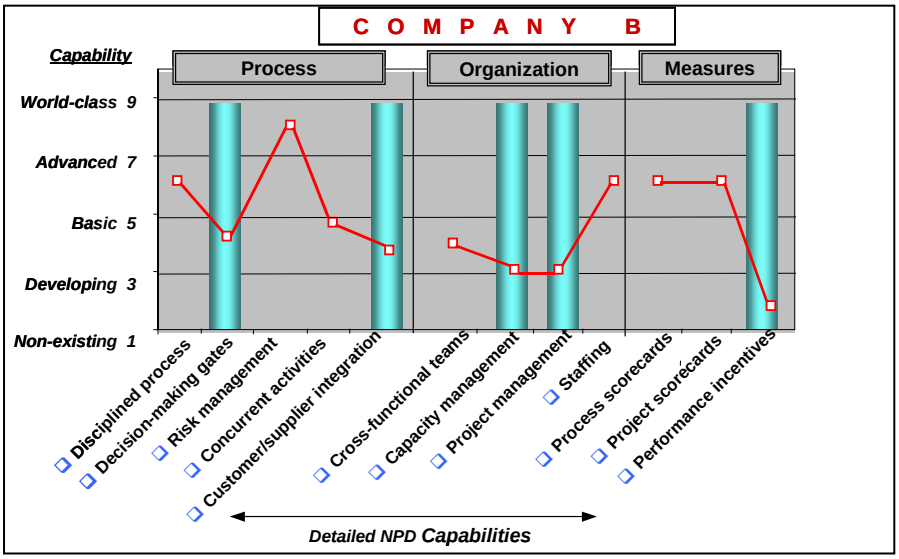

Figure 11. Definition of priorities for company B

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