

## **Innovation in medium and large size Brazilian pharmaceutical companies: restrictions and opportunities**

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### **Summary**

*Product innovation or business innovation? What should companies follow? Based on products and business innovation concepts and Concurrent Engineering (CE), Integrated Product Development (IPD), Stage Gates and Product Based Business (PBB), this paper presents an innovation reference model developed to Brazilian pharmaceutical companies. A qualitative research was conducted in six pharmaceutical companies in order to better understand its scenario and to allow comparisons about their reality of innovation processes. The focus of this paper is to understand how these companies identify opportunities of innovation (in pre-development phase) and what constraints they face to implement it. Some comparisons are realized among them and some recommendations about innovation process are presented.*

*Keywords: Pharmaceutical Product Development, Innovation Patterns, Reference Model*

### **1. Introduction**

De Paula (2004) had developed a reference model for pharmaceutical product (innovation process) based on recognized development methods as Concurrent Engineering (CE), Integrated Product Development (IPD), Stage Gates and Product Based Business (PBB). The reference model was developed using: (i) literature about product development, (ii) pharmaceutical product development literature and legislation, and (iii) interviews with professionals, which work in Brazilian medium and large size pharmaceutical companies. The developed model presents three macro stages and seven phases, embracing from business opportunity recognition to product market launching, and reflects the Brazilian pharmaceutical companies' product development reality. The innovation reference model also presents six stage gates which are associated checklists and development process control documents. The pre-development macro stage, which is not frequently described in the pharmaceutical literature, is well detailed in the model. The innovation pattern suggested in the pre-development macro stage is based on best innovation practices of Brazilian pharmaceutical companies and pharmaceutical literature.

The purpose of this article is to discuss the innovation pattern from the reference model for the pharmaceutical product development, compare it with the best innovation practices from literature, and, simultaneously, consider the constraints faced by medium and large sizes pharmaceutical companies in performing the innovation activities.

The literature that supported this analysis will be presented in this paper as described: initially will be presented the innovation process theoretical reference accordingly to different authors; then the reference model of innovation and other models from large and medium Brazilian pharmaceutical companies and, at last an analysis of the constraints and the opportunities faced by these companies.

## 2. The innovation process

The “innovation” word has been distinguished from the “invention” by several authors. Schumpeter (1971) affirms that innovation is a new combination of ways of production and it is the key elements of the economy; and invention, if not developed turns out to be economically irrelevant. Drucker (1998) establishes that innovation it is not invention, nor discovery. It can involve both, and most of the time it does, but focus in economical performance. Recently, Barbieri (2003) describes invention as a technical action and innovation as a combination of technical, economical and organizational facts. Innovation can be understood as an invention with added value to client and economically viable.

Garcia and Calantone (2001) reviewed 21 researcher’s opinion to finally define *innovation* as “an iterative **process**, which begins with the perception of a **market opportunity** for a technologically supported product and/or service, that leads to development, production and marketing activities, in order to achieve product’s commercial success” and *innovativeness* as “an indicator that is used to reveal the product and/or service degree of innovation.” Innovation can be new to the company, to the clients or to the market. The authors also affirm that innovation may be described in two ways, **incremental or radical**, the first one happens in about 90% of the cases and the second one, more uncommon, happens only in 10% of the cases.

Moreover, innovation is related either to “product improvement”, increasing the company product’s family or to “business innovation”, what means the search for new business opportunities. The latest one is about to incorporate more strategic diversity in a specific business or competitive domain (HAMEL, 2000). In this sense, Loewe et al. (2001) consider the “strategic innovation” in five possible types of innovation management in companies, depending on their behavioral pattern.

Summarizing, the innovation may be related to processes, product/technology or business. Parasuraman and Colby (2002) explain that an innovation may involve technology, but it must not be taken as a synonym of it. These authors affirm that exist inhibitors and stimulators factors that may influence the client’s acceptance of new products with technology associated. The factors that stimulate the acceptance are optimism and innovator style” and the ones that inhibit are discomfort and uncertainty.

Nowadays, innovation is considered to be the most important competitive force in companies, beside costs, quality, time and flexibility. Barbieri (2003) presents the company’ maturity in five levels of competencies, as they present a sum of these forces. The first level of maturity aggregate only cost’s competence, the second aggregates “costs + quality”, and so forth, towards the highest maturity level aggregates “costs + quality + time + flexibility + innovation” competences. The author also declares that any improvement in costs, quality, time or flexibility is considered innovation and, therefore, might occur at any step of evolution.

Hamel (2000, p. 71) presents that the concept of the business is compound of four components (i) *core strategy* (including mission, market and differentiation); (ii) *strategic resources* (considering core competences, strategic assets and core processes - methods and routines to transform raw materials); (iii) *interface with clients* - communication’ channels, information and product solutions); and (iv) *value chain* (including suppliers partnerships and coalitions). The pillars of these four components of the model are: efficiency, singularity, compatibility to business and profit driven. This four pillars are aligned to the SCV (Sustainable Competitive Advantage) concept (PORTER, 1996).

Cooper (1993), Roozenburg and Eekels (1995), Patterson and Fenoglio (1999); Crawford and Benedetto (2000) and Baxter (2000) suggested similar procedures in product

development methods. The methods known as Integrated Product Development (IPD) and the philosophy of Product Based Business (PBB) emphasize the change from “product development supported by engineering” to an innovation vision of “business supported by product development”. In this sense, the corporate strategic planning is generally at the top of the models and should drive the decisions along the development course. The “pre-development” stage, followed described in the model presented in this paper, is similar to Hamel’s model components because has the same logic to enhance product development’ chances of market success. This success is attributed to product planning based on client or market demand (need-pull or market-pull development) as extensively postulated by other authors (DESHPANDÉ and FARLEY, 1998; KOHLI and JAWORSKI, 1990; BAKER and SINKULA, 2002; KOTLER, 2002; McDONALD, 2003). Patterson and Fenoglio (1999: 414) discuss another relevant aspect in these models. They affirm that product innovation is “enterprisewide system that not only involves coordinated effort among the members of each product innovation team, but also promotes a vertical teamwork linking business leaders to the effort of individual product innovators”. This reinforces the importance of multifunction working teams, information management and high-level involvement.

The pharmaceutical innovation process reference model mentioned in this paper was structured based on the former methods, in addition of Concurrent Engineering methods and Stage Gates. The innovation best practices of large and medium sizes Brazilian pharmaceutical companies also contributed to the reference model. Part of the reference model and the companies practices, accessed via interviews, will be presented in the sequence.

### **3.0 Pharmaceutical innovation process reference model**

The pharmaceutical innovation process reference model, developed by De Paula (2004) shown in (figure 1) presents three macro stages (pre-development, development and post-development) and seven phases, embracing from business opportunity recognition to product market launching. Nevertheless, only the macro stage entitled pre-development and its first phase named “identification and selection of business opportunity” will be focused in this paper. The objective is to compare the opportunity identification’ best practices, published in specialized literature, with what is really practiced by Brazilian’s pharmaceutical companies. This is justified by the importance of the opportunity identification in the innovation process.

CORPORATE STRATEGIC PLANNING		INNOVATION TEAM						
MACRO STAGE	PHASE	Regulatory affairs	Quality assurance	Production	R&D	Marketing and sales	Financial management	High-level management
Pre-Development	Business opportunity identification and selection							
	Product or service concept generation							
	Product or service concept detailing							
Development	Product and Process Development and analysis							
	Product and Marketing plans implementation							
	Product conclusion and ANVISA authorization							
Post Development	Product launching and post marketing							

Figure 1. Reference Model of Pharmaceutical Innovation Process - macro vision (Source: adapted from De Paula, 2004)

Before presenting the Brazilian pharmaceutical companies' practices, it will be described the best procedures suggested by the authors as mentioned in item 2.

The competitive scenario faced by companies obligates them to thoroughly plan the development of new products and/or services in order to reduce the market uncertainties and chances. In this sense, the Corporate Strategic Planning (CSP) defines the business strategies (Figure 1). The decision team (high-level management) needs to be concerned in defining adequate innovation policies, for example, going through new markets or to move towards radical, instead incremental innovation can means the success of the failure of the business. In such case this decision must be supported by information gathered by the multifunctional innovation team. Figure 2 summarizes the team activities at this phase (team represented in gray columns).

It is important to pay attention to every group of activities presented in figure 2, especially to the group concerning the evaluation of strategic resources. The evaluation activities have two focuses. The first one based on the underused resources as financial; legal level; structural, technical, equipments, patents, data bases, research institutes and universities. The second focus includes the analysis of the current marketing, product portfolio and corporate planning. The objective at this phase is to optimize resources uses in order to better plan the innovation.

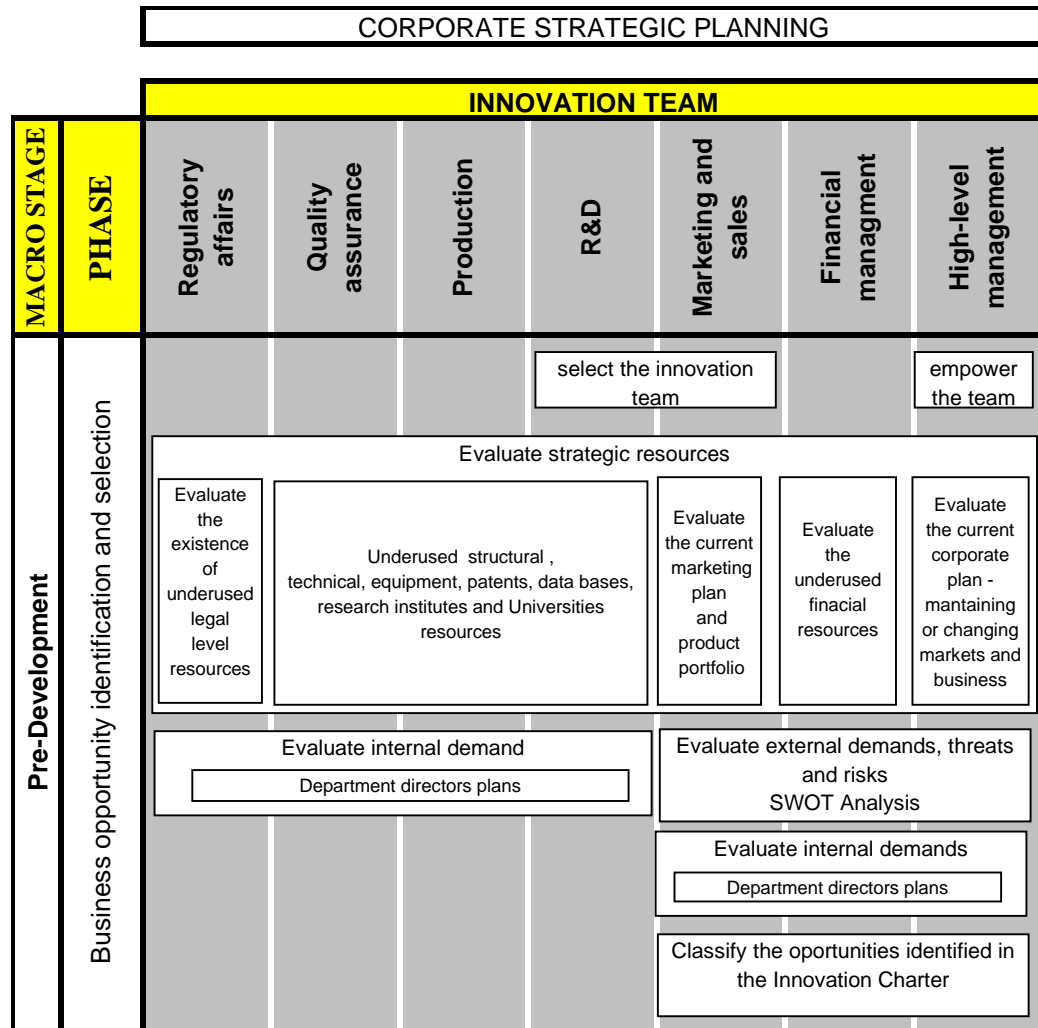


Figure 2. Business opportunities identification and selection phase – detailed vision  
Adapted from: DE PAULA (2004)

Other activities into the opportunity identification phase should be taken care. They are the internal and external evaluation of demands, implementation of the SWOT analysis and the prioritization of opportunities in the Innovation Charter. These activities complement the comprehension of the scenario.

*Evaluation of internal demands* means that every professional, in each functional department, may express ideas and observed demands in current or past projects. The historical data may be important aiming to avoid past project failures. It must be also considered the opinion of high-level management, which ultimately will aligned the ideas with the strategic direction of the business. The *evaluation of external demands* can be worked out by the application of SWOT Analysis. In this case, internal and external benchmarking is helpful to e company's strengths and weakness. The analysis of competitors emerge their marketing strategies, technological strengths and weakness, facilitating the detection of new opportunities. The analysis of its own products life cycle and concurrent products, searching for new market shares; market research (from institutes as IMS Health or Close Up International); clients demands analysis or ideas of new products, services or business must be considered. Some tools are recommended to better accomplish this activity. Baxter (2000) suggests the adoption of consumer panel tool, reminding that in case of medicine and cosmetics investigation hospitals and drugstores environments are relevant, as the opinion of physicians and patients. Regarding the risks, the frequent analysis of ANVISA

(Governmental Regulatory Agency) databases is actually important, in searching potential constraints or new rules. The cost of human pharmaceutical essays as bioequivalence, toxicity and pharmacological investigations may represent a limitation and must be considered in broader decisions as “to start the development of reference medicines (breakthrough innovation, radical innovation)”, for example.

The last activity in this phase is to *Classify the opportunities identified in the innovation chart* and result from a meticulous data analysis and selection of opportunities, which are aligned with the corporate strategic planning and high-level management’ interests. Certainly not all the opportunities will be promptly explored and, therefore they are allocated in the innovation chart. The decision team communicates the chosen opportunities to be worked out to the innovation group, which will start the next phase “Product or service concept generation”. The former phase is not the scope of this paper.

After presenting the ideal innovation model, accordingly to the literature, it is time to elucidate and analyze the Brazilian pharmaceutical companies’ practices.

### **3.1 Innovation models in large and medium size Brazilian pharmaceutical companies**

The objective of this investigation was to identify the innovation practices of Brazilian pharmaceutical companies, medicines and cosmetics producers. A qualitative research was carried out with professionals of two large size companies and three of medium size ones. Data from another large company, from the cosmetic area, was collected from specialized literature. The professionals interviewed were responsible for the areas of production, R&D, quality control and/or assurance, marketing, sales, regulatory affairs, financial management and high administration.

The interviews were accomplished from July to October 2003 and the questionnaires were divided in three groups of questions: (i) general information (companies’ characteristics); (ii) existence of innovation or product development models; and (iii) model stages and their main difficulties or constraints. The interviews were recorded for future transcription and analysis.

The general information items allowed to extract information about aspects, which reveal the companies’ way of conducting their innovation processes, including corporate strategic planning (when formalized), social economic influences (governmental rules, standards), type of organizational system (project oriented, hybrid, not project oriented) and organizational structure depending on the corporate size (functional, cross functional, staff). This information is summarized in Figure 3.

Incremental innovation is predominant in Brazilian pharmaceutical companies. Most of medicines and cosmetics products are not totally innovative, but similar to the competitors. The regulatory copy of a reference medicine, previously launched by a pioneer industry is called a “generic medicine”, and can be interchanged with a reference medicine without the physician authorization. This type of product is endorsed by government regulatory agencies via the presentation of *in vivo* (human) tests called bioequivalence assays. All the interviewed companies develop generic and similar medicines. The similar product is a copy from a reference medicine, but not bioequivalent to it and, therefore, may not be interchanged. Similar and generic products are expected to be cheaper than reference medicines, consequently with larger market competitiveness. They are the most challenging type of product developed in Brazilian pharmaceutical companies, since the technology demanded in radical innovative products is limited and the costs are extremely high (approximately U\$ 800 million).

<b>Company Product (size)</b>	<b>Strategic planning /Organizational structure</b>	<b>Source of innovation ideas</b>	<b>Project team (Departments)</b>	<b>Project leader</b>
Company 1 Medicine (medium)	Not formalized /Functional structure	Ideas from financial management and R&D List of drugs/medicines which dispense bioequivalence studies ( <i>human research</i> )	Multifunctional (Production, R&D, quality control, marketing, sales, regulatory affairs, financial management)	Financial management and R&D
Company 2 Medicine (medium)	Not formalized /Functional structure	Ideas from sales and marketing department/ ideas from high administration /ideas from clients	Multifunctional (Production, R&D, quality control, marketing, sales, regulatory affairs, financial management and high administration)	Distributed by the team
Company 3 Medicine (medium)	Not formalized /Functional structure	Ideas from sales department/ ideas from clients (physicians and patients)/ high administration and list of products previously authorized by the Brazilian Regulatory Agency (ANVISA)	Functional – sequential (Production, R&D, quality control, marketing, sales, regulatory affairs, financial management and high administration)	Distributed by the team
Company 4 Cosmetics (large)	Yes, formalized/Matrix structure	Ideas from marketing department, from market research, from research institutes and Universities, tendencies in the area, analysis of concurrent products (benchmarking)	Multifunctional (Production, R&D, quality control, marketing, sales, regulatory affairs, financial management and high administration)	Marketing department
Company 5 Medicine (large)	Yes, formalized/ Matrix structure and Business Strategic Units (BSU)	Ideas from marketing, sales, patents, market research, from research institutes and Universities	Multifunctional (New product committee: Product management, sales, R &D, regulatory affairs)	Product management – marketing
Company 6 Cosmetics (large)	Yes, formalized/Matrix structure and BSU	Ideas from market researches, patents, consumer habits, from research institutes and Universities, tendencies in the area	Multifunctional (Innovation Vice Presidency: segment manager (marketing); process and packing engineer, logistics control and planning technicians, R&D, business committee, advanced concept technology, Commercial Vice Presidency)	Segment management - marketing

Figure 3. Main characteristics of Brazilian pharmaceutical companies interviewed

The six companies innovation practices comparison is presented in figure 4. The Figure 4 informs if the business opportunity identification and selection activity is performed or not by the company. The activities mentioned in Figure 2 are presented in Figure 4 as an ideal reference from the literature.

Figures 3 and 4 show clearly that medium size companies do not perform formally the corporate strategic plan, and present a similar profile. They execute part of the internal and external investigations. On the other hand, large companies, carry out most of the activities suggested in literature.

MACRO STAGE	PHASE	ACTIVITIES	COMPANY 1	COMPANY 2	COMPANY 3	COMPANY 4	COMPANY 5	COMPANY 6
Pre-Development	<b>Corporate strategic planning</b>		N	N	N	Y	Y	Y
	Business opportunity identification and evaluation	<b>Select the innovation team</b>	N	N	N	Y	Y	Y
		<b>Evaluate strategic resources</b>						
		at the legal level	P	P	P	Y	Y	Y
		technical equipment patents, databases, research institutes	P	P	P	Y	Y	Y
		marketing plan/portfolio	N	N	Y	Y	Y	Y
		financial resources	P	P	Y	Y	Y	Y
		<b>Evaluate internal demand</b>						
		department director plan	P	P	P	P	P	-
		<b>Evaluate external demand</b>						
		SWOT Analysis	P	P	P	Y	Y	Y
		<b>Classify the opportunities identified</b>	N	N	N	Y	Y	Y

Figure 4. Comparison of innovation activities observed in pharmaceutical companies  
Legend: Y (yes), N (no), P (in part), - (unknown)

The innovation behavior of each company will be presented as follow.

*Company 1* – The corporate strategic planning did not support the company innovation process, by the time of the interview, so there were no established innovation policies. The guidelines were determined by some “aisle talk” between the high-level management and R&D responsible, based on a list of possible products (which do not demand expensive pharmacological assays). After this, actions are triggered in all functional departments. The R&D professional interviewed declared the existence of a “multifunctional” innovation team, but also informed that they were the same people who performed routine activities. In that case, they just shared their time in different tasks. This reality is frequent in medium size Brazilian companies, since the scarce of financial resource is responsible for a downsizing reflecting in overloading who remains on the company. The extremely succinct pre-development stage gives rise to failures in the next steps, as commented by the interviewed, leading to frequent product abortion and money loss (there is not a financial plan for innovation). The delay in product approval by ANVISA was mentioned as an important constraint. However the company presented an unfavorable innovation scenario, at the time of the interviews, it was investing in generic medicines, considered as a great business opportunity by most medium and large Brazilian pharmaceutical industries at that time.

*Company 2* – This company presents an innovation behavior very similar to company 1, about professional board and responsibility overloading. However, concerning this they use information from clients accessed by the marketing department. It may not be considered a market research, since it captures only the most immediate client’s demand. Another peculiarity is that, although reduced investigation, the professional group involved with the development job have periodical meetings, when they may exchange information and take decisions, what is more similar to the behavior expected of a team. Nevertheless, some product aborts were mentioned due to innovation process failures and, despite the money loss, a higher organizational degree was observed in this company, which was investing in infrastructure and equipment at the time of the interview. The interviewed professionals (production, R&D, quality assurance) recognized the necessity of a formalized procedure and



the need of more investigation in the earlier innovation phases. A major complaint was the reduced investment in human resources by the company high level management, besides the delay at product registration by ANVISA.

*Company 3* – The proximity of this company with large pharmaceutical companies makes its innovation process a hybrid between medium and large size companies. In one hand, they have a strong marketing department and execute some typical tasks, as the marketing plan and some market investigation, what is superior of its competitors. On the other hand the information gathered is informally transferred to the R&D and to the process professionals without any previous discussion, multifunctional meeting or similar. The company has a strong delivery channel, what guarantee a relative sales success. Similar to the other medium companies interviewed they are interested in the medicine generic market, and were suffering profound high-level management changes at the time the interviews were made. The marketing and sales professionals interviewed recognized the need of innovation process formalization, mainly the creation of a model they could follow. They considered the pre-development phase acceptable.

*Company 4* – The culture of corporate strategic planning is present in this company, what makes the innovation process more delineated. There is an innovation team and the development efforts are conducted by guidelines previously established. This company belongs to the cosmetic area in which radical innovation products are more frequent. However, this company is known to be less challenging than its greatest competitor in Brazilian market, the company 6. A strong marketing effort was evident in the interviews, leading to success market products. Some weaker aspect in their model are the little concern with internal opinion (from department professionals) and a formal registration of historical projects failures, which would be worthy in new projects. Although they are interested in broadening their international market, they have no clear strategies in that direction. It was not observed a tendency for business diversification.

*Company 5* – This Brazilian company presents a clear market focus, mainly hospital products, result of the development fidelity to its origins. The culture of planning is strong in this company, which is segmented in Business Strategic Units (BSU), what have boosted the sales and incomes in the last years, accordingly to the interviewed professionals (marketing and R&D). This management option defines the existence of product managers for each BSU who are responsible for the segment innovation, always conducted in agreement with the corporate strategic planning. A peculiarity at this company is the development of products with broader levels of innovativeness, including chemical modifications in drugs, what results in a new or improved pharmacological effect of the drug. These incremental innovation activities make this company an exception in Brazil. Much of this challenging behavior is attributed to the Organization culture. Different from the previous company presented, business diversification is a tendency, what may be reinforced if the product managers provide the appropriate feedback to the corporate strategic planning. A small gap is observed between BSU and corporate strategic planning despite the relative autonomy offered to the product managers.

*Company 6* - This company is indeed a well-known cosmetic producer, competing in the same level of important international industries from this area. Its innovation process was described by Nascimento et al. (2001), which is based in Wheelwright and Clark's (1992) proposal. The Organization culture is strongly oriented towards business diversification, what appears as a clear competitive strategy. The challenging character of its high managers has given rise to creative forms of competing with international cosmetic industries, using local resources and cheaper investigative alternatives (as an investigative patent department locally), other than expensive investments in developing active substances and pharmacological human tests. This company has been served as inspiration to other

Brazilian pharmaceutical producers, from the cosmetic and medicine fields. The qualities mentioned before for company 5 are similar in this Organization.

### 3.2 General analysis

The companies 1 to 6 may be grouped by different classification criteria. Considering the size, companies 1 to 3 (medium) present very similar innovation process behavior, mainly characterized by the lack of formalization in a model, which would standardize the internal procedures providing intervention and quality improvement. The large companies, 4 to 6, are concerned with corporate strategic planning execution, which defines the guidelines for innovation, as specialized literature recommend.

Regarding the Organization culture, the medium size companies (1 to 3) present a very conservative management behavior. The local action over specific processes is predominant, contrarily to the open horizons managerial attitude showed by administration of companies 5 and 6, who are aware of market revolutions and act systemically in the business. Company 4 is located in the middle of the groups. Its administration, despite being aware of the business world revolutions, still maintains a reserved attitude, without challenging changes.

Considering maturity levels, companies 1 to 3 devise the importance of formal innovation processes and emphasize pre-development activities, mainly market-oriented ones. However, it is an external environment imposition, that slowly is taking part in the administrator reality, different from the more entrepreneur administrators, from companies 5 and 6, who have been aware of the competitive driving forces in the last two or three decades. This fact has great consequences, since the former administrators have a barely notion of the background necessary for competition, and, sometimes, underestimate the necessity of investments in human resources, marketing tools and knowledge acquisition. The interviews showed another common situation in medium companies. It was observed the company administrators decided to reinforce pre-development activities and to formalize innovation processes, but lost relation to the starting point, risking acting locally, instead of systemically. Most of the time, this scenario was associated to a lack of financial resources, corroborated by the high costs of contracting external expertise.

The Brazilian historical pharmaceutical low technological level allied to the long period of patent not recognition, established condition for the culture of product imitation. As mentioned, the production of generic and similar medicines predominates in the local pharmaceutical industry (even multinational pharmaceutical industries prefer to reserve the innovation to their main base outside Brazil). Worse than this seems to be the lack of experience in conducting the pre-development activities, which generate market intelligence, and the predominant linear way of analyzing the environment.

For example, taking into consideration the cases from this paper, a meticulous SWOT analysis would have shown that there was not in Brazil a complete infrastructure for generic approving pharmacological essays, two years ago. Even recently, some companies complain that are stuck in long lines waiting for research institutes to perform their products tests. Furthermore, the high costs of such assays prevent the generic cost reductions, at the level expected by patients, in fact, some generic may present final prices higher than the reference medicine in drugstores. Most Brazilian pharmaceutical companies imagined, in a first glance, they would have competitive advantage if invested in generic medicines. Nevertheless, the great number of companies competing and ANVISA generic prices regulation has decreased the profit margins. Periodicals of the area have been questioning if generics are actually an advantage.

Someone would question if this recent scenario would not have been predicted and if it would have changed the innovation decisions of some Brazilian companies, conducing them to the way out of the commonplace.

Concluding, despite the restrictions represented by the high investments necessary for radical innovation in pharmaceutical companies and the high competition levels in internal market, even for generic and similar medicines (by the presence of several multinational industries), the Brazilian pharmaceutical companies' administrators should wonder about the following facts in search for opportunities: (i) past paradigm rupture is necessary but is a difficult task; (ii) non-linear ideas may generate wealth to organizations; (iii) business innovation is more effective competition tool than product/technology innovation; and (iv) alliances are relevant to support business concept innovation.

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