

# **Innovation Management: How it happens in Small and Medium Enterprises? A cut for the Pharmaceutical Industry**

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## **Abstract**

*International institutions that promote economic development have pointed out, in recent years, that the small and medium-sized enterprises' (SMEs) development enables the economic growth of countries and regions, providing a greater economy dynamism and improving its indicators, such as the Gross Domestic Product (GDP). SMEs also show greater diversity in the labor market and thus are also responsible for many of the innovation generated by the countries. For these companies to grow, it is essential that they develop strategic management of their innovations, including all the risks, possibilities and all actors involved in the process. Pharmaceutical industry is part of a high risk sector, because it needs a high investment in research and development of specific diseases treatments without the guaranteed success and therefore, they need a management model that deals with all its specificity, thus this the hypothesis considered in this work. A theoretical grounding was made based on an exploratory and bibliographical research on scientific basis. In this way, it was possible to analyze how happens the innovation process in SMEs and in the pharmaceutical sector and to suggest future studies that will allow a better management of these companies.*

**Keywords:** *innovation management, SMEs, intellectual property, pharmaceutical industry*

## **1. Introduction**

Currently, SMEs are considered, in general, as the countries' economy base, mainly of developing countries, such as Brazil, as they generate jobs, which in turn generate income and, consequently, higher consumption and production, contributing to the countries (GDP). Factor that has benefited this development of SMEs is an innovative initiatives' growth provided by an investment in Science and Technology, allowing them to survive in an increasingly competitive market (OLIVEIRA et al, 2018).

With this in mind, it is increasingly necessary to better evaluate how companies are innovating, which are their difficulties and particularities in internal and external processes, and propose improvements in their strategic management of the business model, as well as the management of innovation processes . This will enable SMEs, in particular, to have leaner, more sustainable processes that provide greater market competitiveness and development in their industry. Brexendorf et al (2015) points out that this would be a way for companies to ensure market success from their assets, and optimizing their processes, allowing greater ease in obtaining and returning.

Within the innovation strategic management, a key point is the intellectual property (IP) assets management.

When it comes to SMEs, the behavior towards the market is very similar, between developed countries or not. According to Baldwin and Hanel (2003), innovations proposed by smaller firms are less original and sometimes do not require IP protection. This may be due to the fact that operational costs of IP protection (learning, obtaining and maintaining intellectual property rights) and their enforcement (monitoring of infringement and litigation) are high (NIKZAD, 2015).

When it comes to the Pharmaceutical industry, it is noticed that one of the most critical factors in relation to innovation structure, besides the high R&D costs, is the whole time from the idea conception to commercialization, which depends on high specificity in the processes, quality control and the evaluation and release of regulatory agencies, a process that can take around 12 years (SMITS and BOON, 2008; HERING et al., 2018).

Thus, this work seeks to make a brief analysis of the processes of innovation management, taking a part for the pharmaceutical industry, assuming that this sector needs more specific innovation strategic management models. It is intended to raise market requirements, how this process happens in companies, especially SMEs in this sector, so that, by this, tools that facilitate and serve as support for companies to make their management can be studied and developed. An exploratory and bibliographic research was carried out in the Web of Knowledge, Science Direct and ProQuest databases, which served as the basis for this article, which was structured in three topics: Innovation in SMEs, Innovation Management and Pharmaceutical Sector and its way to innovate.

## **2. Innovation at SMEs**

Several international organizations such as the United Nations (ONU), the Inter-American Development Bank, the Organization for Economic Co-operation and Development (OECD), among others, have pointed out in their institutional reports in recent years that the development of SMEs has a fundamental importance for the economic growth of countries and regions, in addition to enabling a greater development of social welfare, since they generate more jobs, develop socioeconomically and empower their communities (DOH and KIM, 2014, KERSTEN et al., 2017, LIU et al., 2018; BEAUTIFUL, COUNTRY, 2018; GAGANIS et al, 2018). In countries where there is a stimulus for the SMEs development, their cultural elements are also preserved and developed. SMEs also show greater diversity in the labor market and thus are also responsible for much of the innovation generated in the countries.

The European Union, planning to overcome deficiencies in the structure of the European economy, launched in 2010 the Europe 2020 Strategy with the aim of stimulate growth and development based on smart, sustainable and inclusive growth. In this way, it aims to streamline productivity and increase its competitiveness. In this way, each of the participating states committed to the strategy and defined a plan of action, with specific measures to achieve its objectives. According to the Strategy, for smart growth, it is necessary to strengthen knowledge and innovation by improving the quality of teaching, strengthening research and promoting innovation and knowledge transfer across the EU, transforming innovative ideas into new products and services, creating jobs of quality. All actions should be combined with the encouragement of entrepreneurship and financial support (EUROPEAN COMMISSION, 2010). The

strategies for 2030 have already been worked out. However, the previous strategy was used as reference since it is more directed to the stimulus to entrepreneurship and economic development.

For growing economy countries, stimulating the growth of SMEs becomes the focal point of economic policies. In Brazil, the percentage of micro, small and medium businesses has increased, but the survival period is still very low, due to several factors, such as lack of public policies that allow their development, lack of incentives, too much bureaucracy (SEBRAE, 2018 ).

Innovation is the driving force of the economy, it allows to win new markets, stimulates the export and internal economy. According to Schumpeter (1934), in his Theory of Economic Development, innovation is necessary from the moment it breaks existing standards, bringing the possibility of new products or the development of existing ones in a more efficiently way, as well as new production forms and access to new markets. In order to innovation take place, two main elements are necessary: the Entrepreneur, who independently of the size of the company is the agent of change, of "creative destruction", and credit as a form of financing the necessary changes (Schumpeter, 1934).

For Schumpeter, innovation takes place in two stages. One, where the entrepreneur is concerned with the development of new products, which requires an informal structure, and another where there is an innovation management process, which evaluates effectiveness and costs in improving processes. Changing the perspective that improvements could reduce costs, market has strengthened creating a more competitive environment for SMEs. Baregheh et al. (2009) defined innovation as a multi-stage process where companies turn ideas into new or improved products, services or processes in order to advance, compete and differentiate successfully in their market. For Gogodze (2013) innovation is a system that creates and uses new knowledge and strengthens the competitive position of a company.

Market has demanded flexibility and rapid responses to its needs and the technological changes that occur, at this point, SMEs appear as a dynamic complement to large companies. They become an element of collaboration for innovation, since they possess the entrepreneurial behavior using the structures and resources of the big companies (SEO and CHAE, 2016; BRINK, 2017). The possibility of innovating in their products and processes has also stimulated the internationalization of SMEs, becoming part of the companies strategy, bringing the dynamism of the markets. In this way, they gain competitiveness and reach international markets. The more companies innovate, the greater will be their exports (CHILD et al, 2017, LI et al, 2018, BAGHERI et al, 2018, GANCARCZYK and GANCARCZYK, 2018, SARIDAKIS et al, 2019).

Schumpeter, in 1939, conceptualized two types of innovation, radical and incremental. Decades later, in 1997, Clayton M. Christensen, addressed the concept of Disruptive Innovation. Table 1 shows the main characteristics of each type. Incremental innovation is the most common and where companies invest more. However, the market today expects innovations that change the current concepts of a particular area. The company that can define a new concept of product or service, guarantees, in addition to the greater

competitiveness, a return on the investment of greater development.

Table 1: Three main types of innovation and their characteristics

Innovation Type	Characteristics
Radical	Something new to the market; Create new markets or transform existing markets; Brings a big technological, structural or operational change
Incremental	Improvement of an innovation Enhances a product or service that is already on the market
Disruptive	Can transform an existing market with something simpler and more affordable; Changes an already established business model

But how are SMEs developing and managing their innovations? It’s necessary tha in addition to incentives and stimulus policies, SMEs should be given guidance on which is the best way to internally stimulate innovation processes and how to properly manage their benefits.

### 3. Innovation Management

As a way to ensure competitive advantage and drive future growth, companies have the strategy to achieve success from new products and services and this includes the costs and risks of the project, such as having a product with a short life cycle that could hinder the desired financial return or even the increase and profit of companies (BREXENDORF et al, 2015).

Large companies manage better their assets and their internal innovation processes when compared to small ones. Today, there is a great discussion about the best way to do this management. The truth is that there are still no definitive methods, since each company has its own particularities, which is presented are good management practices that guide companies in this way. What to evaluate in an innovation management? Innovations in internal processes, as previously mentioned or intangible assets, such as brand, patents and others. Small and medium-sized businesses today can not manage their portfolio, evaluate and quantify their assets, or measure the results of their innovations.

Due to the changes in the market, the way companies deal with innovations in their structures has also changed. The changes are mainly based on three trends: a more digitized world, a more open innovation, and a growing increase in service servitization (when a company transitions from a manufacturer of goods to a supplier of product-service solutions). This allows the innovation to be more inward-looking, product-centric and designed for the external environment, highly digitized and with the participation of all actors in the process. These trends bring a new conception of the mechanisms to understand innovation in manufacturing companies (FRISHAMMAR et al, 2018).

Innovation management is to manage the new ideas transformation into monetizable assets and to make it

happen more efficiently, it is necessary to understand how innovation has been implemented from the beginning (conception of ideas), through manufacturing, installation, commissioning and perception of benefits to the business (SAWHNEY et al, 2006; MURPHY et al, 2015). Good innovation management processes leads companies to a sustainable management (not only in the environmental sense, but also in the sense of sustaining itself). Another issue that has been much debated and still needs to be addressed with more attention is the use of open innovation as an innovation mechanism for SMEs, which would strengthen certain areas of activity.

As part of innovation management, there are innovation audits that allow the identification of their strengths and weaknesses, allowing small companies to create and maintain a competitive advantage by building innovative capacity (FRISHAMMAR et al, 2018). New management approaches should be flexible so that adjustments can be made to the project facilitating the adoption and implementation of new technologies (MURPHY et al, 2015).

Salerno et al (2015) found in their research 8 types of innovation processes in the face of four discoveries that emerged throughout the research. One of the findings corroborates with what was said at the beginning of this topic, that in start-ups and small companies, the innovation process happens without major formalities within the company, the opposite of what usually happens with large companies. Another finding confirmed the hypothesis that more than half (53%) of companies use the traditional innovation process, but that in each innovation process, in general, many other companies are involved too, which necessitates adjustments in the project since each company has its dynamics. In addition, companies present different ways of dealing with uncertainties, for some the management of it is project-specific activity and in others, uncertainty shapes the structure, sequence, and content of the innovation process.

Table 2: Types of Innovation Processes.

<b>Type of inovation process</b>	<b>Cases (%)</b>
<b>Traditional process: from idea to launch</b>	53,0
<b>Anticipation of sales: the tailor-made approach</b>	6,1
<b>Sales anticipation of a particular customer specification</b>	5,3
<b>Process initiated by a need</b>	12,9
<b>Stopped process: waiting for the market</b>	6,8
<b>Stopped process: waiting for technology to advance</b>	3,0
<b>Process with standstill: waiting for the market and technology advancement</b>	1,5
<b>Process with parallel activities</b>	11,4

Adapted from Salerno et al (2015)

The traditional innovation management model, which corresponds to ideas generation, selection,

development, diffusion, launch and sales, was challenged by Salerno et al (2015) and confirms the initial hypothesis of this article, which is the need for greater specificity in management models, taking into account particularities of the companies, the innovation itself, the market and its actors. It was verified by the authors the need to include in some models, tools capable of bringing other perceptions of innovation, as well as financial tools that allow an incremental evaluation, such as return of investment (ROI), discounted cash flow (CDF) and present value liquid (PVL)

When dealing with innovation management, it should also be the management of the intellectual property assets that a company can acquire throughout the innovative process. Starting in the mid-1990s, with the knowledge era, private and public companies started to give greater importance to these assets, not only considering their quantity and scope, but also emphasizing their rights and protection. Thus, the protection and management of IP has become one of the cornerstones of corporate strategies (Hanel, 2006). According to Baldwin and Hanel (2003), when comparing small and large firms, small firms innovate less and when they do so, most likely will not be so original, not requiring IP protection. Another reason for small businesses to innovate is the high operational costs of IP protection (learning, obtaining and maintaining intellectual property rights) and their application (monitoring of violations and litigation), according to Nikzad (2015).

For Nikzad (2015), this behavior in relation to the use of IP rights by SMEs is very similar between developed and developing countries. What basically varies are the areas of technology and competitive conditions under which they operate, company profile, sector and country.

#### **4. Pharmaceutical Sector and its way of innovating**

Pharmaceutical industry is part of a high risk industry because it has a high investment in research and development of specific disease treatments without the guarantee of success. On the other hand, if there is innovation in some treatment, this can be highly profitable for this industry (OMER and BLAKE, 2019). The time for a new drug or treatment to be marketed is about 12 years, as they depend on the approval of regulatory agencies such as the Food and Drug Administration. Time combined with high cost and high risk become a challenge for the pharmaceutical industry. Due to investments in R&D, the pharmaceutical sector is able to generate, directly and indirectly, positive economic values. A good example is the generation of jobs, manufacturing, research and technical support (OMER and BLAKE, 2019).

Smits and Boon (2008) show that the innovation structure of pharmaceutical industry was well organized within the linear system of innovation management and, for decades, it was a useful model. However, factors such as increased costs and competition, advances in science and technology, and more informed and demanding users have changed the context for innovations. The linear model used so far does not involve the new actors in this process, can cause resistance and make insufficient use of its creative potential. For Hering et al (2018), there is great pressure in the pharmaceutical industry. Both by regulatory agencies, which demand more R&D and quality control, developing countries that are pushing for prices and medicine that demand more frequent deliveries and in smaller quantity, which reduces the sizes of production batches. However, these are factors that can not be controlled by the pharmaceutical industry.

Hering et al. (2018) believe that properly conducted lifecycle management could lead to a reduction in product launch time, as well as prolong the disposal of their products in the market. As regulatory requirements increase, other aspects of the innovation process must be observed, leaving professionals to lose control of the overall process, as they are focused on specific activities. This cycle is composed of the following steps and each one of them must be managed according to all its particularities:

- Research and Development;
- Approval;
- Commercialization;
- Withdrawal from the market.

The industry invests in areas that offer a more secure return on investment. Today, oncology, central nervous system, infections and cardiovascular diseases account for more than 50% of R&D investments. To define an area, according to Hering et al. (2018), medical 'need', 'disease prevalence', 'technical feasibility', 'research and development costs', 'competition' and 'quota of potential market'.

In their study, Smits and Boon (2008) suggest that the pharmaceutical sector should seek greater involvement with users, even in a prior phase to R&D, showing the importance of their contribution and thereby obtaining a greater social and commercial return on investments. It also suggests that governments should create and stimulate an enabling environment for such interaction. This would create a strategic intelligence infrastructure that would allow such activities to be carried out.

As a strong possibility of reducing time and R&D costs and increasing the agility and competitiveness of the pharmaceutical industry, some companies have relied on open innovation. It brings the possibility of accessing new ideas, technologies and R&D projects outside the company, bringing more dynamism. As with all models cited above, the innovation management model based on open innovation should also be customized to the profile of each company (Schuhacher et al, 2013).

## **5. Final considerations**

It has long been known that innovation is a fundamental part of business growth and increased market competitiveness, and consequently the economic development of countries. However, especially for small and medium-sized enterprises, dealing with innovation in its structure is not always an easy task, because one must deal strategically with factors such as research and development costs, time, difficulty in raising funds and investment, diffusion of knowledge and other risks inherent to each sector. Even if a product, process or service innovation is simple and inexpensive, there are risks and factors that must be measured and managed in order to achieve better results. However, such risks also affect large companies that are currently seeking strategic partnerships with smaller companies that can streamline and optimize innovation processes. This possibility of being part of the processes of large companies, develop SMEs, bringing new market perspectives, such as internationalization, a fact that increasingly requires a better strategic management of their innovation processes.

In the pharmaceutical industry, optimizing the processes of innovation and improving its management begin to be the core of companies. In addition to the aforementioned factors and risks, the industry must deal with waiting time for the release of a drug or treatment, which takes around 12 years, by specific regulatory agencies. Each company, despite being part of the same sector, has its own dynamics of operation, and particularities of structure and market, no longer allowing a linear model of management nor an equal model applicable to all. Each company, knowing its structure, indicators and peculiarities well, must develop its own model of strategic management of innovation. Within these models, it is extremely important that intellectual property rights, which are inherent in the process, be included in order to guarantee the protection of its innovations, as well as to increase the profitability of its assets.

From this paper it is suggested for future studies the introduction of open innovation as part of the company's innovation strategy. This would make the market more dynamic and with a wider dissemination of knowledge and new ideas. It is necessary to evaluate how open innovation can be inserted and what benefits or losses this process can bring to the company. In addition, it is also suggested as an object of future studies, the development of tools that enable SMEs to evaluate and value their innovations, enabling a better negotiation of their assets, as well as better management of their IP portfolio.

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