

## **MANAGING INNOVATION IN THE PHARMACEUTICAL INDUSTRY: THE CASE OF A PUBLIC RADIOPHARMACEUTICAL CENTER IN BRAZIL**

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### **ABSTRACT**

The pharmaceutical industry in Brazil has experienced changes since 1996 when the patents regulation was established and, in 1999, the generic drug policy was implemented. The companies have reviewed their strategy to adapt themselves to the new situation. New products developed and launched still guarantee their future, even within a more competitive market - the generic drugs. On the R&D and innovation activities remains the main response to the survival. The aim of this paper, that is part of a doctorate research, is to understand how the organizations, in pharmaceutical sector, manage technology innovation. A survey methodology was defined as a first screening (phase 1) in order to verify the profile of the company or institution which will be complemented through a case study. The Radiopharmaceutical Center of IPEN, representing a public institution, was selected to participate in a preliminary application of the survey questionnaire. Results showed that the survey utilized is very adequate and could support the research study, but it is highly recommended to get feedback from additional respondents on this survey in order to achieve more representative results. In a next step, another public and private organizations related to pharmaceutical market will be invited to participate.

### **1. INTRODUCTION**

The pharmaceutical industry is basically formed by two types of players: one is innovation-driven and other is specialized on non-patented medicines manufacturing. The first group acts through R&D activities and pushes the market tendency [1]. The R&D on Healthcare sector is one of the highest-spending industries, overtaken only by the Computing and Electronics industry [2]. In fact, the R&D-based pharmaceutical industry is the largest industrial sector investing in health research worldwide. R&D expenditures in 2005, by pharmaceutical and biotechnology companies belonging to the US industry association PhRMA, were close to 40 billion dollars. The industry spends more than the US National Institutes of Health (NIH) – the biggest public health research organization in the world - with a 2005 total budget approaching 30 billion dollars [3].

The cost to launch a new medicine could achieve 400 millions dollars but this investment doesn't increase the low chance of success (could be 1/10.000) and can take a long period to launch due to several barriers (up to 15 years from drug discovery) [4], [5].

About Brazil, there is a clear delay on the pharmaceutical sector related to past decades of low investment in R&D and innovation. The Patent Regulation was established in 1996, when many of the local pharmaceutical companies had a strategy to copy imported products. Since that time it is possible to verify that the investment on R&D in Brazil has grown 10% by year [6]. However, specifically to pharmaceutical industry, a generic drug policy has been implemented in 1999 impacting on local market and strategy of the companies. In summary, the Brazilian government could license a patented product if such product was considered as "public interest". The companies, again, feel insecure due to this regulatory milestone [7].

Based on this perspective, the aim of this paper, that is part of a doctorate research study, is to realize a previous test on a methodology to identify the innovation practices in pharmaceutical organizations (private and public) installed in Brazil. So, a preliminary survey, part of the phase 1 of this research study, was applied in order to review and validate the methodology. Specifically for this paper, it is presented the results of this test applied to the Radiopharmaceutical Center in IPEN (Nuclear and Energy Research Institute).

## **2. CHARACTERIZATION OF THE CASE: THE IPEN RADIOPHARMACEUTICAL CENTER**

The IPEN is located in Sao Paulo State (in University of Sao Paulo campus), Brazil, and its main focus is nuclear technology research, including, among others, radiopharmaceuticals production. The Radiopharmaceutical Center was established in 1959, when the first activities on manufacturing of  $^{131}\text{I}$  were fundamental to enable and consolidate the emergence of nuclear medicine in the country [8].

The Radiopharmaceutical Center is structured in four main areas: Production, Quality Control, Quality Assurance and R&D. The Center has two R&D branches: one is linked to Quality Assurance and other is highly concentrated on development of medicines (mostly adaptation of imported technology appropriate to national priorities) to supply the local market. A program of nationalization was established in 1995 in order to produce, in house, some of the imported radioisotopes [8].

The nationalization program, associated with the development of new products, has enabled IPEN to produce and distribute, throughout the country, several radioactive products for the diagnosis and treatment, among them labeled compounds and reagents for ready lyophilized labeling with  $^{99\text{m}}\text{Tc}$ . Such radiopharmaceuticals are produced with quality control for use in humans, in a form of injectable drugs, for use in the diagnosis and therapy of numerous diseases [8].

## **3. METHODOLOGY**

The research questions should be answered with the following methods and approaches (see Table 1).

**Table 1. Research Questions and Method Planned**

Phase	Research Questions	Method
1	What is the profile of the companies and institutions on managing innovation of products?	<i>Survey</i>
2	How pharmaceutical companies and institutions manage innovation of products?	<i>Case Study</i>

The main question of the phase 1 of the research is to investigate what is the profile of the companies or institutions in the pharmaceutical sector in relation to managing innovation. A *survey method* is being used to provide response for such question. Generally, a question form with *who, what, where, how much* and *how many* could be answered using a survey method and - it also focuses on contemporaneous event [9].

The survey questionnaire was properly structured and developed by Tidd, Bessant and Pavit [10] so that each statement is directed to five dimensions of innovation management: strategy; processes; innovative organization; linkages and learning. The authors argued in favor to those dimensions giving an example to illustrate how they are important. They suggested that it's unlikely that an organization have success on innovation with an innovation strategy not so clear (lack of strategy), with limited technological resources and no plan to acquire more (lack of processes); with weak project management (lack of innovative organization), with few external networks (lack of linkages) and with a rigid organization and not sustainable (lack of learning) [10].

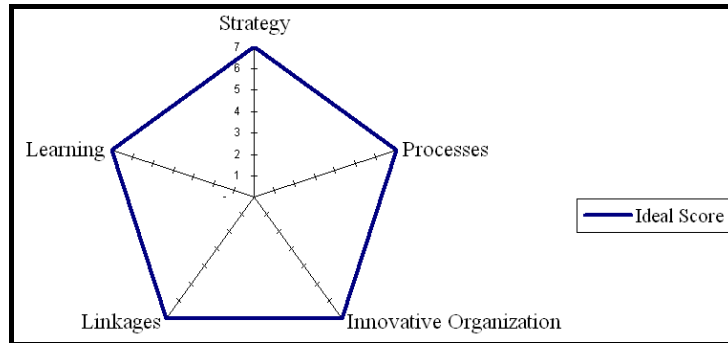
This *survey* is composed of 40 statements, being 8 for each dimension and uses a Likert seven point-scale. Such statements describe "the way we do things around here" and have as proposal to verify which the profile of the organization on managing innovation is [10].

Table 2 gives an example of the statements in the survey in relation to each dimension. The respondent applies a score between 1 (not true at all) to 7 (very true) for each of 40 statements. The full questionnaire is presented in the appendix section [10].

**Table 2. Example of statements applied for each dimension**

Dimension	Statement
Strategy	People have a clear idea of how innovation can help us compete
Processes	We have processes in place to help us manage new product development effectively from idea to launch
Innovative organization	Our organization structure does not stifle innovation but helps it to happen
Linkages	There is a strong commitment to training and development of people
Learning	We have good 'win-win' relationships with our suppliers

The result is a *radar chart* type (Figure 1) obtained by averaging the eight questions in each five dimension [10].



**Figure 1. Innovation profile radar chart**

#### **4. RESULTS AND DISCUSSION**

Two people from Radiopharmaceutical Center of IPEN accepted to answer preliminarily test of the survey. Both of them have worked there for more than six years and had experienced research and development activities.

The results aren't been published in this paper because they are very preliminary and un-conclusive but, instead, a SWOT<sup>1</sup> analysis is being held in order to highlight the observations of this preliminary survey and potential next step of this phase.

##### **4.1. Strengths**

The survey could provide results, as an audit form, as clear as an absolute score. Developing various indicators it's possible to avoid subjective judgment on the capacity of organizations to innovate.

Applying the questionnaire with a suitable number of respondents it's possible to verify what are the areas of concern which requires additional effort or investigation about the root cause, for example, with a deep case study. This approach is suitable when is needed to answer question with *how* or *why* [9].

Other strength of this method is about how easier the results can be managed compared to a case study, mainly because is a quantitative method that can be treated using standard statistical tools.

The questionnaire is formed by clear and simple sentences that save time from the respondent avoiding misunderstanding. No doubt was registered during the preliminary survey execution.

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<sup>1</sup> SWOT: strengths, weaknesses, opportunities and threats

The profile radar chart was prepared to check if any disruption could be noted. Nothing atypical was noted and the Microsoft-EXCEL spreadsheet was validated to this purpose. It shows how the data and results can be easily managed with no loss of information or time.

#### **4.2. Weaknesses**

Criticizing somehow the method, we could say that Likert scales (seven points scale) may be subject to distortion from several causes. 1. Respondents may avoid using extreme response categories or central tendency bias; 2. Sometimes they agree with statements as presented; or 3. In some cases try to portray themselves or their organization in a more favorable light. [11].

Exactly as commented, it was observed that one of the two respondents concentrates its scores in "4", which is the central tendency bias, where the respondent says "neither true nor untruth". However, there was not observed that they simply agree with the statements, as advised before, once the score "7" (as well as the score "1") received the least occurrence.

#### **4.3. Opportunities**

The preliminary survey showed that, as any quantitative method, it should have had major number of respondents, although this is a previous test for application of this methodology. On the other hand, is important to consider the coverage of areas that are related to R&D activities at IPEN, for example, Quality Assurance and Production areas which have discrete, but not irrelevant innovation activities (incremental) being performed.

Furthermore it's also relevant to reach levels of the Radiopharmaceutical Center's leadership for completion of the survey. Generally, the leadership has better overall understanding and vision of the innovation profile of the organization as a whole.

In addition, taking responses from different areas and hierarchic levels is the way to minimize the distortion of the information when respondents try to portray their organization in a more favorable light.

#### **4.4. Threats**

The most important threat observed is to get agreement and availability of the respondents to cover as much as possible the observations highlighted on this preliminary survey application.

### **5. CONCLUSIONS**

The questionnaire used in this preliminary application of the *survey* is very adequate to the proposed objective of the research study phase (phase 1). A complementary step for this survey phase should include other areas in the Radiopharmaceutical Center at IPEN and leadership staff from Radiopharmaceutical Center in order to complete the survey and permit to get the results and conclusion.

Once the survey is concluded at IPEN, it's also being planned to include other public institutions (Butantan Institute and FIOCRUZ) to permit comparing results from each other, and also to identify peculiarities on different markets (pharmaceuticals, vaccines, radiopharmaceuticals) in respect to managing innovation. This approach is also beneficial to avoid that the analysis becomes addicted in radiopharmaceutical sector and enables getting more comprehensive information.

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## Appendix 1: Full Questionnaire of the Survey

	Statement
1	People have a clear idea of how innovation can help us compete
2	We have processes in place to help us to manage new product development effectively from idea to launch
	Our organization structure does not stifle innovation but helps it to happen
4	There is a strong commitment to training and development of people
5	We have good 'win-win' relationships with our suppliers
6	Our innovation strategy is clearly communicated so everyone knows the targets for improvement
7	Our innovation projects are usually completed on time and within budget
8	People work well together across departmental boundaries
9	We take time to review our projects to improve our performance next time
10	We are good at understanding the needs of our customers/end-users
11	People know what our distinctive competence is – what gives us a competitive edge
12	We have effective mechanisms to make sure everyone (not just marketing) understands customer needs
13	People are involved in suggesting ideas for improvement to products or processes
14	We work well with universities and other research centres to help us to develop our knowledge
15	We learn from our mistakes
16	We look ahead in a structured way (using forecasting tools and techniques) to try and imagine future threats and opportunities
17	We have effective mechanisms for managing process change from idea through to successful implementation
18	Our structure helps us to take decisions rapidly
19	We work closely with our customers in exploring and developing new concepts
20	We systematically compare our products and processes with other firms
21	Our top team have a shared vision of how the company will develop through innovation
22	We systematically search for new product ideas
23	Communication is effective and works top-down, bottom-up and across the organization
24	We collaborate with other firms to develop new products or processes
25	We meet and share experiences with other firms to help us learn
26	There is top management commitment and support for innovation
27	We have mechanisms in place to ensure early involvement of all departments in developing new products/processes
28	Our reward and recognition system supports innovation
29	We try to develop external networks of people who can help us – for example, with specialist knowledge
30	We are good at capturing what we have learned so that others in the organization can make use of it
31	We have processes in place to review new technological or market developments and what they mean for our firm's strategy
32	We have a clear system for choosing innovation projects
33	We have a supportive climate for new ideas – people don't have to leave the organization to make them happen
34	We work closely with the local and national education system to communicate our needs for skills
35	We are good at learning from other organizations
36	There is a clear link between the innovation projects we carry out and the overall strategy of the business
37	There is sufficient flexibility in our system for product development to allow small 'fast-track'

	projects to happen
38	We work well in teams
39	We work closely with 'lead users' to develop innovative new products and services
40	We use measurements to help identify <i>where</i> and <i>when</i> we can improve our innovation management