

PHARMACEUTICAL INDUSTRY DEVELOPMENT IN BRAZILIAN HEALTH INNOVATION SYSTEM

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ABSTRACT

Given the importance of the health industrial complex, which is extensively technological, and the possibility of increasing the competitiveness of their systems through innovation, this research aims to present the structure and development of the pharmaceutical industry within the health innovation system in Brazil. To achieve such goal we used secondary data obtained by means of publications and sites which were organized with the objective of research. The results indicate that, despite the potential for innovation in the pharmaceutical industry, in Brazil there is still a gap in the field, with low investment in R & D for domestic innovation, which makes it dependent on imports and foreign technology. The support policies in innovation and legislation can help this process by providing resources, mainly financial, for R & D investments. Also, the partnerships with universities are critical to research development, making the Brazilian pharmaceutical industry more competitive. This can also be achieved through the production of generic drugs, which have, in the smaller industries, a suitable structure for its production.

Key words: innovation system, innovation system health, pharmaceutical industry

INTRODUCTION

Health is related to the welfare of people, and to promote that welfare there is a health complex involving industrial sectors, together with public and private health sectors (GADELHA, 2003). Its role is emphasized by a productive complex responsible for the production of consumer goods and equipment (COSTA; GADELHA & MALDONADO, 2012). It reveals itself as a field of high knowledge and innovation that incorporates and develops strategic technologies which have an interdependent impact on both the Health Industrial Complex (HIC) and the economic and productive area (ABDI, 2013).

“The Industrial Health Complex consists of a wide group of economic activities which form the basis for goods production and services related to health services”, thus being a key element in the development of the country. “The pharmaceutical industry can be considered one of their main productive activities, including producing industries of pharmaceuticals (pharmaceutical raw material) and medications” (CUNHA *et al.*, 2008: 2).

The pharmaceutical industry has developed in recent years. Its importance in the social scene is of great importance, especially when we refer to questions related to discoveries and innovations which refer to social welfare. Its relevance is such that one should observe how these innovations affect the production chain. If we considered the service industry as the applicant to other industries we would notice how complex it is to manage these innovation-focused variables. Although it seems that innovations are not directly focused on social issues, we must consider the profit of large oligopolies which holds the market focused on the pharmaceutical industry. Therefore, analyzing such a large sector as the innovation in healthcare is an intricate task since it involves wide social and economic issues.

Within this context, the goal of the present work is to contribute to academic debates on innovation in the healthcare industry and also to present relevant aspects of the innovation system for the pharmaceutical industry, which may inform public policies.

The work initiates presenting some constitutive definitions and basic aspects of innovation, the innovation system and the sector system of innovation. It proceeds to introduce the methodological procedures and the results of the analysis of the Innovation System of Health. It finishes with the final considerations.

THEORETICAL FRAMEWORK

Innovation

“Innovation is the implementation of a new or significantly improved product (good or service), or a process, or a new marketing method, or a new organizational method, in business practices, in the organization of the workplace or in external relations” (OCDE & FINEP, 2005: 55).

A common ground between forms of innovation found in the innovation literature refers to innovation in product / service and process. However, some authors provide other forms.

Schumpeter (1997: 76) contribute by providing five forms of innovations:

- i. introduction of new products;
- ii. introduction of new production methods;
- iii. opening new markets;
- iv. developing new sources of raw materials and other inputs; and
- v. creating new market structures in an industry.

Innovation in products / services involves several levels of coverage and may be an innovation for the company, from the development and implementation of a product / service already adopted by competitors; an innovation to the market, through the introduction of an innovation in the

enterprise market in local or sector level; or innovation to the world by the introduction of new products / services for domestic and international market (CARVALHO; REIS & CAVALCANTE, 2011).

Actions to develop new products and production processes have a direct result on the financial performance of organizations. The innovation of products and processes is of great importance when it comes to economics. According to Lemos (1999), there are two types of innovation: radical and incremental. The radicals are those which refer to discoveries, innovations aimed to the new. On the other hand, incremental innovations are small innovations on an existing context. Other authors such as Dosi (1998) conceptualize innovation as a search, discovery, experimentation, development, imitation and adoption of new products, processes and new organizational techniques.

The innovation process in general is widely related with entrepreneurship. Innovation and entrepreneurship complement each other according to Schumpeter (1997). He says that the entrepreneur within the economic and social development plays an important role and the entrepreneur alone is an innovator. He then proceeds referring to the changes that are discontinuous and spontaneous and, in this innovation process, consumers are educated to seek new things. There are theories that mention innovation strongly linked to industry. However, other segments may be related, as in the case of service-oriented innovations.

“The research and innovation has been a fertile field of research in various disciplines. Most of these studies have not revealed explicit interested in different industries, but the innovations in many industries have been studied, and it should be possible to make comparisons between industries” (NELSON & WINTER, 2000: 191).

Innovation is present in various fields. Another variable is research and development, also called R & D, presented and highlighted by many authors. It is always related to forms of innovation and, according to Pelegrin *et al.* (2007) the social structure that characterizes an innovation network is a reflection of a complex coordination of numerous activities that are interdependent and, at the same time, complement each other between those involved, which include: finding new markets, conceptual design, partnership development and R & D.

Innovation system

While innovation can be seen as a complex process, as well as entrepreneurship, some authors argue that both can be born from a need for others; an opportunity; or from planning and learning. Therefore, Pelegrin *et al.* (2007) sees the process of innovation as something endogenous, and yet there is a constant awareness that innovation is much associated with intense competitiveness. As a result we can say that there are different ways of interpreting the innovation system. The authors also say that the innovation process is similar to a chain of activities that develops the application and combination of internal and external resources to organizations. Other authors conceptualize the innovation system differently. Malerba (2002) relates sector innovation systems which seek to fill the gap on the needs of customers. Besides, the sector system seeks to divide processes, competencies, behaviours and origin in sectors.

There are those who approach the innovation system not entirely aimed to economical but also social purposes. Also, it can be applied in other systems according to Strachman and Deus (2003) who interpret the innovation systems that can also be used for non-social systems such as biological and physical systems. Besides, innovation systems can be divided in sector, local and technological

ways where we use the terminology of the National Innovation System (NIS), contemplating different variables in this category, not only specifically but also for others.

Sector system of health sector innovation

The sector system of innovation in health care is shown as one of the key drivers for economic and social development. According to Malerba (2002), sector innovation systems are composed of heterogeneous agents in the market, i.e. different levels compose this segment. Knowledge is the key structure in the sector system; however organizations which are not firms (such as universities, financial institutions and the government) contribute to develop the sector because they have interest in it. According to Gadelha (2002), the health sector provides an important framework for innovation, which creates investment opportunities, and thus can be called essential "locus" of human development.

Therefore, the innovation sector plays different roles within this context and it is also present in social and economic development. Gadelha Quental and Fialho (2003) state that a health system can be decomposed by a social demand on health services and organizations aimed at generating human, financial, technological, and productive infrastructure services. "The health sector is an important component, given its role as the intersection between the innovation system and the system of social welfare" (ALBUQUERQUE & CASSIOLATO, 2002: 149).

Another matter that draws attention is the dynamism and the results that the system of innovation in the health sector can promote, not only by development issues, but also characterized by economic results. According to Guimarães (2004) the health sectors are very dynamic and profitable industrial segments in global aspects. However this dynamism may seem larger and Malerba (2002) says that when it comes to sector system it has a wider meaning. However, some sectors may consist of local systems of innovation and production.

Similar to other areas that require high amounts of funding for research in the area of innovation, the health sector is perhaps the most notable regarding to financial support. Gadelha, Quental and Fialho (2003) say that activities related to health have high funding, with heavy investments by large companies in a constant process of innovation through the search for new products.

Therefore, it is undeniable to accept the profit of practices that are linked to health innovation sector, Gadelha (2003) recognizes the capitalist basis in the health sector, as well as the mass production, business and financial logic as being the dynamic of innovation in order to establish policies that conceive an alternative to the logic of the capitalist system and the pursuit of profit markets with social and individual development needs.

METHODOLOGY

A qualitative research was conducted, not focused on numerical representations (GODOI & BALSINI, 2006), which enables to capture phenomena in social sciences as the analysis of organizational structures (BRYMAN, 2005). The strategy used was the case report, which (GIL; LICHT & OLIVA, 2005) means analyzing the event using data available. The case report was exploratory and descriptive, aiming to report in detail a social phenomenon, not from assumptions (GODOY, 2006), regarding the Brazilian pharmaceutical industry, which is part of the health system, and the innovation sector system within the referred industry.

Literature review and analysis of pharmaceutical industry innovation was carried out within the sector system of health innovation. Secondary data obtained through scientific research, publications and websites (MCTI, FIOCRUZ, ANVISA, IBGE and ABDI among others) was utilized, in a cross section, but in a longitudinal perspective including a prospective vision. Data was organized and analyzed in order to present the structure and development of the pharmaceutical industry within the health innovation system in Brazil.

INNOVATION SYSTEM OF PHARMACEUTICAL INDUSTRY

The pharmaceutical industry is related to health thus becomes timely a stint on the Health Complex which is formed by the industries and the service sectors. Figure 1 shows a schematic of the value chain of health with its various links.

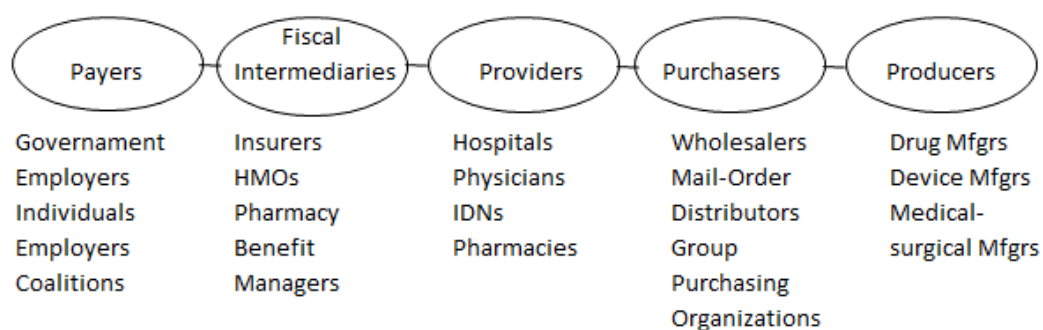


Figure 1: Health care value chain, Source: Burns et al, (2002: 4)

Vianna (2002) indicates there are two key attractors in the healthcare system. The first one is the medical and financial and the second is the medical-industrial. The first has intensive technology and decreasing costs, while the second has growing cost and intensive technology. We find the relation to the Health Industrial Complex (HIC) in the latter.

The HIC consists of a wide group of economic activities that form the basis for the production of goods and services related to health care services. The pharmaceutical industry can be considered one of their main productive activities, including pharmaceuticals-producing segments (pharmaceutical raw material) and medications (CUNHA *et al.*, 2008).

Before the 1930s drugs used in medicine were mostly of natural origin. In the 1930s the first pharmaceutical companies with manufacturing characteristics were formed, known as apothecaries. They represented a milestone in the consolidation of the pharmaceutical industry (SELAN; KANNEBLEY JR. & PORTO, 2007). The development of the pharmaceutical industry, the production of drugs obtained by chemical synthesis, was enhanced and synthetic based drugs, i.e., those formulated or manufactured from Pharmaceutical Assets (IFA) or chemically synthesized drugs - were considered classics and represent the largest part of the therapeutic arsenal available today (FIOCRUZ, 2014).

While the pharmaceutical industry was being structured the national capital accounted for only 14% of the Brazilian production of drugs, and the increasing appeal of multinational corporations intensified the involvement of businesses with foreign capital in domestic production, which reached 35% in 1940 and 73% in 1960 (PALMEIRA FILHO & PAN, 2003). However, there was significant

change in the Brazilian pharmaceutical market, with increased participation of national capital firms which accounted for 47% in 2011 (PALMEIRA FILHO *et al*, 2012).

While discussing experiences in technological innovation in the pharmaceutical industry, Benetti (2014) shows that development occurred in the twentieth century by obtaining drugs through chemical synthesis, but that the framework for the development of this industry was the discovery of penicillin G in 1929 in England, which was produced on an industrial scale only in 1941, by the United States, as they had the financial resources needed to produce it in large-scale.

The early 1990s brought major institutional changes that have modified several aspects of the Brazilian pharmaceutical industry. For example, the behaviour of national and multinational companies and the market structure. Therefore, the beginning of this decade was characterized by the reduction of import taxes on drugs and medicines along with the elimination of the restrictions and prohibitions on the import of pharmaceutical raw materials, on the logic of trade liberalization. Finally, the policy of drugs price control was abandoned, allowing the capitalization of companies as well as large investments for the expansion of the pharmaceutical capacity. In 1999, however, price control was re-established and the National Health Surveillance Agency (ANVISA) - whose area of expertise is not a specific sector of the economy, but all sectors related to products and services that affect the health of the Brazilian population (ANVISA, 2014) - was created. A remarkable fact was the enactment of the Generics Act, encouraging competition within the industry and, consequently, reducing prices of medicines internally, as well as the enactment of the current Intellectual Property Act 9.279 of 1996 (SELAN; KANNEBLEY JR. & PORTO, 2007).

The innovation in the global pharmaceutical industry was a result of the knowledge from advances in technological development within mechanical engineering and telecommunications sectors, achieved due to the Second World War (OLIVEIRA; GADELHA & CASTRO, 2013). The authors also show that with the economic opening, after the 50s, multinational pharmaceutical companies have become interested in the Brazilian market, consolidating its subsidiaries in the country.

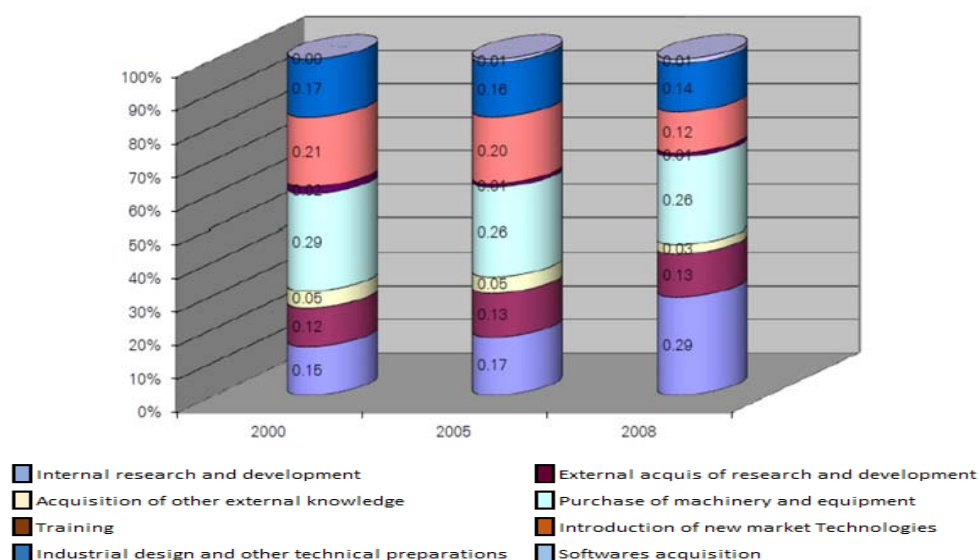
“Within the pharmaceutical industry, there are four technological stages: Stage I - research and development of new drugs; Stage II - production of new drugs; Stage III - clinical research and production of pharmaceuticals (medicines); Stage IV - marketing and sales of pharmaceutical specialties” (BENETTI, 2014: 107).

The pharmaceutical industry acknowledges the importance of activities in science, technology, research and development of new products such as the drugs production, which can be seen mainly in stages I and II (CUNHA *et al.*, 2008), i.e. research, development and production of new drugs. In Brazil, basically only stages III and IV are carried out. Stages I and II didn't grow in Brazil due to the high cost and long period of dedication to research. According to Benedetti (2014), it is common for firms to import drugs already researched and developed in other countries, a process that, without investment in R & D, makes the country technologically dependent on more industrialized countries.

In regards to the trajectory of pharmaceutical industry innovation in Brazil, Benetti (2014) indicates that there was a period of development until the mid-1940s, a period in which the Manguinhos Research Institute (Rio de Janeiro) was created, in order to supply serums and vaccines, along with the Butantan Institute (São Paulo); and a decline period from the post-war age, when the country began more raw materials.

Concerning innovative activity, Palmeira Filho and Capanema (2010) observe that the funding of the Brazilian pharmaceutical industry in internal R & D was little because, according to data from the Survey of Innovation (PINTEC, 2005), it was 0.72% of the net income of companies (IBGE, 2007), while the top 11 global pharmaceutical companies invested the sum of US \$ 46.5 billion in R & D in 2006, equivalent to 14% of their total revenues. Although the percentage of investment in innovation by the pharmaceutical industry increased to 1.44% in 2008 (IBGE, 2010) and to 2.39% in 2011 (IBGE, 2013), it still falls short of the required investments. As a result, although the pharmaceutical market “figure among the top 10 globally, it was not able establish an integrated pharmaceutical industry with a reasonable degree of technological complexity” (PALMEIRA FILHO & CAPANEMA, 2010: 308).

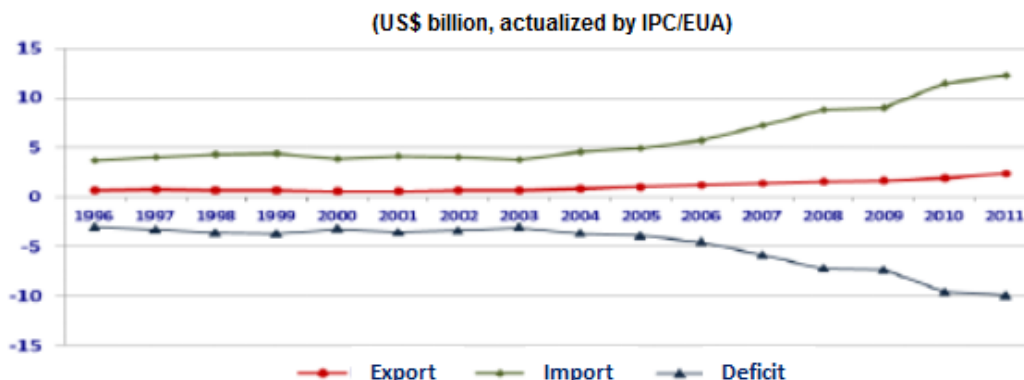
The Graph 1 shows the structure of expenditure on innovative activities by pioneering companies in the Brazilian pharmaceutical sector. Data of PINTEC-IBGE, for the years 2000, 2005 and 2008, in which the evolution of the investments structure can be observed in the pharmaceutical industry innovative activities, specially increased in internal research and development.



Graph 1 - Structure of expenditure on innovative activities in the pharmaceutical industry - Brazil - 2000, 2005 and 2008 (% of total expenditure), Source: ABDI (2013: 27)

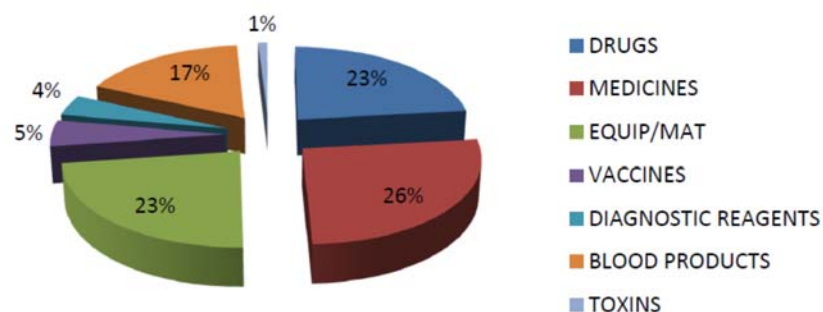
However, due to low investment in R & D most companies in the Brazilian pharmaceutical industry suffers major competition of the highly competitive market. Without innovation, they achieve lower profit rates, and the integration of universities and research institutes is essential to engage in cooperative activities in R & D (CALIARI & RUIZ, 2011).

Gadelha, Maldonado and Costa (2012) notice that despite the recognition of the HIC strategic importance for development there are still difficulties in the implementation of public policies for its strengthening. Such difficulties are seen in the trade deficit of health, according to Graph 2, in which the increasing trade deficit of health from 1996 to 2011 is visible, indicating an inclination, if R & D resulting in innovations in the industry is not practiced.



Graph 2 - Evolution of the trade balance for health - cis 1996-2011, Source: Gadelha, Maldonado & Costa (2012)

Graph 3 shows the share of productive sectors in the trade deficit of health. It can be observed that in 2011, the deficit generated by the importation of drugs and medicines accounted for nearly half of all the results in the HIC balance of trade. The sector reveals particular health vulnerability, representing implicit risk for the implementation of policies on access to health goods and services (GADELHA; MALDONADO & COSTA, 2012).



Graph 3 - Participation of Productive Sectors In The Health Trade Balance Deficit – 2011, Source: Gadelha, Maldonado & Costa (2012)

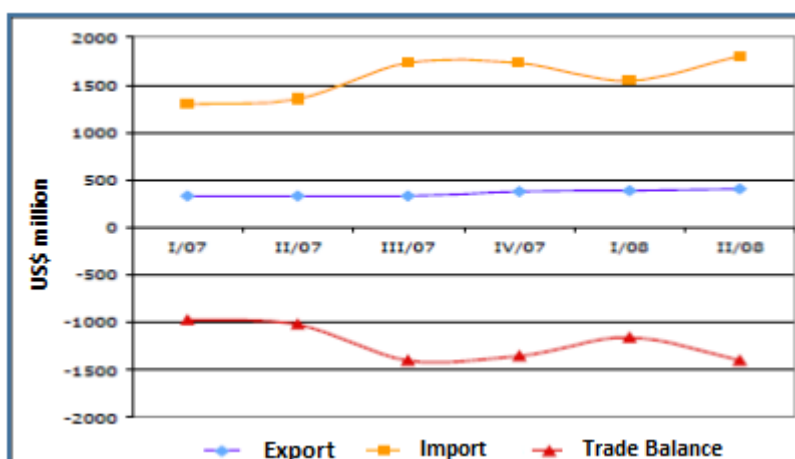
The pharmaceutical industry show a structure of economic oligopoly (BENETTI, 2014; CUNHA *et al.*, 2008; IPEAD, 2013; PALMEIRA FILHO & CAPANEMA, 2010; QUENTAL, GADELHA & FIALHO, 2001). The big companies are vertically integrated and operate in most countries (both developed and under development), whether to produce or to commercialize medicines.

Despite the fact that its limited structure lies in the hands of large transnational companies, the pharmaceutical industry also includes a significant number of smaller, active niches in the pharmaceutical market existing companies, which does not require significant economies (CUNHA *et al.*, 2008).

The Brazilian pharmaceutical market was placed ninth in the ranking of the global pharmaceutical market (pharmaceutical retail) in 2008, registering sales of \$ 17.13 billion. Despite showing a continuous growth in Brazilian Real (Brazilian currency) since 1997 (and also in U.S. dollars, from 2003), the national pharmaceutical industry has registered modest growth in units sold. In the 2003-2008 period, the annual compound growth, in units, was 3.6%. It is worth mentioning that in 2008 alone the industry volumes reached the same level as in 1997 (PALMEIRA FILHO & CAPANEMA,

2010). The estimative in emerging markets such as Brazil is for growth. Brazil might be ranked sixth place in 2015 within the global ranking of the largest pharmaceutical markets (PALMEIRA FILHO *et al.*, 2012).

Graph 4 shows the growing movement of imports against the modest performance of exports, resulting in a negative trade balance. Rising imports inhibits the development of the Brazilian pharmaceutical industry, reinforcing its technological dependence. Thus, Brazilian companies can hardly compete with global companies in regards to the integral development of radical innovations. However, some analysts report that they can certainly participate as partners in innovation processes, as long they hold a strategic asset to present at the negotiating table. For example: the institutional and human resource capacity to innovate (CUNHA *et al.*, 2008).



Graph 4 - Evolution of Pharmaceutical Products Foreign Trade (I / 2007 to II / 2008), Source: CUNHA *et al.*, (2008: 26)

The Figure 2 shows the structure of the Brazilian Health Innovation System in regards to their agents and their interactions. All the agents in the diagram have some role in the Brazilian Health innovation system and there are technological, financial and demand flows (CALIARI; RUIZ, 2011). The segment of the pharmaceutical industry is composed of multinational companies, national biotechnology companies and public companies (FIOCRUZ, 2012), while the segment of medical equipment production by multinational and national companies. These two segments form the CIS, which cooperate with universities and research institutes for the development of research. Some of them have financial support from agencies such as BNDES, FINEP and CNPq. The NHS, private hospitals, clinics and private consumers represent those who demand equipment, materials and products provided by HIC. Regulating this structure, we have the National Health Surveillance Agency (ANVISA), the National Health Agency (ANS) and the National Institute of Industrial Property (INPI).

Within this structure there is a complex interaction, challenges and opportunities, especially when we consider the participation of multinational companies and the commercialization of products worldwide.

Among the opportunities, there is the production of generic medicines, promoted by the Act 9787 / 99 (BRAZIL, 1999), better known as the Generics Act, which created the category of generic drugs – “interchangeable pharmaceutical product, i.e. one that contains the same active ingredient at the

same dose and pharmaceutical form of the drug reference, is administered by the same route and have the same therapeutic indication of the reference drug, it must provide the same security and the same clinical efficacy” (PRÓ GENÉRICOS, 2014).

The Generics Act enabled an interesting and long-lasting (so far) integration of the pharmaceutical industry of domestic capital. “Some domestic capital companies experienced significant growth with the exploration of the generics segment, i.e. those marketed without brand, named after the active principle and bioequivalent to the original product or reference” (PALMEIRA FILHO & CAPANEMA, 2010: 308).

The introduction of generic drugs is seen by Quental *et al.* (2008) as a successful experiment in integrating social policies directed to grant access to medicines with guaranteed quality for the larger population, with economic policies concentrating in industrial development. The authors report that the development of productive capacity in the generics segment could be part of a wider strategy to consolidate the country a solid production base of domestic companies.

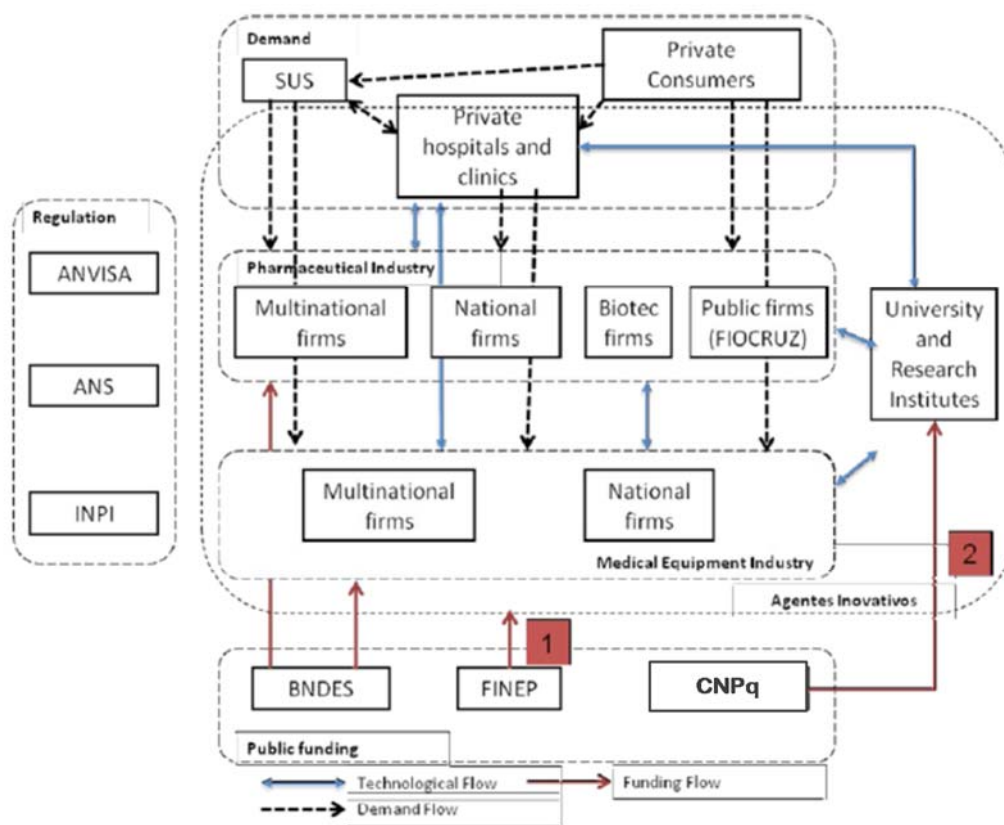


Figure 2 - organic and Linkages in the Innovation System of Health of Brazil, Source: Caliarí & Ruiz (2011: 4).

In this segment there are smaller companies specialized in the production of non-patented drugs with trademark (similar products) or generic drugs, which compete primarily through production costs and final product prices, as well as the distribution structure, from which they can benefit (CUNHA *et al.*, 2008).

National pharmaceutical companies led the competition in the generic drug market, generating sufficient resources to start investing in R & D. “The approval of the biosimilar drugs regulation -

cheaper version of biological drugs already available - open a field of similar opportunities to domestic companies, since important biopharmaceuticals that have gained patent protection during the 1980s are or soon will be unprotected. The introduction of copies from these high added value products would introduce competition in the market and allow a reduction in prices. Studies required for comparability between the biosimilar and the reference product, to prevent product approval without satisfactory evidence of efficacy and safety, are more complex than those required for generics: biopharmaceuticals are considerably more complex than pharmaceutical drugs, and the need for additional clinical and non-clinical data may increase corporate costs with R & D, reflecting on the scientific and technological infrastructure” (FIOCRUZ, 2012: 238).

In the end of 2004, two important laws were adopted in Brazil, one of them regarding the incentives for innovation and scientific and technological research in the production environment - Act 10973; and the other establishing general rules for bidding and contracting public-private partnership within the public administration - Act 11079. These laws represent the concern of governments to make the country fit for creating its own technologies, produced by both the public researcher and the independent inventor, in order to achieve the long awaited technological autonomy and industrial development in the country (BENETTI, 2014).

Some challenges and opportunities also arise through certain regulatory milestones, as shown in Table 1, some of these apply to other sectors besides the pharmaceutical industry, others relating to this sector.

Table 1 - Potential Constraints and associated Regulatory Framework, Source: ABDI (2013: 34)

REGULATORY FRAMEWORK	
RESTRICTIONS	POTENCIAL
RDC 57/2009 which regulates the registration of IFAs from ANVISA still has limited application to 20 products and benefits the entry of imported APIs without requiring sanitary control.	Biological products registration already has a normative from ANVISA (RDC 55/2010) which benefits the production of biological products.
Research in biotechnology is still restricted by the current regulatory access to genetic resources (MP 2186-16 / 2001) under the responsibility of CGEN	Significant advances in regulation of the state's purchasing power (list of strategic products, margin of preference, etc.).
Margin of preference (25% max) is an important tool although, according to producers, insufficient to counter the appreciation of Chinese and Indian prices	New instruments to support the health industrial complex have been adopted within the Executive Group of the Health Industrial Complex (GECIS).

Opportunities also arise from innovation support policies for the pharmaceutical industry. The creation of the Support Program for Development of the Pharmaceutical Supply Chain (Profarma / BNDES) has become an important initiative in health funding, with an emphasis on investments in production innovation and modernization, as well as the strengthening of domestic producers, by stimulating the movement of acquisition and merger of companies. It also (Cunha *et al.*, 2008) “contributed to a technological consolidation in the Brazilian pharmaceutical industry, especially in the internalization of pharmacotechnis skills in business” (PALMEIRA FILHO *et al*, 2012: 85).

The Health Industrial Complex (HIC) was considered one of the strategic priorities of the Growth Acceleration Program (PAC - 2007-2010), within which there was a program for the health sciences (Health-PAC) with 7 basic lines, containing specific guidelines for the pharmaceutical industry in order to “stimulate production internalization of pharmonochemicals, medicines and herbal medicines of greater impact for the National Health System; and encourage 'research and innovation in the production of neglected drugs and their raw materials, overcoming the gap between the production effort and innovation from developed countries and national needs” (CUNHA *et al.*, 2008: 33).

Within the Action Plan of the Ministry of Science, Technology and Innovation 2007-2010 one of the strategic areas for Research, Development and Innovation was the Inputs for Health, including: Drugs and medicines; Biomaterials and medical products; Diagnostic kits; blood products; and Vaccines (MCTI, 2007). Finally, the Brazilian pharmaceutical industry is included in the Productive Development Policy (PDP - MDIC, 2008), which suggests “mobilizing programs in strategic areas”, including the HIC (CUNHA *et al.*, 2008: 33).

The attention to the pharmaceutical industry and the adoption of policies to encourage their innovation are justified by the fact that it is an industry heavily based in science and technology, presenting itself as a strong inducer and spreader of advanced technologies in the economy. “In addition to its role as an inducer of the ‘new sciences’, the development of the pharmaceutical industry seems to contribute positively with two expensive variables to any government - economic and social” (PALMEIRA FILHO & CAPANEMA, 2010: 307).

FINAL CONSIDERATIONS

While studying the health innovation system in Brazil it is possible to observe the complexity of this structure. Time data shows the evolution of the health innovation area in Brazil, but it is still far behind the structure of the pharmaceutical industry in developed countries. Starting with the large oligopolies, where the structure is concentrated in the hands of large transnational companies

However, despite the difficulties, the health innovation system in Brazil has shown an evolution, albeit gradual, in the development of the pharmaceutical industry, with some landmarks such as in the 1940s, with the creation of the Research Institute for supplying serum and vaccines at Oswaldo Cruz Institute (Rio de Janeiro) and the Butantan Institute (São Paulo). Another major milestone was the Act 9787 / 99 (the Generics Law) which enabled significant changes in the pharmaceutical industry. Among them, the evolution of the national companies in sales of generic drugs, which rose from 28.2% in 2000 to 43% in 2008 and reinforces the importance on the system as a whole.

The improvements resulting from the Generics Law correspond to the involvement of small businesses that have suitable structure to its production and which gained competitiveness with the law. This can be strengthened, as it represents a way to reinforce the industry and its competitiveness (QUENTAL *et al.*, 2008), in addition to allowing greater access to medicine by the population.

It is certain that isolated facts by themselves do not demonstrate a significant innovation. A radical innovation might be needed to boost research in this sector, given the restricted market oligopolies and the fact that some Brazilian companies could hardly compete with global companies in the integral development of radical innovations, as the study shows. Therefore, the state (as regulator of strategic sectors such as health and as a supporter of public policies) could intensify their efforts in

this sector, whose development, as Palmeira Filho and Capanema (2010) notice, has the potential to contribute to the economic and social variables.

It is also essential to promote partnerships with universities and research institutes in the pharmaceutical industry in order to develop internal R & D, reducing dependence on foreign technology, aiming to make the Brazilian pharmaceutical industry more competitive. Thus, results of funding (such as Profarma) would be enhanced, which should continue to be part of public policy for the pharmaceutical industry development, because of the importance in innovations development. Competitiveness improvement can also be achieved through the production of generic drugs, which have in the smaller industries a suitable field for their production. Such scenario highlights an important social aspect, because the low-income population may have greater access to necessary medicines due to lower costs of generic drugs.

REFERENCES

- Agência Brasileira de Desenvolvimento Industrial (ABDI). 2013. *Relatório de Acompanhamento Setorial*. Análise de nichos estratégicos para indústria de base química e biotecnológica em saúde no Brasil. ABDI.
- Agência Nacional de Vigilância Sanitária (ANVISA). 2014. *Agência*. Available from: <http://portal.anvisa.gov.br/wps/portal/anvisa/anvisa/agencia>. Accessed on: 15 Jun, 2014.
- Albuquerque, E.M. & Cassiolato, J.E. 2002. As Especificidades do Sistema de Inovação do Setor Saúde. *Revista de Economia Política*, 22(4), 13-151.
- Associação Brasileira das Indústrias de Medicamento Genérico (PRÓ GENÉRICOS). 2014. *Glossário*. Available from: <http://www.progenericos.org.br/index.php/glossarios>. Accessed on: 14 Jun, 2014.
- Benetti, D.V.N. 2005. Saúde e inovação científico-tecnológica em medicamentos. *Revista Tecnologia e Sociedade*. Curitiba, v. 1, n.4, pp. 103-118. Available from: http://files.dirppg.ct.utfpr.edu.br/ppgte/revistatecnologiaesociedade/rev04/05_saude_e_inovacao_cientifico_tecnologica_em_medicamentos.pdf. Accessed on: 06 Jun, 2014.
- Brasil. 1999. *Lei 9787* de 10 de fevereiro de 1999. Altera a Lei no 6.360, de 23 de setembro de 1976, que dispõe sobre a vigilância sanitária, estabelece o medicamento genérico, dispõe sobre a utilização de nomes genéricos em produtos farmacêuticos e dá outras providências. Brasília, 1999.
- Bryman, A. 2005. *Research methods and organization studies*. London: Routledge.
- Burns, L.R.; De Graaff, R.A.; Danzon, P.M.; Kimberly, J.R.; Kissick, W.L. & Pauly, M.V. 2002. *The Wharton School study of the health care value chain*. The health care value chain: producers, purchasers and providers. San Francisco: Jossey-Bass, pp. 3-26.
- Caliari, T. & Ruiz, R.M. 2011. *Innovation and Transaction Costs Theory: Interactions in the Brazilian Health System of Innovation*. Paper presented at the DIME Final Conference, 6-8 April 2011, Maastricht. Available from: http://final.dime-eu.org/files/Caliari_Ruiz_B4.pdf. Accessed on: 09 Jun, 2014.
- Carvalho, H.G.; Reis, D.R. & Cavalcante, M.B. 2011. *Gestão da inovação*. Curitiba: Aymarã.
- Costa, L.S.; Gadelha, C.A.G. & Maldonado, J.M.V. 2012. A perspectiva territorial da inovação em saúde: a necessidade de um novo enfoque. *Rev. Saúde Pública*, v. 46 (supl.), pp. 59-67.

- Cunha, A.; Araújo, R.; Mello, C. & Leite, C. 2008. *Indústria farmacêutica*. Brasília: ABDI; Campinas: NEIT-IE-UNICAMP, 35 p. (Relatório de acompanhamento setorial: complexo da saúde, v. 1).
- Dosi, G. 1988. The nature of the innovative process. In: DOSI, G.; FREEMAN, C; NELSON, R.; SILVERBERG, G. & SOETE, L. (eds.), *Technical change and economic theory*, pp. 221-238. London: Pinter Publishers.
- Fundação Instituto de Pesquisas Econômicas, Administrativas e Contábeis de Minas Gerais (IPEAD). 2011. *Diagnóstico do complexo industrial de saúde: Estrutura nacional e inserção da região metropolitana de Belo Horizonte*. Relatório de pesquisa. Belo Horizonte.
- Fundação Oswaldo Cruz (FIOCRUZ). 2014. *Rota Sintética*. Available from: <http://portal.fiocruz.br/pt-br/content/rota-sintética>. Accessed on: 18 Out, 2014.
- Fundação Oswaldo Cruz (FIOCRUZ). 2012. *A saúde no Brasil em 2030: diretrizes para a prospecção estratégica do sistema de saúde brasileiro*. Rio de Janeiro: Fiocruz/Ipea/Ministério da Saúde/Secretaria de Assuntos Estratégicos da Presidência da República.
- Gadelha, C.A.G.; Maldonado, J.M.V.; Costa, L.S. 2012. *O complexo econômico-industrial da saúde*. Available from: http://abresbrasil.org.br/sites/default/files/trabalho_26.pdf. Accessed on: 18 May, 2014.
- Gadelha, C.A.G. 2003. O complexo industrial da saúde e a necessidade um enfoque dinâmico na economia da saúde. *Ciência & Saúde Coletiva*, Rio de Janeiro, 8(2), 521-535.
- Gadelha, C.A.G; Quental, C. & Fialho, B.C. 2003. Saúde e inovação: uma abordagem sistêmica das indústrias da saúde *Cad. Saúde Pública*, Rio de Janeiro, 19(1), 47-59.
- Gil, A.C.; Licht, R.H.Z. & Oliva E.C. 2005. A utilização de estudos de caso na pesquisa em administração. *Revista Base (Administração e Contabilidade) da UNISINOS*. 2(1), 47-56.
- Godoi, C.K. & Balsini, C.P.V. 2006. A pesquisa qualitativa nos estudos organizacionais brasileiros: uma análise bibliométrica. In: GODOI, C.K; BANDEIRA-DE-MELLO, R. & SILVA, A.B. (orgs). *Pesquisa qualitativa em estudos organizacionais: paradigmas, estratégias e métodos*, pp. 89-112. São Paulo: Saraiva.
- Godoy, A.S. 2006. Estudo de caso qualitativo. In: GODOI, C.K; BANDEIRA-DE-MELLO, R.; SILVA, A.B. (orgs). *Pesquisa qualitativa em estudos organizacionais: paradigmas, estratégias e métodos*, pp. 115-146. São Paulo: Saraiva
- Guimarães, R. 2004. Bases para uma política nacional de ciência, tecnologia e inovação em saúde. *Ciência & Saúde Coletiva*, Rio de Janeiro, 9(2), 375-387.
- Instituto Brasileiro de Geografia (IBGE). 2007. *Pesquisa de Inovação Tecnológica 2005 – Pintec*. IBGE.
- Instituto Brasileiro de Geografia (IBGE). 2010. *Pesquisa de Inovação Tecnológica 2008 – Pintec*. IBGE.
- Instituto Brasileiro de Geografia (IBGE). 2013. *Pesquisa de Inovação Tecnológica 2011 – Pintec*. IBGE.
- Lemos, C. 1999. Inovação na era do conhecimento. In: LASTRES, H.M.M. & ALBAGLI, S (orgs). *Informação e globalização na era do conhecimento*, pp. 122-144. Rio de Janeiro: Campus
- Malerba, F. 2002. Sectoral System of Innovation and Production. In: *Research Policy*, 31(2), 247-264.
- MCTI. 2007. *Plano de ação 2007/2010: Ciência, Tecnologia e Inovação para o desenvolvimento nacional*. Available from: http://www.mct.gov.br/upd_blob/0021/21439.pdf. Accessed on: 12. Mar, 2014.

Nelson, R. & Winter, S. 2000. En busca de una Teoría útil de la Innovación. *Revista Cuadernos de Economía, Colombia, Bogotá*, 19(32), 179-223.

OCDE & FINEP. 2005. *Manual de Oslo*: diretrizes para coleta e interpretação de dados sobre inovação. 3. ed. Available from: http://www.finep.gov.br/dcom/brasil_inovador/aquivos/manual_de_oslo/prefacio.html. Accessed on: 12 Feb, 2014.

Oliveira Jr., D.O.; Gadelha, T. & Castro, A.A. 2013. Monitoramento dos indicadores de inovação, importação e exportação na indústria farmacêutica. In: Simpósio Internacional de Inovação Tecnológica, 4, 2013, Aracaju. *Anais...* Aracaju: SIMTEC.

Palmeira Filho, P.L. & Capanema, L.X.L. 2010. A indústria farmacêutica nacional: desafios rumo à inserção global. In: ALÉM, A.C.; GIAMBIAGI, F. (orgs). *O BNDES em um Brasil em transição*, pp. 307-318. Rio de Janeiro: BNDES.

Palmeira Filho, P.L. & Pan, S.S.K. 2003. Cadeia farmacêutica no Brasil: avaliação preliminar e perspectivas. *BNDES Setorial*. Rio de Janeiro, n. 18, pp.3-22.

Palmeira Filho, P.L.; Pieroni, J.P.; Antunes, A. & Bomtempo, J.V. 2012. O desafio do financiamento à inovação farmacêutica no Brasil: a experiência do BNDES Profarma. *Revista do BNDES*. Rio de Janeiro, v. 37, pp.67-90.

Pelegrin, I; Balestro, M.V.; Antunes Junior, J.A.V. & Caulliraux, H.M. 2007. Redes de inovação: construção e gestão da cooperação pró-inovação. *Revista de Administração*. São Paulo, 42(3), 313-325.

Quental, C.; Abreu, J.C.; Bomtempo, J.V. & Gadelha, C.A.G. 2008. Medicamentos genéricos no Brasil: impacto das políticas públicas sobre a indústria nacional. *Ciência & Saúde Coletiva*, n. 13 (sup.), pp. 619-628.

Quental, C.; Gadelha, C.A.G. & Fialho, B.C. 2001. O papel dos institutos públicos de pesquisa na inovação farmacêutica. *RAP*. Rio de Janeiro, 35(5), 135-161.

Schumpeter, J.A. 1997. Teoria do desenvolvimento econômico: uma investigação sobre lucros, capital, crédito, juro e o ciclo econômico. In: *O fenômeno fundamental do desenvolvimento econômico*, pp. 69-99. São Paulo: Nova Cultural. (Coleção Os Economistas).

Selan, B.; Kannebley Jr. S. & Porto, G.S. 2007. *Relatório setorial sobre inovação tecnológica na indústria farmacêutica brasileira*: uma análise a partir dos indicadores de inovação. Ribeirão Preto: FIPASE. Available from: [m:http://fipase.com.br/pt/imagens/RelatSetFarmaceuticaBrasileira.pdf](http://fipase.com.br/pt/imagens/RelatSetFarmaceuticaBrasileira.pdf). Accessed on: 23 May, 2014.

Strachman, E. & Deus, A.S. 2005. Instituições, inovações e Sistemas de Inovações: interações e precisão de conceitos. *Ensaio FEE*. Porto Alegre, 26(1), 575-604.

Vianna, C.M.M. 2002. Estruturas do sistema de saúde: do complexo médico-industrial ao médico-financeiro. *Physis*. Rio de Janeiro, 12(2). 375-390.