The pharmaceutical industry in Brazil: Is innovation the next step for the domestic industry?

PEDRO L. PALMEIRA FILHO1*, ADELAIDE ANTUNES2, JOSÉ VITOR BOMTEMPO2

1. Federal University of Rio de Janeiro (UFRJ), Technology Centre, Chemistry School – Doctorate in Chemical and Biochemical Processes (on-going),
   UFRJ, Centro de Tecnologia, Bloco E, Ilha do Fundão, Rio de Janeiro, RJ 21941-909, Brazil
2. Federal University of Rio de Janeiro, Technology Centre, Chemistry School, UFRJ, Centro de Tecnologia, Bloco E,
   Ilha do Fundão, Rio de Janeiro, RJ 21941-909, Brazil

*Corresponding author

ABSTRACT

The so-called “pharmerging markets” have been the driving force behind the global growth of the pharmaceutical industry. Brazil is highlighted as one of the only countries with a population of more than 190m that has a universal health care system. After the regulation of the generic market, pharmaceutical groups have shown significant growth rates. However, the pressure surrounding competition among generics should incite a change in strategy by trying to create market differentiation via innovative products. Therefore, the present article examines the trajectory and behaviour of Brazilian pharmaceutical companies with regard to the threats and opportunities ahead.

INTRODUCTION

It comes as no surprise that emerging markets have been driving the growth of pharmaceutical industry throughout the world. According to IMS Consulting Group, the growth forecast in the “pharmerging markets” is in the order of 11-16 percent per year, whereas in the developed countries, such as the USA and Europe, the rate is at around 0-3 percent. Specifically regarding Brazil, the optimism is much greater and even justified.

The country has a stable democracy, solid institutions, sustainable growth despite external turbulence, and is undergoing a historic moment of social inclusion – between 2002 and 2008, no less than 19.4m people crossed over from the poverty line [1]. Life expectancy in Brazil also increased significantly, reaching 73.5 years in 2010 [2]. With regard to the Brazilian business environment, the country has a stable intellectual property system that is committed to the Trade-Related Aspects of Intellectual Property Rights (TRIPS) agreement. The regulatory framework of the industry has been rapidly aligning itself with those of major countries and the development agencies offer credit lines in accordance with the demands of the industry.

When analysing the local demand, Brazil is the only country in the world with more than 190m inhabitants that has a universal healthcare system – which is an enormous challenge – but which at the same time offers countless opportunities as new treatments, protocols and technologies become incorporated into the national health system.

For decades, the domestic pharmaceutical industry has been focusing its efforts much more on marketing than on research and development activities. Once Brazil began to recognize pharmaceutical patents in 1997, the Brazilian pharmaceutical industry was put in a checkmate, since its enterprises had not developed the know-how to allow them to innovate systematically, and the commercial strategy of copying medicines became very restricted. However, a new opportunity for the domestic industry was created in 1999, when the regulation for generic medicines was passed, inciting a rapid and opportune movement among Brazilian entrepreneurs and the political will of the government to foster the production and commercialization of generics within the country. The movement brought new life to the domestic pharmaceutical industry, as well as a new importance to Brazilian companies.

The object of the present article is to examine until what point the new opportunities in the generics segment have caused the Brazilian pharmaceutical industry to develop new capabilities. Might the strategy of the major domestic pharmaceutical groups have been changed to take on the higher risk investments that could, in the long term, place the domestic pharmaceutical industry on the global scene?

THE PHARMACEUTICAL MARKET IN BRAZIL

According to the report “Pharmerging Markets”, of the IMS Consulting Group [3], the Brazilian pharmaceutical market has grown in its global ranking. In 2005, it was in 10th position, moving up five years later to the 7th position. The forecast indicates that the Brazilian pharmaceutical market will occupy the 5th place in the global ranking, ahead of countries such as Italy, India, Spain, Russia and the UK. In the same report, a comparative analysis of the compound annual growth rate (CAGR) of the pharmaceutical markets per region around the globe for the 2011-2015 period indicates Latin American rates of 11 to 14 percent. This two-digit growth is only less than Asia
EMERGING COUNTRIES

Pacific (13-16 percent) and is in strong contrast to the scenario of stagnation forecasted for North America and Europe [0-3 percent] (3). According to the São Paulo Pharmaceutical Industrial Union (Sindusfarma) (4), the Brazilian pharmaceutical market should close 2011 with sales of approximately US$ 26bn, only considering the pharmacy segment. Between 2003 and 2011, the market had a growth rate of around 23 percent for sales in US$ and 8.4 percent in units sold. The growth trend can be seen in Graph 1.

Considering that the Brazilian public sector is responsible for approximately US$ 6bn in annual sales, the total Brazilian pharmaceutical market can be estimated at around US$ 30bn in 2011. From a supply-side perspective, the Brazilian pharmaceutical market has changed significantly in the last few years. In 2003, domestic companies were responsible for 33.5 percent of medicine sales; in 2010, this market share increased to 53 percent (5). While in 2003 Aché was the only domestic enterprise among the top ten pharmaceutical companies operating in Brazil (6), in 2011 there are four domestic companies among the top ten: Grupo EMS, Grupo Hypermarcas, Aché and Eurofarma.

The domestic companies that were responsible for 33.5 percent of medicine sales in 2003 increased their market share to 53 percent in 2010. Considering that the Brazilian public sector is responsible for approximately US$ 6bn in annual sales, the total Brazilian pharmaceutical market can be estimated at around US$ 30bn in 2011. From a supply-side perspective, the Brazilian pharmaceutical market has changed significantly in the last few years. In 2003, domestic companies were responsible for 33.5 percent of medicine sales; in 2010, this market share increased to 53 percent (5). While in 2003 Aché was the only domestic enterprise among the top ten pharmaceutical companies operating in Brazil (6), in 2011 there are four domestic companies among the top ten: Grupo EMS, Grupo Hypermarcas, Aché and Eurofarma. As of June 2011, these four Brazilian companies had projected gross annual sales at US$ 6.5bn, which represents 25 percent of the domestic, private sector, pharmaceutical market (pharmacy segment) (7). Although the major domestic enterprises have had impressive growth rates, especially after 1999 with the regulation of generic medicines in the country, there seems to be no clear indication that the Brazilian pharmaceutical market has already reached a level of organizational and technological capabilities for more favourable and sustainable competitiveness (8). Upon a closer look, however, it can be noted that the companies are indeed on their way to acquiring the organizational and technological capabilities that will allow them to capture the opportunities on the horizon not only in the Brazilian market, but in the regional and global markets as well (9).

THE GENERICS MARKET AND THE POSITION OF DOMESTIC INDUSTRY

The first generic medications hit the market in 2000. Since then, the segment has shown significant growth in the Brazilian pharmaceutical industry. In 2003, the segment represented 6.4 percent in value and 7.8 percent in units sold, in relation to the total Brazilian pharmaceutical market. In 2011, these values should reach 20.3 percent and 22.7 percent, respectively (4). The sales in US$ of generic medicines in Brazil grew at a CAGR of 42.3 percent for the 2003-2011 period (4). The domestic pharmaceutical industry took full advantage of the new business environment created by the regulation of generic medicines.

At the time, Brazilian companies found themselves at a competitive crossroads. Barred from copying innovative medicines, their strategy lied in releasing exact copies – or with small improvements – of products without patent under new commercial brands that were undoubtedly similar to the originals. A marketing effort to capture doctors was fundamental to attain some kind of differentiation with products that were more and more alike. Some Brazilian enterprises experienced accelerated growth by placing generic drugs on the open market. Although the generics market operated on smaller profit margins, the former high costs of marketing were practically eradicated, since it was mandatory that generics be sold only under the name of their respective active ingredients. Bioequivalence tests – verified by a registered third party – guaranteed their interchangeability, which obligated many companies to begin a process of acquiring the pharmotechnical capabilities that would become important for a new future of competitiveness.

The domestic groups that most enthusiastically embraced the generics market were: Biosintética, Eurofarma, Medley and EMS. In 2005, Biosintética was acquired by Aché. In 2009, Grupo Hypermarcas consolidated a strong position in the domestic pharmaceutical market and also in the generics segment, via the subsequent acquisitions of Farmasa, Neo Química and Mantecorp. Also in 2009, the first major movement of big pharma in the Brazilian generics segment: the Sanofi Aventis group acquired Brazil’s Medley for US$ 500m in February of that year. After all these acquisitions, by July 2011, the Brazilian generics segment became strongly concentrated in the hands of five companies that together hold 82.0 percent of the market share: Medley, Grupo EMS, Eurofarma, Grupo Hypermarcas and Aché (6). It is important to point out that only Medley is controlled by foreign capital.

The trajectory of the first domestic movers reflects the classic example of the great international companies, although on a smaller scale. With growing cash reserves and gains of scale from producing generics, some international companies sought the higher risk challenges of developing innovative drugs. In Brazil, this trend has been inexpressive. However, management of the four largest domestic groups have shown signs of dissatisfaction with the current strategic alternatives. Forming independent scientific committees and contracting executives to organize and conduct innovation strategy in these companies is a positive undertaking.

<table>
<thead>
<tr>
<th>Company</th>
<th>Generics</th>
<th>Brand (Rx(*) + OTC)</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>21%</td>
<td>79%</td>
</tr>
<tr>
<td>B</td>
<td>18</td>
<td>82</td>
</tr>
<tr>
<td>C</td>
<td>38</td>
<td>62</td>
</tr>
<tr>
<td>D</td>
<td>6</td>
<td>94</td>
</tr>
</tbody>
</table>

Table 1: % Revenues 2011 (human health) – drug category. Source: Primary data informed direct by the companies (*) Drugs sold under prescription
In 2010, some strategic alliances between domestic companies and universities, as well as between competing companies – as far as sharing the risk of projects – as well as the forming an association of the biggest Brazilian pharmaceutical companies, are all examples of the change in attitudes regarding the need to innovate. The recent declaration of domestic entrepreneurs on the importance of the biotechnology route for the Brazilian industry also indicates the concern regarding the strategic importance of biotechnology drugs in the Brazilian and global markets.

For the moment, although the innovation of the biggest domestic pharmaceutical groups has mostly been limited to developing new formulations, new associations and new usage of existing drugs, there is indeed a small volume activity around developing new drugs. Despite the confidentiality of the research, some developments have been observed with molecules from Brazilian biodiversity and improvements to already existing molecular designs.

Table 1 shows the share of generic drugs (commercialized by name of their active ingredient) in the revenues of the four largest Brazilian pharmaceutical companies.

Despite the fact that the growth of the domestic industry was based on the generics segment, the Brazilian companies have not let their sales be too dependent on this category of products. By heavily marketing their products in the medical segment, these companies have acquired gains of scale, which have allowed them to release, at the same time, brand name products – placing themselves at the two extremes of the demand curve for their products. The losses that were the result of depleting margins in competition amongst generics were, in some part, offset by the new brand name products with higher profit margins and the same active ingredient as the generic.

As patents expire on more intricate formulas, developing generics has begun to impose a certain level of organization of the internal process management. Table 2 indicates the evolution of the Research & Development (R&D) efforts of the companies in focus, regarding R&D personnel and R&D expenses relative to net revenues:

Despite the efforts in R&D the domestic pharmaceutical Market has mostly been associated with pharmotechnics, the table above now demonstrates a growing commitment to innovation.

**FINAL CONSIDERATIONS**

Contrary to what statistics may indicate, the Brazilian pharmaceutical industry, herein represented by the four largest domestic enterprises, has shown signs of capabilities in order to change strategy.

The need to incorporate innovation as systematic activity in order to include differentiated products in their portfolios that are capable of sustaining higher profit margins for longer periods, has obliged domestic companies to change their behaviour. The evolution of R&D efforts, represented by the internal staff of companies involved in R&D and expenditures on R&D compared to net sales, undeniably demonstrate a trend for change in the strategic orientation of these groups.

Therefore, from a trajectory perspective, it is possible to infer that the Brazilian pharmaceutical industry is undergoing a process of acquiring the capabilities necessary for innovation. As far as the level and rates of the process of acquiring capabilities is concerned, there are still questions to be answered that must be explored in a future investigation.

**REFERENCES AND NOTES**

The world’s leading Pharmaceutical Event is ready for business

Benefits of attending:
1 ticket = entry to 4 shows
Save on travel costs - Meet clients in 1 central location
See what your competitors are doing
Stay up to date on latest Industry trends;
- 100 Free Seminars
- Conferences run by industry experts
- Pharma Awards

What our visitors say:
94% agree it is the meeting place for the Pharma industry
92% satisfied with the event for meeting Pharma contacts
90% say that the event is the perfect place to source products and services from the global market

Entire Pharma Supply Chain Under 1 roof

30,000 Pharma Professionals from 140 countries

“Meetings at the event have opened up new ideas and new areas of discussions with clients.”
Head of Business Development, Butterworth Laboratories Ltd.

“Making personal contact is an important reason for attending shows.”
Business Development Manager, YMC Europe GMBH

09-11 October 2012
Feria de Madrid, Spain