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**Exit strategies of Pharmaceutical multinational companies from Portugal
and the successful implementation of new Portuguese companies**

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Abstract

In 2001 and 2004, two multinational companies (MNC) of the pharmaceutical industry, respectively Bayer and Janssen, left its manufacture operations in Portugal. From its exit, other two Portuguese small and medium enterprises (SME) were born: Bluepharma and Lusomedicamenta. These companies have been highly successful due to the representativeness of exports, contract-manufacturing and generic production. This report intents to study the exit of the MNC and the implementation of the Portuguese SMEs.

Key-works: pharmaceutical industry, Portuguese SME, exports, contract manufacturing, generics

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1 Case description

Back in 2001, the German pharmaceutical company, Bayer, announced the closure of its Coimbra's production plant. A group of four Portuguese saw this event as an opportunity to buy the industrial unit and establish a new company. Hence Bluepharma (BPh) was born. Its success is shown by its annual turnover growth of €3M in 2001 to roughly €18M in 2011 (+83%; CAGR: 19.62%), [1] in sharp contrast with a CAGR of 6.72% for the worldwide pharmaceutical sales from 2003-2012. [2] In 2004, Janssen-Cilag (the pharmaceutical unit of Johnson & Johnson), also announced its intent to close its Portuguese plant. A group of the former Janssen's Portuguese management team bought the industrial facilities (management buy-out – MBO), to, thus, create the Portuguese company Lusomedicamenta (LM). From 2005 to 2010, LM grew in an average growth rate of 11%, [3] whereas the Portuguese drug sales grew at an average of 4% during the same period of time. [4]

This report intends to (1) study and explore the conditions under which the Multinational companies MNC (Bayer and Janssen) had to leave Portugal, (2) study the factors underlined the successful implementation of the new Portuguese companies (BPh and LM) and, finally, (3) highlight strategies companies should adopt to keep-up with the demanding pharmaceutical industry.

2 Understanding the differences between the business models

Despite the fact that all four companies referred in this report operate in the pharmaceutical industry, there are some underlying differences that should be previously addressed.

The MNCs are companies that have its business model centered in the discovery and commercialization of brand-name new drugs, under patent protection. When the patent expires, other companies can produce and commercialize the molecule, as long as it shows its

bioequivalence. These are the generic companies, like BPh and LM. These, besides producing generics, it also buys licenses to produce and commercialize brand-name drugs, after its patent is expired. Lastly, there is a third way by which these Portuguese companies operate. Alongside with the two-abovementioned practices, BPh and LM also produce, in its industrial plants, pharmaceutical forms (brand-name drugs or generics) to a third client, mostly international costumers – contract manufacturing.

3 Literature review

3.1 International Business Strategies

A company's entry and exit movements into and from a foreign country, relay at the heart of International Business strategies. Its motivations and entry modes are important to understand "why" did it decide to invest in a certain country. [5] Portugal's FDI and exports incentives – especially from the 80s, upon Portugal's adherence to EEC, until now – and access to "low-cost" labor were two of the main drivers for the high inflow of FDI registered during the 80s decade in Portugal. [6]

3.2 Challenges of the Pharmaceutical Industry in the XX century

Traditionally, the global pharmaceutical industry was characterized by a rapid growth, high profits, and structural stability, despite showing disrupting innovation. However, companies were losing brand-name drug patent at a higher rate than these could be replaced, [7; 8] which led to the emergence of generic products. The highly regulated industry was demanding extra costs to guarantee the quality of its products, which aligned with lower margins resulting from fierce competition, the pharmaceutical industry started to consolidate and form strategic alliances. From 1986 to 1993 the number of strategic alliances in the pharmaceutical industry increased from 121 to over 400. [8] These challenges may be at the heart of the exit rationale behind the pharmaceutical MNCs that exited Portugal.

3.3 The arise of the pharmaceutical SMEs

Parts of these alliances were with manufacturer pharmaceutical small and medium enterprises (SMEs), to which a company could outsource some of its production. [8] This could result in a lower risk for the contractor company as it didn't need to heavily invest in production facilities, when demand for a specific product was, as seen by the emergence of generics, volatile. [9; 8] The flexibility provided by the SMEs, alongside with its innovatory capability, contributed for the important acknowledge of SMEs. [5; 8] reflected in '11-'12 growth of 62% registered at EMA. [10] Another important aspect of the SMEs is its export capability. [5] In Portugal, AICEP¹ reunites all the conditions and incentives not only to attract foreign capital, but also to encourage the Portuguese companies, especially SMEs, to internationalize and export its products. [11] These incentives may be the reason for the successful implementation of the Portuguese companies. In association with AICEP, PharmaPortugal was created in 2005 with the objective of increase the exports associated with the pharmaceutical industry. [12] This project can depict the profile of both pharmaceutical Portuguese companies.

4 Methodology

In order to understand the entry and exit movements of the MNCs into and out of Portugal, and the success stories of the aforementioned Portuguese companies, it was initially performed an extensive literature review in regards to International Business, especially concerning the international production strategies. Moreover, it was of utmost importance to understand what were the economic conditions under which Portugal in during the following

¹ In 2007. the merger between Agência Portuguesa para o Investimento (API) and ICEP resulted in the creation of the Agência para o Investimento e Comércio Externo de Portugal (AICEP), the Portuguese governmental trade & investment agency. [11]

the events: (1) when the MNCs came to Portugal, (2) when the MNCs sold the industrial plants to the Portuguese companies, and (3) from that period until the present. Alongside with the Portuguese economy, it was indispensable to understand the trends and shifts *within* the pharmaceutical industry, both in Portugal and on a worldwide basis. Secondly, an extensive research in the companies' websites, public journals and magazines was conducted in order to obtain information about its reasons and motivations to act the way they did. Since there is no systematic literature on this topic, the majority of the information used in this report is public, available in the aforementioned references. Finally, the support for the hypothesis generated to explain the movement of the companies was based on both the Industry analysis and company analysis. Some comparisons with other pharmaceutical companies were also done to support or reject the hypothesis generated. However, due to some information not being publicly available, some conclusions may be subject to further review.

5 Part 1: Why did the Multinational Companies leave Portugal?

Over the years we have witnessed the exit of important pharmaceutical MNC from Portugal; this is the case of Bayer and Janssen. The objective of this chapter is to understand the conditions under which these companies abandon Portugal, i.e. whether it was purely due to political and country-related events or conditions, or if it was due to a corporate strategy shift that led them to leave Portugal.

5.1 The case of Bayer Pharmaceuticals

The history of Bayer in our country started back in the IX century: in 1884, commercial agents from the German pharmaceutical started its the commercial activity in Portugal. Over the years, subsidiaries of Bayer were installed in Lisbon and other Portuguese cities, and the business evolved. It was only in 1972, through a greenfield [5;13] investment in Coimbra that

Bayer finished its plant facility – Centrofarma, which later changed its name to Bayer Portugal. [13] This move was in accordance with the Uppsala model, which states that the last stage of the internationalization process is the installation of a production facility. [5] The company had already some expertise and knowledge about the Portuguese secondary sector, which can be seen as a driver for their motivation: Bayer had already some production facilities in Portugal - anilines production integrated in the Chemist area of Bayer, which served the Portuguese textile industry; and it had some manufacturing plants to produce agriculture products, which served this sector. [13] Furthermore, during the late 70s and 80s, Portugal was economically preparing to enter the EEC, which was marked by the implementation of reforms to attract FDI to our country. The spread of faith of an improved country, alongside with a drop in export barriers to EEC countries, was also a motivation for Bayer to invest in Portugal. [6] The 60s, 70s and 80s were called the “Bayer’s golden years” in Portugal.² The German company achieved huge visibility and exposure in Portugal, which Bayer had never seen before. [13]

In 2001, Bayer’s Head Office in Germany announced a restructuring process – it would now operate under a three-branch approach: (1) Bayer Healthcare (which includes Pharmaceuticals), (2) Bayer CropScience (which includes all of the agricultural segments) and (3) Bayer MaterialScience (which includes all kinds of other materials. from automobile to electronics). In the words of Dr. Manfred Schneider, then Bayer’s CEO, “*The pharmaceuticals business is crucial to the performance of Bayer HealthCare. (...) We will therefore step up our restructuring program to improve efficiency and reduce costs, and adapt*

² Not only Bayer Healthcare, which included the Pharmaceuticals, but all the business areas.

our structures to temporarily diminished growth expectations". [14] Part of this restructuring program involved the closure of the Portuguese pharmaceutical plant.

By this time, the pharmaceutical industry was turning its attention to SMEs, specialized in production, to which they could outsource the manufacturing of some of their products (in a process called *out-licensing*), otherwise produced in Bayer's plant. [15; 16] This process reduces the risk of investing significant capital for highly specific manufacturing facilities, to produce a particular product, which sales and returns of which may not compensate the initial investment. [9]

Another hypothesis that can be discussed is the voluntary withdrawal of Lipobay®,³ the leading growth driver of Bayer's Pharmaceuticals business, which had a heavy impact in the company stock price and results in 2001. [14] Since this was an oral solid formulation (pills), and assuming⁴ that Centrofarma only produced solid formulations, the loss of one of the most representative drugs, could eventually generate a break in the plant's productivity. Besides that, in 2000, Bayer had expanded their solids plant in Bitterfeld, Germany, [14] which could hypothetically assure the production of the closed Portuguese plant. Or, in line with the former hypothesis, production could be outsourced to SMEs abovementioned.

Alongside with these company rationales, the FDI incentives provided by the Portuguese government to MNCs did not meet the expectations created by ICEP, when they listed the pharmaceutical industry as being one of the major drivers for the Portuguese development.

This lack of competitive incentives for MNCs linked with an intensification of regulatory

³ Cerivastatin (Lipobay®) was withdrawn from the market because of 52 deaths attributed to drug-related rhabdomyolysis that lead to kidney failure [17]

⁴ Assumption made by the analysis of BPh portfolio that mostly consists in oral solid formulations, and the BPh website that states it "only" produces oral solid formulations.

issues and quality standards demanded at this time, [6; 8] may justify the concentration of manufacturing in some regions in order to control and certify the standards demanded by the European Union (EU) and the European Medicine Agency (EMA), which obviously are highly cost demanding.

In this context, in 2001, after reading in the newspaper that Bayer was going to close their Portuguese plant, a group of four Portuguese entrepreneurs decided to buy Bayer's Portuguese plant and hence BPh was born. [18] This move will be further discussed in chapter 5.2.

5.2 The case of Janssen (Johnson & Johnson's Pharmaceuticals)

J&J entered the manufacturing business in Portugal more than a decade after Bayer constructed Centofarma. In 1988, Cilag (the then Pharmaceutical branch of J&J), bought the Portuguese pharmaceutical company Laboratórios Medicamenta, creating Cilag-Medicamenta.⁵ [19] Contrarily to the entry mode of Bayer, J&J decided to enter the Portuguese pharmaceutical market by acquiring an existing plant, manufacturer of pharmaceutical forms. The highly specialized labor in producing pharmaceutical forms already put in place by the previous company, was one of the drivers for their investment in Portugal. [5] By buying an active and certified pharmaceutical manufacturing plant, J&J was able to shorten the time-to-market, as quality and control directives were already assured and certified, and labor was of the most qualified in the market (but without college education), and it was available at "low-cost". [6]

Additionally, in 1988 Portugal had already been a member of the EEC for two years, which means that all the reforms to attract foreign capital were already in place together with the

⁵ In 1995 the Belgian Janssen merged with Cilag resulting in "Janssen-Cilag Pharmaceuticals". Later in 2010, Janssen-Cilag was rebranded as Janssen. [20]

export incentives. This movement goes along with what was happening in Portugal in this decade: it was also during this time that Portugal received the highest inflows of FDI in the manufacturing sector, contrarily to the service sector, which was what happened in other developed countries. [6] Following its purchase by J&J, the manufacturing plant continued its operational activity for 16 more years: in 2004, Janssen announced it would close its Portuguese plant, [21] just like Bayer had done 3 years before. The reasons behind this movement were (1) the fact that this manufacturing facility was prepared to produce small lots of a variety of pharmaceutical products, which no longer was the company's core business; and (2) J&J also reached to the conclusion that it would be cheaper to assure the production under an outsourcing regime than to assume all the costs of manufacturing. [21]

Janssen initially entered Portugal with the objective of producing "miniseries" or small lots of capsules, pills and syrups. All these products were produced by a specific order and in accordance with a chemical formulation developed by the company, answering small requests specific to some markets. However, the MNCs are abandoning this type of units, since they now needed to produce big lots, and carrying and financing these types of plants are not in their core business nor of interest to them, even because they are not going to produce to competitors. [21]

Furthermore, in 2003 and 2004 the pharmaceutical industry was starting to experience unprecedented pressures. [8; 22; 23] Particularly in Janssen's case, by 2005 it would lose the patent protection of a group of products that accounted for approximately 6% of revenues, [22] meaning they would be subjected to the generic sales hunt. However, another group of pharmaceutical products were approved in 2003 and 2004. These latter were formulations that could not be produced in Portugal, without a huge investment from J&J: its Portuguese plant

was equipped with state-of-the-art technology to produce oral solids, semi-solids and liquids,⁶ but new products waiting for approval were mainly intravenous, transdermal and other sterile formulations, [24] which were not aligned with this plant production capability. Plus, Centocor, the manufacturing facility Janssen already had in Cork, Ireland,⁷ was undergoing a restructuring and growth program to produce more and new pharmaceutical products. [24] Additionally, acknowledging that outsourcing some of the product manufacturing would create a competitive advantage by lowering the cost of production, *just like Bayer had done*, can also explain the closure of the Portuguese plant that only produced small lots of products, and not their core ones.

Furthermore, as previously referred in Bayer's case, the FDI incentives in Portugal did not meet the expectations created by ICEP, and the regulatory and political regimes in Portugal were starting to become unstable and unpredictable environments, [9] making Ireland a better and more secure bet to invest in production. [25] Moreover the concentration of control and certification rationale to only one plant in one country instead of more than one, can also justify their decision to transition to Ireland.

Hence, in 2004 after a negotiation period, Janssen Portugal's management team bought out the plant with 100% Portuguese capital, leading to the creation of LM. [21] As in the case of BPh. this step will be discussed in chapter 5.2.

⁶ Assumption made by analyzing the LM's portfolio and website, as it states LM only produce oral solid, semi-solid and liquid formulations.

⁷ Ireland is one of world's countries where most Pharmaceutical companies have manufacturing operations. The low tax burden and the quality of work force are pointed as the major drivers to invest in Ireland. In 2008 more the 50% of Ireland total exports were in the pharmaceutical field. [9; 25]

5.3 Discussion notes

After carefully analyzing these two cases, some similarities can be withdrawn. These may explain the exit of the MNC from Portugal – as one can see, a variety of factors contributed to the departure of these companies from Portugal, both company-specific and country-specific.

1. The first hypothesis concerns their motivation to operate in Portugal: they *both came to Portugal because they were attracted by the conditions delineated for the MNC operate in our country*, despite some specific motivations (Bayer already knew the Portuguese manufacturing sector from past experience, for example). This is a strong hypothesis because during the 80s there was a high influx of FDI into Portugal, especially in the manufacturing sector. [6]
2. The second hypothesis concerns one of the factors that made these companies leave Portugal: Over the years, the incentives provided by Portugal to MNC were not aligned with the expectations created by the ICEP. Plus, the technological sector was not the focus of the Portuguese government. [6] This created a *lack of incentives for the MNCs to operate in Portugal*. However, besides the abovementioned facts, the FDI in Portugal has been growing since 2000, registering an “increasing in industries and innovative activities and technological base turned for the international markets.” [26] As so, this hypothesis, *per se*, cannot explain their exit motivations.
3. Another hypothesis that may explain their exit is that *both companies underwent by a restructuring process, in which the products manufactured in the Portuguese plant were not their core business anymore*. Although for Janssen this was one of the reasons indicated for their disinvestment, [21] for Bayer it was not possible to confirm that they

changed their core business. It is, however, possible to say that both decisions had a strategic managerial rationale behind.

4. Finally, both *companies realized that the out-licensing, and manufacturing SMEs were becoming an important player in the Pharmaceutical field, to which they could outsource some of their production.* This was the other reason given by Janssen to abandon Portugal. [21] While for Bayer there isn't information regarding this topic, the fact is that SMEs have emerged in Europe (and the World) at a high rate, [10; 27] which highlights their importance.

6 Part 2: How successful are the newly formed Portuguese Pharmaceutical Companies?

From the analysis of the previous chapter, one could think that the disappointment of one company in one industry would determine the disaster of the other companies that would take their place. In addition, Portugal is the country of the EU that has the highest rate of firm failure. [28] However that wasn't the case for BPh and LM. Therefore, this chapter aims at highlight the factors that made (and make) them success cases in such turbulent times for both the industry and country in which they operate.

6.1 The case of Bluepharma

BPh was born after a group of four Portuguese entrepreneurs bought Bayer's Portuguese plant, in Coimbra, in 2001. [29] As Bayer was going to leave Portugal, Paulo Barradas, a Portuguese pharmacist, saw an opportunity to buy the state-of-the-art industrial facility. [18]

6.1.1 The opportunity: generics, contract manufacturing and out-licensing

6.1.1.1 The generic's Portuguese reality

By 2001, the pharmaceutical industry was already facing major challenges, with the loss of patent protection of blockbuster drugs at a higher rate than they could be replaced, with the increasingly demanding regulatory issues, resulting in higher production costs, and with the

generics gaining their space in the market. [8] However, for the latter, the reality in Portugal was quite different: in 2000 and 2001 the consumption of generic drugs was nearly null, [9] compared with other countries where generic sales were 30% of the total drug sales, [30] namely USA and Germany where this percentage was more than 50%. [18] Taking this into account, the generic market was one of the bets of BPh – through BPh Genéricos -, as in Portugal the reality was very different from what was seen in other countries.

6.1.1.2 Contract manufacturing and out-licensing activities

At the same time, and as said in the previous chapter, the Big Pharma companies were turning their attention to smaller companies specialized in production, to which they could outsource some of their product manufacturing. [8] In this light of this, Bayer was BPh's first client: Bayer contractually-agreed that it would continue to be BPh client for three years,⁸ giving BPh time and stability to position in the market, perform R&D processes needed to develop a drug's dossier (CTD format) and commercialize it (in an out-licensing perspective). [18] BPh's out-licensing offer relies on the opportunity generated by the loss of patent protection: since a many drugs were losing their patent protection, they could in-license those expired patent and produce the brand-name drugs in their plant and export them to other countries. Portugal, as a member of the EU, could export to most of the European countries with almost no barriers. In 2005, BPh began to sell other products aside from Bayer's: they started to sell a niche antiepileptic generic (through BPh Genéricos branch), which sold more than the original; they also sold 60M pills of a cold medicine to France (Through BPh Indústria branch); and also began the production of an antidepressant. [18]

⁸ This period was later increased to four years, because a three-year period was very short to conclude all the phases for developing a drug. [18]

6.1.2 Financial incentives

The incentives provided by Portugal (through ICEP) and the UE to SMEs and exporter companies were an important factor towards the decision to purchase Bayer's manufacturing plant – 30% of BPh was bought with capitals from “PME Capital”. [1] However the specific incentives provided for the pharmaceutical industry, only appeared in 2005: PharmaPortugal in Portugal, [12] and a special program developed by EMA to help SMEs. [31] BPh also participated in several projects from QREN (Quadro de Referência Estratégica Nacional), oriented to innovation and development, and through them it is now internationally recognized. [32] The pharmaceutical industry is one of the most capital intensive, and access to capital is one of the most important drivers to R&D and, consequently, to growth. [16] Although the typical financing system, through loans, could eventually initiate the kick-off of the company, in the first years the returns would not compensate the initial offer, alongside with a high repayment risk associated. As so, UE play an important role in this field, as they offer financial aid and incentives to the start of SMEs. [22]

Hence, with the help of European funds, from 2001 to 2005, BPh grew from an annual turnover of almost €3M to almost €7M (+57%; CAGR: 18.47%), [1] while the Portuguese market grew at a CAGR of 4.33%, from 2003 to 2005. [4] Although these are not the exact same periods it is visible the extensive growth of the company without the external help of PharmaPortugal. This growth was mainly accomplished by the R&D projects that the company submitted and the representativeness their exports activity.

6.1.3 The export activity as a key success factor

Like Hikma, a Jordanian pharmaceutical company, which has a production plant in Portugal, [34] BPh's management also attributes their success to exports and contract manufacturing.⁹ [35; 34; 36] An OECD report states that, "by 2010, sixteen pharmaceutical companies were exporting 81% of their production per year to over 60 countries, with high quality products and affordable pricing driving demand". [37] This description is very similar to that of BPh, which in 2010, had more than €16M in revenues, where €12M (73%) were due to exports. [38]

6.1.3.1 PharmaPortugal as a booster of internationalization

In 2003, without ever having benefited from integrated structured project in the "export" segment, the Portuguese pharmaceutical industry was already positioned at the same level to other sectors that were beneficiating from this support, namely in internationalization: Household textiles - €861M; Port win - €323M; Pharmaceuticals - €293M. [39] However, though pharmaceutical exports were having a significant weight in the sector, its growth rate was slowing its pace, going from 53% in '99-'00 to roughly 2% in '02-'03. [39] This was the rationale behind the PharmaPortugal project. PharmaPortugal¹⁰ as a partnership between AICEP, INFARMED and APIFARMA, "is the brand name that identifies national exporting pharmaceutical companies and their products and communicates an image of European quality to the world". [12] Integrated in this program, BPh could benefit from the incentives and aid and position itself in the international market as a quality and reliable medicine manufacturer. Inserted within this program, BPh saw its annual turnover grow from €7M in 2005 to €18M in 2011 (CAGR: 14.44%), [1] against a CAGR of 0.70% for the national

⁹ Interview available at <http://sicnoticias.sapo.pt/programas/successopt/2013/07/08/successo.pt-06-07-2013>

¹⁰ PharmaPortugal initiative was able to duplicate the exports of pharmaceuticals in just 10 years: in 2011 the value of exports hit the €528M in pharmaceutical products, almost the double than in 2001. [40]

pharmaceutical industry for 2005 to 2010. [4] In 2009 its exports accounted for 60% of production, [41] whereas in 2012 this number outperformed the 80%. It would be interesting to have systematic data regarding its exports from 2001 to 2005, but this data was not available in the public data sources. The year of 2009 was also an important year for BPh, as it got the FDA approval to develop and produce solid formulations, becoming the first Portuguese pharmaceutical certified to export to the USA. [29]

6.1.3.2 Drivers for innovation and expansion

6.1.3.2.1 Luzitin – the fruit of collaborations

Several articles refer that cooperation with other institutions will be one of the keys to success of Pharma companies, especially in what regards R&D processes. [7; 16] In fact, BPh has several collaborations and cooperation with other institutions. One of these collaborations with Universidade de Coimbra (and InovCapital capitals) originated a spin-off company: Luzitin. The Luzitins are proven to have antitumor activity in the Photodynamic Therapy field and clear advantages over the competitor products already on the market”. By now, the Luzitins are in clinical trials, and have strong perspectives of being in the market in 2015, turning BPh into the second Portuguese pharmaceutical company to successively launch a drug in the market.¹¹ [42]

6.1.3.2.2 Physical international expansion

BPh is going to begin the construction of a new plant in Columbia. Part of this strategic decision is based in the fact that in Latin America is legal to industrially produce the generic version of a brand-name drug *before* the patent expires, without yet commercializing the product. This enables the company with an edge to make a reservoir of generics before it can

¹¹ The first Portuguese pharmaceutical company was Bial when it launched Zebinix® (Aptiom® in the USA), an antiepileptic drug.

be commercialized, reducing the time-to-market. In the words of Paulo Barradas, “this project may represent 5 to 10% of total revenues which in 2012 was of €32.5M”. [43]

6.1.4 Bluepharma’s current position

Through BPh Industria, the segment responsible for the exports, the group grew 50% in 2012 against a 10% industry loss. [35; 44] Exports represent 82% of the company results, and its exports to more than 40 countries in Europe, USA, Africa, Australia, Middle East and Asia. [29; 32; 35] Additionally, since its exports business has such a significant and positive impact on its results, the company is able to finance the production costs without the recourse to bank loans. [35] The success of the company led them to be awarded with “PME Excelência” (Excellence SME) for both 2011 and 2012, by IAPMEI; BPh also won the INSEAD Entrepreneurship 2011/2012 award, among other recognitions displayed in BPh’s website. [29]

6.2 The case of Lusomedicamenta

LM was born after the old Janssen-Cilag management team purchased the plant left by the American company in 2004. All the workers kept their job, with a little twist: they were going to produce drugs to other companies beside Janssen (which contractually agreed to be LM’s client for five years. just like in BPh and Bayer’s case. Janssen represented 55% of LM orders in 2005). [21] As also seen for the previous case, the fact that the former remained LM’s client for five years gave the Portuguese company a stable source of income and time to prepare its international expansion. Janssen perpetuated this agreement with LM in 2012: they both signed a significant contract for an annual production of 200M pills until 2016. [45]

6.2.1 The opportunity: contract manufacturing and out-licensing

As seen in the previous case, there was an important acknowledgement by the Big Pharmas regarding the crucial role of SMEs for the success of this Big companies; this also created an opportunity for LM.

6.2.1.1 Not pursuing the generic's Portuguese market

In 2005, the generic consumption in Portugal was starting to rise: the Government was creating incentives to increase the generic consumption in a way to decrease the Healthcare expenditures, in what regards the drug consumption. [9; 46]

As so, with the rapid intensification of the generic market in Portugal, LM decided not to pursue this practice. This might have been a strategic move, as it could immediately start to chase the international market and the international players, almost entirely dedicating to exports. Plus, the generic companies in Portugal, as BPh, have to be extremely competitive in terms of pricing and market position, as small country like Portugal with just 10M habitants and a GDP *per capita* of €15,702.2 in 2012, [47] the domestic consumption, alongside with the intense competition, cannot hold up a company in the domestic market.

6.2.1.2 Contract manufacturing and out-licensing activities

In 2005, just one-year after the creation of LM, it had production agreements with more than 150 brands in a total of 850 references, with the projection of producing more than 30M pillboxes,¹² [21] which contrasts with Medinfar,¹³ another Portuguese pharmaceutical company that produces 12M units (in 2013) in its Farmalabor facility.¹⁴ [48] Exports accounted for 45% of the total produced by for 47 countries to which the plant is certified: Spain, France,

¹² With capacity to increase up to 40M units per year. [19]

¹³ Medinfar Group is a Portuguese Pharmaceutical company that is in the Market since 1970. In 2000 it opened a subsidiary in Morocco to keep-up with international demand and expansion. [48] Medinfar is present in a variety of businesses, from Consumer Health, Biotechnology, Generics, Medical Devices, among others. In 2006 it had a global sales volume of €61M. [49] In 2011, this volume increased to €67M (+0.10%), where €3M represented exports. [45]

¹⁴ However there is room to increase the capacity to 40M units per year. [48]

UK and Germany are the top destinations, but the company is also producing to Middle East, Canada and Brazil. LM not only dedicates to exports, but also to in-licensing products to sell in Portugal. The portfolio comprises all the pharmaceutical forms that the company produces, from solids and semi-solids to liquids. However, though it has a large portfolio regarding this practice, it represents only 35% of its business. [19; 46]

6.2.2 Financial incentives

Just like BPh, LM leveraged from the incentives provided by the Government, including the aid for PharmaPortugal right from the start. From 2005 to 2010 LM grew in an average growth rate of 11%, [3] whereas the Portuguese drug sales grew by an average of 4% in the same period of time; [4] in 2010, its sales volume grew to €50M – outperforming its initial expectations -,¹⁵ where 75% represented exports; [50] the Portuguese market, in contrast, suffered from a break of 2.5% between 2009 and 2010. [4] Hence, the aforementioned numbers clearly show how LM was able to outperform the Portuguese market.

6.2.2.1 Drivers for innovation and expansion

6.2.2.1.1 Focus in a niche market

LM produces solids, semi-solids and liquids, and have in its portfolio Pharma giants like Novartis or Bayer. [19] The Bayer's case is an interesting one, as it is also a client of BPh, as seen in the previous chapter. While one can argue that LM puts in place competitive prices that put BPh in a delicate position, it is more likely that LM produces the pharmaceutical forms that are not available in the BPh plant, such as semi-solids and liquids.

In R&D companies the more specialized the company is in a particular disease or therapeutic category, the more likely it is to have success by leveraging in its expertise. [7; 9; 16] As so, it

¹⁵ In 2009 LM bought the Seber manufacturing facilities in Póvoa de Santo Adrião. With this move LM was expecting to grow 25% from €32M to €40M sales in 2010. [50]

decided to specialize in one pharmaceutical form: effervescent pill. Specializing in niche products makes them an important and competitive player in the markets, and a reference in that type of formulation, which can help them to sustain its position. [16] Hikma also attributes part of its success by strategically concentrating one of its operations in a niche product: the cephalosporins – an anti-infective drug with similar uses to penicillins. This product accounted for 20% of sales in 1990 and 46% in 1996. [34] It would be interesting to have data to analyze and compare the companies' market position for its niche product, but unfortunately there is no public data available regarding this topic.

Just like BPh. another factor that makes this company so successful is the partnerships established by LM. These partnerships enable them to reach the latest technology and the most modern R&D processes. [16; 19]

6.2.3 Lusomedicamenta's current position

In 2010 its revenues were of €50M of which 75% were exports. [51] In 2012, 65% of the company production is exported, against a 10% exports for the Medinfar Group [48] -, to more than 40 countries in the five continents. [19] It is interesting to analyze that the exports representativeness drop by 10% in 2 years. This may be due of an intensification of the SMEs all over Europe, [10] or due to the lack of accurate data, as one of the references regards an interview for a Portuguese newspaper and the other one regards the company website. Either way, in both cases exports represent the largest bulk of revenues.

6.3 Discussion notes and main conclusions

From the previous analysis, the two aforementioned cases outline a set of four interesting conclusions:

1. The implementation of their initial operation was largely due to the *community incentives provided by the Portuguese government and EU*. These funds allowed the companies to access capital needed to fund its R&D activities. Although not specific to the pharmaceutical industry, it may have a key role due to the intense capital requirements characteristics of this industry. As so, community funds may be said to be an important driver for the initial growth, but not the critical one. If this was decisional, all SMEs would have the “same” success, which is not the case. [28]
2. Either in BPh or in LM case, its former companies, respectively *Bayer and Janssen, agreed to be its clients*, permitting the companies to establish in the market – national and international, by allowing the companies to have access to stable income during the kick-off stage. Together with conclusion 2, this may have been the key and differentiated factor for its successful implementation.
3. Also, in both cases, the key success is the *exporting activity*. By acknowledging that Portugal was a small country with little capacity for domestic expansion and consolidation, both companies turned its eyes to foreign markets. Besides, its expertise in the business allowed them to understand possible outcomes of production partnerships with Big Pharma companies. However, the domestic market, including the generics, plays an important role in both companies revenues. However, in Medinfar’s case the exports activity only have a 10% representation in its €64M revenues in 2012. [48] As so, other areas aside from exports may become also important in these companies business models.
4. Price pressures and political instability felt in Portugal in the latest years had little effect in these companies, due to the weight of its export activity. [35; 50] Nevertheless,

there are reasons to believe that if this pressure assumes tighter contours, the domestic activity may become unsustainable to these, and other, companies. [48]

7 Part 3: What will be the future for the Portuguese Pharmaceutical Companies?

In the previous chapters it was shown how the *failure* of one company can become the fortune of another, through the success cases of BPh and LM. Nevertheless, given the “fast-change” and reinvention nature of this industry, it is important to look upon the future of these companies. As so, the objective of this chapter is to assess the three major future trends, and how these companies can or should adapt to them.

7.1 Price pressures and tighter regulatory policies will continue

Price pressures and regulatory policies are topics that were present throughout this report, as being two of the biggest drivers to companies lower margins and the need for restructuring: with higher costs, the price pressures reflect lower margins and, thus, lower profits. [52] The Portuguese government announced that the drug prices would decrease, again, in 2014 [53] However, after further consideration, decided to maintain the price for the generic drugs. [54] This continuous price instability already led Bial to delay the production of a new drug developed by this company, for at least two years. [55] Although there isn't much that companies can do to run from these reforms, should continue to explore international markets rather than the domestic market. The higher the prone towards exports and diversification, the more likely are to overcome this domestic instability.

7.2 Emergence of manufacturing SMEs – the rise of the competition

The importance of SMEs as drivers to innovation for the pharmaceutical industry is starting to show some results. As said in previous chapters, the number of companies registered as SMEs with EMA increased 62% from 2011 to 2012. [10] The Indian pharmaceutical industry is estimated to have 9.456 units in the SME, which account for around 87% in production by

volume. [27] Although these numbers clearly show the acknowledgment of these companies, it also shows that competition is fiercely arising. As so, to protect themselves, companies should specialize in niche products and markets in order to leverage from its expertise.

7.3 Emergent economies

Emerging markets offer the biggest growth opportunities for the pharmaceutical industry, once its market share is set to rise to almost 40% by 2016, although with smaller margin. [81] BPh and LM are already exporting to emergent markets, like Venezuela and Columbia. Another country in which BPh and LM should focus is the Angolan, where the drug market is one of their strategic focus. [56]

8 Conclusion

The objective of this report was to clearly highlight the key success factors that make BPh and LM two admired companies, born after an apparent failure from two MNC. The major driver of its success has to be attributed to the exports of its products. However, due to lack of systematic information some additional information would be needed to better support some affirmations..

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