Chapter 6
Pharmaceutical Industry and R&D in Puerto Rico

In today's advanced technological and competitive era, where globalization takes place, multinational companies expand their competitive advantages to use research and development (R&D). Each market needs to develop new technologies, products, services and processes to face up the economic challenges. The pursuit of competitiveness has led multinational enterprises to develop new strategies to inquire into the key factor for differentiation, using new R&D processes. This chapter discusses R&D and the development of the pharmaceutical industry in Puerto Rico.

R&D and Pharmaceuticals

The pharmaceutical companies are part of the group of multinational companies, which have gained competitive advantages to developing new products and processes to optimize its product portfolio. The R&D process has been one of the mechanisms used to enter in new markets and develop innovative processes. This is also relevant to biotechnology.

The concept of R&D has been used in a large number of investigations as a measure of innovative activity of multinationals. However, there may be discrepancies in the results mainly due to the difficulty in measuring innovation activity. One of the most popular ways to measure innovation is using companies' spending on R&D. Spending on R&D in the pharmaceutical belonging to the Pharmaceutical Research and Manufacturers of America (PHRMA) accounted for about $48.5 billion in 2012 (PIE 2013). This indicates to the importance and growth of R&D activities in the pharmaceutical industry (see Table 6.1).

The chapter is derived from a dissertation done by Dr. Torres-Morales (2013) and other presentations and works realized by INDUNIV Consortium (2013) and PIE (2013).

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Table 6.1 R&D spending by PHRMA members

Year	US$ billions
2012	48.5
2011	48.6
2010	50.7
2009	46.4
2008	47.4
2007	47.9
2006	43.4
2005	39.9
2000	26.0
1990	8.4
1980	2.0

Source: Adapted from the presentation of the Pharmaceutical Industry Executives at the Annual Meeting of the Puerto Rico Economist Association, August 30, 2013

R&D represents a very heavy economic burden for companies seeking to innovate. To stay competitive in the industry, pharmaceuticals need to keep their growing product portfolio, so that when patents expire main drugs can substitute with other drugs approved. As such the pharmaceutical industry is highly regulated and with extensive and expensive R&D process, pharmaceuticals constantly need to innovate. The innovation process is carried out in different countries and varies according to the companies. The R&D centers in the pharmaceutical industry are mostly in the United States, but many have a presence in European and Asian countries. This movement has been both establishing R&D centers and manufacturing relocation to countries where they have these research centers (see Table 6.2).

Because of its great intensity in R&D, the pharmaceutical industry has been one of the research topics of economists. This has been examined from different research approaches, including pricing strategy, the intensity of competition, economies of scale, economies of scope, and innovation activity. In recent years it has been part of the new economy in the global arena. Not only have developed new drugs, used in many cases large budgets for R&D, otherwise pharmaceuticals have established research and manufacturing in various parts of the world, such as India, China, Singapore and Ireland, among other countries that perceived as fully developed for these purposes. However, the economic development of these countries has led to major pharmaceutical companies to establish and develop new facilities with large investments, giving a boost to the local economy of each country, especially with the establishment of new centers of biotechnology.

However, many countries have been adversely affected by these new R&D centers, due to the closure of operations within their borders and re-establishments in other locations. Among these countries is Puerto Rico. In recent years, several pharmaceutical operations have ceased. For example GlaxoSmithKline and Wyeth no longer have a presence on the Island, and in 2009, Pfizer acquired Wyeth in a

Table 6.2 Countries with R&D center of companies with some operations in Puerto Rico

Pharmaceuticals	Countries with R&D centers
Pfizer	USA, UK
GlaxoSmithKline	US, France, Spain, Italy, Croatia, China, UK
Sanofi-Aventis	US, Canada, France, Germany, Hungry, Japan, UK, Italy, Spain
Novartis	USA, Switzerland, Italia, China, Japan, Indonesia, Singapore, India, UK
AstraZeneca	USA, Canada, France, Sweden, Japan, India, UK
Johnson & Johnson	USA, Spain, France, Belgium Switzerland, China, India, UK
Merck	USA, Canada, Italia, France, Japan, UK
Roche	USA, Canada, Austria, Germany, Switzerland, Japan, China, UK, Australia
Eli Lilly	USA, Canada, Spain, Japan, China, UK, Australia, Singapore
Wyeth[a]	USA, Ireland, Japan, China, Africa, Australia
Abbott	USA, Germany, Japan, China, Singapore
Bristol-Myers Squibb	USA, France, Belgium, UK
Schering-Plough[b]	USA, Scotland, Germany, France, Japan

[a]In 2009 merged with Pfizer
[b]In 2009 merged with Merck

transaction of $68 billion, and has recently closed some of its plants. Other pharmaceutical as Abbott, Amcor, Boston Scientific, Ivax Pharmaceuticals, Ortho Pharmaceuticals and Patheon announced relocations during the period from 2005 to 2012. Other personnel have decreased considerably. These changes have had different effects on the industry and the economy of Puerto Rico.

In many cases, pharmaceutical companies have withdrawn from Puerto Rico for lack of successful competitive strategies, loss of patents, the fierce competition of bio-equivalent, lack of approval from the US Food and Drug Administration (FDA) of new products and the high costs of R&D. Furthermore, loss of the benefits of Section 936 the emergence of global, such as more regulatory controls less success rate in bringing treatments to market and increases in production costs will be added pressures. Each of these problems has worsened over the years, and has pushed the pharmaceutical industry to find new strategies for the development and maintenance of their products (Custodio 2010).

Employment and Economic Activity in the Pharmaceutical Industry of Puerto Rico

The pharmaceutical industry in Puerto Rico has been one of the fastest growing industries in the past four decades. Traditionally, this industry is one that has contributed most to exports and employment to manufacturing industry in Puerto Rico. For the period 2006–2012, the industry contributed between 20 and 25 % of jobs in

the manufacturing sector.[1] In 2006 the pharmaceutical industry even claimed around 30,000 direct jobs in Puerto Rico, representing 26 % of total manufacturing jobs. It also represented 26.5 % of GDP in Puerto Rico and generated 60 % of total exports of the Island.

In Puerto Rico, 20 world leading pharmaceuticals are established and manufacture 16 of the top 20 drugs of the US market. The pharmaceutical industry in Puerto Rico has concentrated on the manufacture of pharmaceuticals, biotechnology and medical devices. The pharmaceutical industry has maintained four competitive industries on the Island including medicinal and botanical products; pharmaceutical preparations; surgical and medical instruments; and electronic components for medical use.

Pharmaceutical companies operating in Puerto Rico have centers of R&D for new products outside the Island. Subsidiaries located on the Island are mostly extensions of manufacturing operations, where a variety of products distributed locally in the US and foreign markets. Furthermore, activities in the pharmaceutical sector generates about 68,000 indirect jobs and promote jobs in the rest of the economy, such as professional organizations, various services including jobs are in banking, engineering, insurance, transportation and communication (PIA 2011).

However, the industry has shown an important reduction in job creation. The decrease in the number of jobs in the manufacture of pharmaceutical products in recent years has been evident; by 2005 the number of jobs in the pharmaceutical industry stood at 28,200 jobs and by 2012 had 16,700 jobs, which represents a decrease of about 11,500 jobs over a period of 7 years (Planning Board 2012).

Despite the reduction of jobs in industry, pharmaceutical exports continue to represent a large portion of total exports of Puerto Rico. In 2012, exports of pharmaceutical products accounted for 69 % of total exports (see Fig. 6.1) and 28 % of GDP. Also, to contributed about 34 % of jobs in the manufacturing sector. A greatest in economic sectors multiplier effect on job creation of 3.3 is estimated. Similarly, it is estimated that 79 % of revenues of the Treasury of Puerto Rico comes from taxes paid by the industry (INDUNIV 2013).

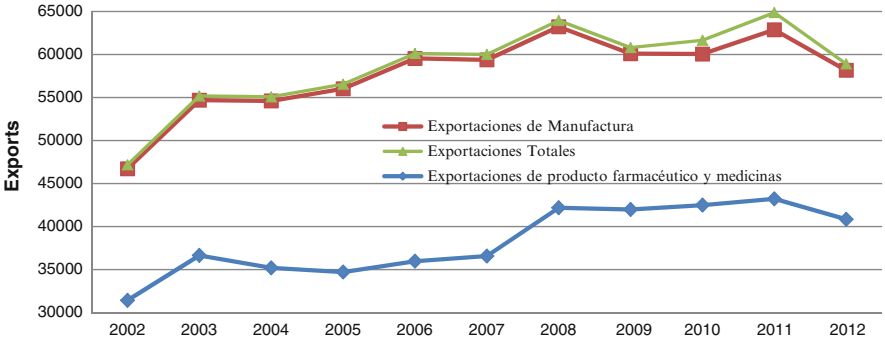

Fig. 6.1 Puerto Rico exports during 2002–2012

[1] Planning Board of Puerto Rico (2012).

R&D and the Pharmaceutical Industry in Puerto Rico

It is noted that the efforts of the Government of Puerto Rico to strengthen value-added activities in the biotechnology sector is one devoid of guarantees for the pharmaceutical long term activity on the Island due to an erosion of the global market. It argues that the Island faces the threat of development and manufacturing of medicines in low-cost jurisdictions such as India and China. It also faces the loss of competitiveness in the R&D sector in countries like Ireland and Singapore. Furthermore, changes in tax incentives at the local level have also weakened the mood of industry for economic activity in Puerto Rico. Considering adverse aspects, the financial crisis of local government is also added. This situation is added to other events such as the maturity of the exemptions provided by Section 936 in 2006 and the increasing of labor costs (Business Monitor International 2006; Morales et al. 2012).

As presented by the Pharmaceutical Industry Executives some of the considerations for establishing both pharmaceutical operations and R&D include the following factors: the transaction costs, the economy, infrastructure, human resource, quality of life, technology, enabling environment for trade, education, cost of living and access to capital (PIE 2013). When analyzing the economic indicators of the countries with high establishment of the pharmaceutical R&D, these countries offer incentives and have a number of economic advantages over Puerto Rico; they have competitive advantages to multinationals for R&D center establishment. The economic indicators show how these countries are developing positively, with low unemployment rates and positive growth of GDP. Similarly, educational indicators can be used as a measure or important for the establishment of R&D centers factor. Higher education plays a key role in innovation, important part of R&D. Also, the location of the best universities in the world matches the host countries of R&D centers.

Puerto Rico despite having a pharmaceutical presence of many years in as manufacturing operations has not been fully developed in R&D. In Puerto Rico, basic research that do not generate patents are held. However, currently only has a limited amount of R&D centers, 12 in total (see Fig. 6.2). Of these, seven centers were established as a result of R&D incentives granted by Law 73 of 2008 (i.e. Law on Economic Incentives for Economic Development of Puerto Rico).

Also, some universities have limited investment in R&D funds. In addition, several companies are developing biotechnology activities on the Island (see Table 6.3). However, the lack of data on economic indicators and the R&D activities on the Puerto Rico do not help to promote the importance of R&D in the economy.

To compete in the new global economy and to compete with countries like Singapore, Malaysia, Ireland, Finland, India and Indonesia, it is recommended to direct efforts to promote and develop a knowledge-based economy. Puerto Rico has begun to develop initiatives in the development of knowledge. As part of the efforts that have been developed are partnerships with universities, academic programs in biotechnology and the collection of data on R&D in Puerto Rico by the Statistical Office of Puerto Rico.

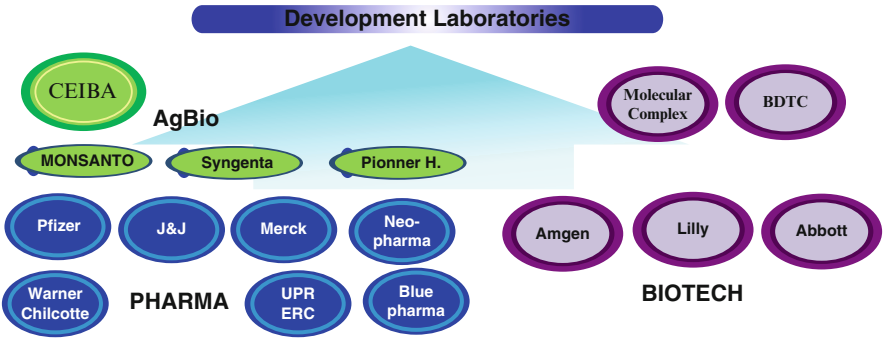

Fig. 6.2 R&D centers in Puerto Rico. *Source*: Adapted from the presentation The Life Science Industry, INDUNIV Research Consortium, 2013

Table 6.3 Bio-pharmaceuticals operation in Puerto Rico

Abbott Pharma operations/Barceloneta	J&J/McNeil Healthcare LLC: Las Piedras
AbbVie/Barceloneta	J&J/Ortho Biologics—Manatí
AbbVie/Jayuya	J&J/Ortho Pharmaceuticals—Manatí
Amgen/Juncos	Merck Sharp & Dohme/Arecibo
AstraZeneca/Canóvanas	Merck Sharp & Dohme/Barceloneta
Bristol Myers Squibb/Humacao	Merck Sharp & Dohme/Las Piedras
Bristol Myers Squibb/Manatí	Novartis Ex-Lax/Humacao
Eli Lilly del Caribe/Carolina	Pfizer/Barceloneta
Eli Lilly del Caribe/Guayama	Pfizer/Vega Baja
Eli Lilly del Caribe Biotechnology/Carolina	Pfizer Consumer (Wyeth)/Guayama
J&J/Ethicon LLC—San Lorenzo	Warner Chilcott/Fajardo
J&J/Janssen Ortho LLC—Gurabo	Warner Chilcott/Manatí
J&J/Lifescan Products—Aguadilla	

Source: Adapted from the presentation of the Pharmaceutical Industry Executives at the Annual Meeting of the Puerto Rico Economist Association, August 30, 2013

The partnership between the University of Puerto Rico and the MD Anderson Cancer Center (located in Texas and known for its comprehensive center dedicated exclusively to the treatment, research, education and prevention of cancer), for purposes of research and treatment of the Hispanic population is such example. Puerto Rico participation in R&D is limited and disadvantage over other competitors, yet efforts increase. It is starting to generate an infrastructure aimed at the knowledge economy and is expected to innovation activity in the Island increase in the years to come (see Fig. 6.3).

The pharmaceutical industry in Puerto Rico is an important and integral part of the economy and if a significant reduction of it is occurred, the results would be unfavorable for the whole economy of Puerto Rico. Among the negative effects are the unemployment rate would rise and GDP is significantly reduced.

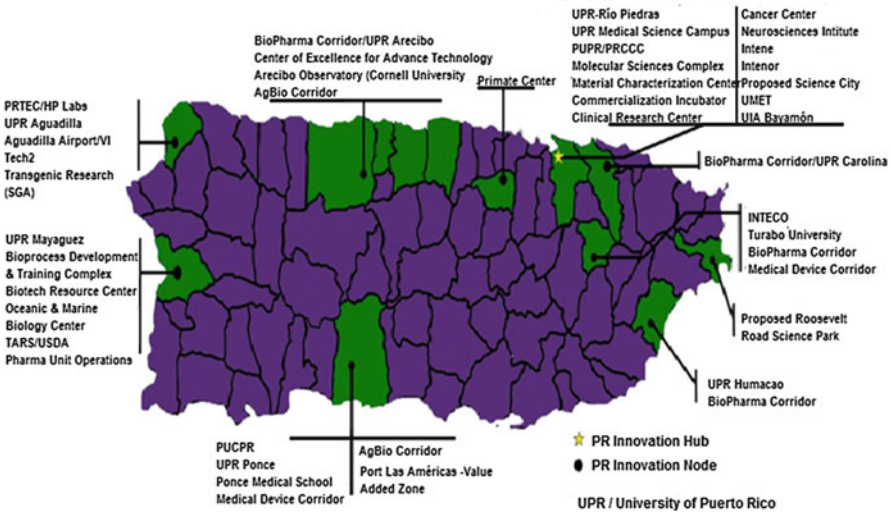

Fig. 6.3 Puerto Rico innovation center map. *Source*: Adapted from the presentation The Life Science Industry, INDUNIV Research Consortium, 2013

The competitiveness of Puerto Rico is declining. Possible factors for the loss of competitiveness include the political uncertainty in Puerto Rico, high energy costs and lack of partners in scientific research. These factors lead to a difficult Puerto Rico when attracting new projects for the manufacture of products (Guillen 2009) situation.

The Island still has the presence in pharmaceutical manufacturing of the best in the world and produces a large amount of drugs with overall higher market sales. Moreover, in recent years have prompted efforts to maintain the presence of existing companies and develop new areas such as biotechnology and R&D. But Puerto Rico is not the only country to develop these efforts. Countries like Taiwan, Malaysia and Singapore have aimed their efforts to develop biotechnology. Aspects such as a strategic location to develop pharmaceutical and biotechnology industries contribute to the positioning of competing countries like Ireland and Singapore. Also, the economic incentives that these two countries offer may be similar to those of Puerto Rico.

Despite the disrupted of Section 936, Puerto Rico still has a skilled workforce, a work tradition focused on quality, infrastructure facilities and high-level communication. Industry executives indicated that they still observe a level of competitiveness that can be aimed to the development of specific sectors in the industry, so the refocus of the pharmaceutical industry in Puerto Rico is proposed, one directed to the manufacture of generic drugs.

The generics market represents an area of growth and opportunity for Puerto Rico. Generic drugs accounted for 80 % of the global market for 2012, and it is projected to continue to grow (see Fig. 6.4). It is noted that the Island still has some strengths that contribute significantly to competitiveness and make it attractive to

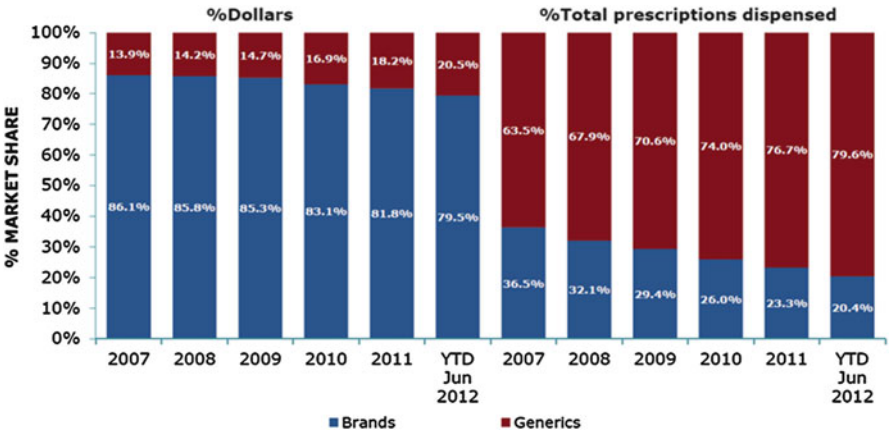

Fig. 6.4 Market growth of generics. *Source*: IMS Health, National Sales Perspectives, June 2012, National Prescription Audit, June 2012, disaggregated Branded generics. Presented by the PIE at the Annual Meeting of the Puerto Rico Economists Association on August 30, 2013

develop a generic industry (PIE 2013). These strengths are listed as: high technical knowledge, acuity and managerial experience, plants (infrastructure) available, diversity of human resources, lots of universities and technical colleges, some centers of R&D existing infrastructure for water, electricity and communications, location and logistics system, and the new Investment Act (PIE 2013). Furthermore, a high expertise arises in the process of quality control that leads to Puerto Rico in compliance with FDA regulations over other competing countries, especially India and China face.

On other hand, some weakness are identified that include poor education of English language and mathematics, poor entrepreneurship, deficiencies in the use of tools and improvement processes, the lack of a development of long term plan and agility to issued licenses and permits (PIE 2013). But business groups in the pharmaceutical industry; betting convert Puerto Rico in generic drugs manufacturing center.

Conclusions

Puerto Rico faces the decline of the manufacturing sector and its main industry branch, the pharmaceutical industry. The loss of competitiveness and macroeconomic factors contribute to this situation. This raises the need for assertive strategies to address the negative implications for the economy, such as reducing jobs and GDP.

It is necessary not only to establish strategies for the retention of established pharmaceutical plants, but also completely re-focus the development strategy and industrial promotion. Apparently the address could be more feasible in this new strategy is based on developing a generic manufacturing, in which the business

community itself has identified some competitive advantages for Puerto Rico compared to those competitors and emerging countries, particularly Ireland, Singapore and Malaysia.

It is also important to increase the activity of R&D on the Island. Although formulated initiatives in order to promote the establishment of centers of R&D and the creation of new knowledge, they may not be enough, so it is necessary to evaluate and redirect these measures.