

Estrategias de innovación de las empresas farmacéuticas mexicanas

Innovation strategies of Mexican pharmaceutical firms

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Abstract

Mexican pharmaceutical market is the most important in Latin America and a significant number of global firms have different business activities in this country: production, licensing of patents, alliances with Mexican firms, distribution facilities or partnerships, etc. In terms of innovation, global pharmaceutical industry has passed through structural changes mainly of technological and institutional nature. These changes have been influential along the whole value chain and have triggered transformations in firm's organization, market structure and sector's investments. Mexico's industry, in spite of having a very attractive domestic market, has serious limitations for technology development. Very little resources are invested in R&D and lack of articulation between research labs and industry provoke that Mexico has only exceptional innovation achievements and a high technological dependence. At the same time, some Mexican companies have developed new strategies to be competitive in open markets and have shown that a combination of competitive intelligence, rapid adoption of technologies, collaboration with advanced firms and research institutes, permanent training and continuous improvement are key factors for success. This paper deals with the results of a piece of research aimed at developing a model for the effective transfer of technology for Mexican pharmaceutical firms, with a strong component of knowledge and skills to manage the flows of information, people and technologies among firms, research labs, universities and other health organizations.

Keywords: Pharmaceutical industry; Mexico; innovation strategies; technology

1 Pharmaceutical industry in Mexico

Pharmaceutical industry's value chain is integrated by labs dedicated to R&D, production of active compounds and drugs; distributors; and drugstores and other final sale outlets. Globally, this is a highly regulated sector.

In 2005, value of world's production of pharmaceuticals was U\$602 billion, having had a growth rate of 94% between 1998 and 2005. IMS Health reported in 2009 that the value of the global pharmaceutical market in 2010 is expected to grow 4 - 6 percent on a constant-dollar basis, exceeding \$825 billion, driven by stronger near-term growth in the U.S. market. The forecast, the leading annual industry indicator of market dynamics, predicts global pharmaceutical market sales to grow at a 4 - 7 percent compound annual growth rate through 2013, and takes into account the impact of the global macroeconomy, the changing mix of innovative and mature products, and the rising influence of healthcare access and funding on market demand. Global pharmaceutical market value is expected to expand to \$975+ billion by 2013. The main producing countries are USA (32%), Japan (9%), Germany (4%) and France (4%). Latin American market represents almost 4% and reached over U\$34 billion in 2008, and the main producing countries are Mexico (28.4%) and Brazil (36%). This shows clearly that Mexican market has been one of the most important in Latin America and a significant number of global firms have different business activities in this country: production, licensing of patents, alliances with Mexican firms, distribution facilities or partnerships, etc.

In Mexico, market is shared by three groups: innovators with high investment in R&D that is mainly conducted in the country of origin; manufacturers of generics identified by their

brand with a moderate investment in R&D; and manufacturers and distributors of so called "similar" with very little investment in R&D.

In terms of innovation, global pharmaceutical industry has passed through structural changes mainly of technological and institutional nature. These changes have been influential along the whole value chain and have triggered transformations in firm's organization, market structure and sector's investments. Concurrently, strengthening of IP protection in most countries (mainly as consequence of the standards imposed by WTO's TRIPs Agreement) has led to increasing opening of markets and flow of investment and technologies. Therefore this industry can be considered a system or network of innovative activities to support the development, production and marketing of medicines. Many different actors participate in this network: different types of companies, research organizations, universities, consultants, regulatory authorities, governments, health systems (public and private), health professionals, consumers, etc.

In 2009, Mexican market reached U\$9,542 million and is integrated by two well defined segments: the so called "institutional" related to public sector procurement of drugs that demands generics and low-cost products; and the private characterized by the demand of innovative products with higher value added and protected by trade marks. The latter is the most dynamic.

Mexico's industry, in spite of having a very attractive domestic market, has serious limitations for technology development. Very little resources are invested in R&D and lack of articulation between research labs and industry provoke that Mexico has only exceptional innovation achievements and a high technological dependence. Only a few companies conduct R&D and clinical research. Foreign multinational firms normally rely on external inputs of technology and just a few of them involve themselves in development. This limits capacity building and the spillover effect of the operation of such firms.

There are currently 224 pharmaceutical labs belonging to 200 firms, 46 are subsidiaries of leading multinational groups. Ten multinational firms have control of the market (Expansión, 2006). In terms of geographical distribution, pharmaceutical industry is highly concentrated in Mexico City, the state of Mexico and Jalisco.

This industry is one of the most attractive in terms of earnings and growth, and according to KPMG (2006) it has a growth rate of 8%, one of the highest of Mexican industry. Pharmaceutical market represents 2.7% of manufacturing GDP.

2. Innovation in the pharmaceutical industry.

In terms of the science base of this industry, it can be said that we witness the era of molecular biology and genomics, as well as the improvement of business processes to contain costs. These new drivers of innovation impose new challenges to manage discovery, development, learning and operations. Innovation requires new capabilities and skills that need to be developed in a rapid way. Accelerating innovation demands intensification of collaboration among the different actors through different effective mechanisms. It is now clear that competitiveness depends on the efficient access to knowledge which in turn depends on firm's ability to build and use collaborative networks and technology market.

Markets show an over-supply of "me-too" launches which makes it difficult to generate sustainable revenues. According to Gassman et al. (2008), "the most sustainable approach to create value in pharmaceutical innovation seems to be very simple: offer a drug with a superior clinical profile compared to competitors' drugs".

The big question is how to achieve this objective and a greater challenge is to do it with limited resources. Some Mexican companies have developed new strategies to be competitive in open markets and have shown that a combination of competitive intelligence, rapid adoption of technologies, collaboration with advanced firms and

research institutes, permanent training and continuous improvement are key factors for success. Most of these firms are following a differentiation strategy based on the generation of so called “super-generics” through sound technological collaboration networks.

This paper deals with the results of a piece of research aimed at developing a model for the effective transfer of technology for pharmaceutical firms in the state of Mexico, with a strong component of knowledge and skills to manage the flows of information, people and technologies among firms, research labs, universities and other health organizations.

The main question is how to capitalize lessons from successful Mexican firms to build a useful technology management base to strengthen competitive capabilities of Mexican industry.

3. Methodology

In order to assess technology management in pharmaceutical firms, we developed a questionnaire with a systemic approach. Five sections are included reflecting fundamental processes determining firm’s performance (see Table 1).

Questions are then oriented to offer the base for an integral analysis. Metrics to evaluate variables is based on nominal, ordinal and continuous scales, with the goal of having greater precision when running a statistical analysis. The diagnostic tool is then integrated by the questionnaire, an Excel-based program for processing information and a data base. Questionnaires were applied interviewing directors and senior managers of firms which offered additional qualitative information for the analysis.

Tabla 1. Organizations as sustainable systems: functions and fundamental processes.

Manufacturing firms	
• Direction and policies	
	Planning Markets Profitability
• Intelligence, foresight and innovation	
	Competitive technological intelligence and sources of information Interorganizational collaboration Innovating activities and impact of innovation Training
• Management and control	
	Financial management and use of policy incentives for innovation Technology management Intellectual capital and intangible-asset generation
• Coordination	
	Information technologies Organization
• Operation management	
	Logistics and operations Quality management Marketing

Sample characteristics.

There are 52 pharmaceutical firms operating in the state of Mexico (Cambiotec, 2010). The size of the sample (13 firms) leads to a rather high confidence interval (23.8%) but such interval could only be reduced when covering the universe of firms, but that was impossible because many of them refused to answer the questionnaire. Analysis was conducted using indexes and profiles of organizations, descriptive statistics and qualitative analysis. Indexes were built using weighted average of variables to measure firm's performance in each of the processes integrating the organizational functions as well as a general score. This allows a graphic representation of firm's diagnosis and benchmarking it before the other firms in the sample.

It is important to consider that these scores indicate trends and do not represent absolute values, because we had to normalize data responding to the dispersion of the answers in the sample. Results are then a good approach to the actual situation of pharmaceutical firms in the state of Mexico. It is also important to mention that firms in the sample were reluctant to provide some information (remarkably financial data) and that provoked that some data were missing, which affected global results for some variables. For that reason, to enhance the quality of the analysis, 25% truncated median values were used (an

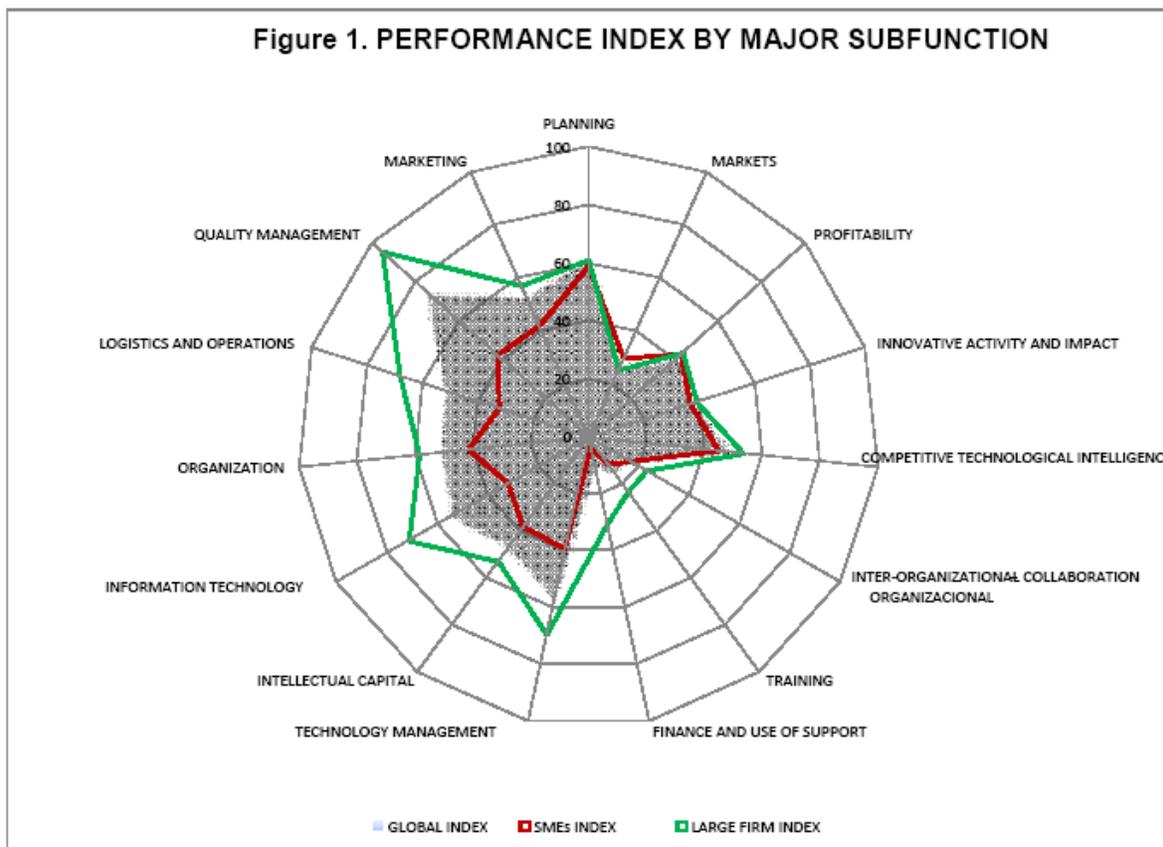
intermediate point between mean and median). Qualitative information supplied by interviewees was incorporated as complementary input for the general diagnosis.

4. Results

Figure 1 shows the general diagnosis pointing out that main weaknesses, regardless the size of the firm are related to financial management and use of policy incentives; training; inter-organizational collaboration; and markets. There are significant differences between SMEs and large firms in variables such as quality management, information technologies, logistics and operations and technology management. But it is quite surprising that very little difference exist for other variables.

This indicates that pharmaceutical firms need to improve their insertion in the new model of open innovation.

Two of the firms in this small sample have obtained the National Technology Award. We conducted detailed case studies of technology management at these two firms. These successful cases of Mexican companies clearly show that managing collaboration, establishing networks and defining strategies to finance technological development using government incentives are keys for success.



5. Lessons from successful firms

The two firms we studied (Probiomed and Instituto Bioclon) have defined that their competitive strategy must be grounded on the innovation of its products, the continual enhancement of its manufacturing practices, the comprehensive compliance with regulations and market development worldwide. It is clear that the supply for this strategy depends on the capability for developing, adopting, and incorporating state-of-the-art products, equipment, process, operation and organizational technologies. Therefore, the

companies have developed a technology management model essential for the proper definition and execution of their technology plans.

Competitive technology intelligence (CTI).

Companies conduct evaluations concerning the competitive context on a permanent basis, as well as regarding worldwide markets and the scientific and technological progress in their areas of interests. The technological monitoring implemented by these companies implies the following phases:

Clear and accurate identification of objectives sought with the CTI process;

Identification of relevant informational sources;

Entering into agreements with informational sources;

Selection and recovery of technological documents;

Analysis of recovered documents using text and data mining tools,

Results production, and

Use of such results in decision making.

Benchmarking is used as a technological surveillance method permitting to obtain or develop new technologies¹. Surveillance activity is essential since development and acquisition of new technologies is determined by the results obtained through market and competitiveness strategic studies.

1 The Benchmarking Exchange and Best practices Homepage, www.benchnet.com/wib.htm

As regards market strategic analysis, they are conducted on a continual basis aimed at detecting opportunities in new niches as well as the patient needs. Epidemiological studies are usually the starting point for research steered towards developing improvements in products and treatments. Likewise, competitiveness strategic studies are conducted to determine the competitive advantages of products with respect to those of the competition. Both firms have developed a top level scientific and technical network of connections (McCrohan, 1998) resulting in the production of benefits not only as to technology matters but also regarding commercial issues. This has been influential to start exports to new markets. Alliances with local companies and R&D centers have served for purposes of identifying demand issues and the best way to take advantage of opportunities on market development and the compliance with regulatory requirements.

Planning: strategic orientation resulting in projects

Both companies are linked to strategic planning processes. This was the only way of entering into niche markets of biotechnology drugs. Planning is carried out in accordance with a meticulous evaluation of the opportunities to identify, realize, and articulate new and feasible directions. Use of consultants' advice has contributed to build capabilities to identify the routes for development. The company's business outlook stems from an orientation towards the outside because penetration into new markets compels to cope with different conditions and regulations in each country or region.

Once such opportunities are identified, they are treated as a priority through a process where directors of the commercial, research and development, finance and production areas as well as the chairmanship of the company become involved. By the time the prioritized list of products and target markets is in place, it is proceeded to perform a technological diagnosis focused on assessing available technological capabilities, the potential of existing collaboration networks and the technological needs.

With this basis the technological plan is shaped. Such plan is used to set out clear routes to penetrate new markets, or else, to determining eventual modifications needed to make

¹ The Benchmarking Exchange and Best practices Homepage, www.benchnet.com/wib.htm

such processes consistent with the regulatory requirements, always pursuant to the plot for good manufacturing practices essential for this industry.

The execution of the technological plan rests in determining a project portfolio (García Torres, 2009). Such projects may be for internal development of technology, cooperation research with any academic institution or company or to purchase equipment or external technology. Projects are selected according to their significance for strategic objectives, budgetary availability (supplemented by external resources), and technical and scientific feasibility. Computer software is used to allow a stringent control in programs or technological projects and managing the budget of resources spent, documentary files supporting the project and the logbook to supervise progress accomplished. *Organization to execute the technological plan* In order to meet the conditions to carry out projects for product and process innovation, firms require capability to carry out projects for research, design, validation and scaling up of biological processes, including recombinant proteins. To develop such capabilities firms have entered into agreements with research institutions having research staff, equipment and infrastructure. Collaboration and technology transfer are supported through agreements regarding the adequate distribution of intellectual property rights, and terms of licensing. Financing of R&D and collaboration is anticipated when technology plans are drafted and both companies define strategies to use government funds for innovation. Likewise, tax incentives have been secured due to R&D investments. *Protection of intellectual property.* These two firms have defined clear strategies to manage intellectual property. They avoid conflicts with patent holders by considering expiration dates to adopt technology in the public domain. But investment in innovation is generating proprietary technology. Care is given to protect their technological patrimony in alignment with the commercial strategy. Doing so, patent portfolios have been developed protecting new technologies in the main potential markets. Firms have developed strategies to manage trade secrets by classifying information and executing confidentiality agreements with consultants, employees, providers and customers. Table 2 summarizes success factors identified through case studies.

Table 2. Success factors in Mexican innovative pharmaceutical firms

Success Factor	Strategic Actions
Business strategic Outlook	Top management engagement in technology planning process. Structured system for identification of market opportunities. Competitive technological intelligence and benchmarking Participation of operational areas in decision making regarding product development.
Opportunities identification and new markets development.	Networks in attractive regions. Continual communication with the medical community. Markets surveillance and competitive intelligence. Epidemiological studies to identify needs Worldwide strategic alliances.
Technological Innovation	Capacity building and training. Research and development investment. Scientific and technological collaboration network with R&D

	<p>centers worldwide.</p> <p>Budgeting combining internal and external resources</p> <p>Product and process innovation</p> <p>Use of tax incentives</p> <p>Integral use of intellectual property (protection, licensing-in and use of public-domain information)</p>
Integral compliance with regulations	<p>Definition of technological goals in regards to specifications derived from standards.</p> <p>Development of a system of good manufacturing practices.</p> <p>Internal department for clinical trials</p> <p>Collaboration with CROs in different regions</p> <p>Quality assurance.</p>
Technological projects management	<p>Alignment of projects with priority development lines.</p> <p>Participative project management process.</p> <p>Follow-up and control through software tools</p> <p>Combination of financial sources: own resources and public funds for innovation.</p>
Commercialization capability	<p>Development of marketing strategy, including alliances with distributors.</p> <p>Alliances with suppliers.</p> <p>Contact with physicians and patients.</p>

6. Final remarks and future work.

Mexico is considered a newly industrialized country with a strong exporting economy. Nevertheless, Mexico's competitiveness has been falling during the last five years and one of the reasons of this negative performance is the lack of investment in R&D and innovation. National GERD is around 0.4% of GDP with a private sector's contribution of less than 30%.

Mexican innovative firms have to operate in a rather adverse environment because innovation policy offers little support. For that reason, studying firm's innovation strategies is very important to shed light on how small firms can innovate and participate in global markets of high technology products even in a weak policy environment. In this paper, we have identified sound strategies to compete in a very complex sector characterized by the intensity of innovation. Most literature on innovation management in the pharmaceutical industry is dedicated to analyze leading firms' strategies. This paper is based on empirical information of an industry in a country with an attractive domestic market, but with a very short experience and limited resources for R&D. We have developed a proposal to manage innovation in firms that are technology followers.

Based on the results of the diagnosis of technology management and the detailed analysis of the two successful firms, we developed the model of innovation management and the structure for a program to train technology managers in this sector.

The main outcome of this research is a model of innovation management for pharmaceutical firms with limited resources for research. The model includes following components:

Technological monitoring and competitive intelligence that implies the following phases:

- o Clear and accurate identification of objectives sought with the process;
 - o Accessing relevant sources of scientific, technical, regulatory and commercial information;
 - o Use of data and text mining software to accelerate analysis;
 - o Selection and recovery of technological documents;
 - o Analysis of documents with technology and roadmaps;
 - o Decision making based on technology maps and market opportunities.
- Alignment of technology strategy with competitive strategy.
 - Feasibility analysis to support decision making
 - Internal communication and organization for rapid response to opportunities.
 - Networks of experts and opinion leaders to identify opportunities and sources of knowledge and technology.
 - Human resource management to execute technological plans combining internal capabilities with technological outsourcing and collaboration.
 - Competent R&D staff and basic infrastructure for research activities (laboratory equipment and facilities that comply with every regulatory provision).
 - Management of licensing and cooperation agreements with universities, technology consultants, competitors and start-ups.
 - Access to external infrastructure to carry out research, clinical trials, formulation, validation and scaling-up of processes.
 - Financial strategy and practices to raise funds for R&D.
 - Use of tax incentives and funds for innovation, as well as alliances with other firms.
 - Project follow-up and documentation through simple and effective procedures.
 - Knowledge management to support learning processes and documentation requirements for certification purposes.
 - Technological assimilation to assure sound operations fulfilling requirements of good manufacturing practices.
 - Implementation of quality assurance and good manufacturing practices.

References and Notes

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