“MANAGEMENT IN THE HEALTH CARE SECTOR”

THE ARGENTINEAN 2000 PATENT LAW AND THE PHARMACEUTICAL SECTOR

Javier Bronte Peñalva
Ana Cristina Brutscher
Professor: Magda Rossenmoller
THE ARGENTINEAN 2000 PATENT LAW AND THE PHARMACEUTICAL SECTOR

EXECUTIVE SUMMARY

The new legal environment in Argentina – with the approval of the new Patent Law in 2000 – will have a deep impact on the structure of the pharmaceutical industry. Until now local companies could compete against international pharmaceuticals by just copying their products, since there was not patent protection.

Following this new situation, the market will be divided into the branded products – protected by the patent – and generic products, as it currently happens in the other world markets. Therefore, local companies will need to adapt themselves to compete in this new environment.

As a consequence of the Patent law and of the depressed economical situation of Argentina, the Government passed by decree in 2002 the Generics Law. The overall effect of this law on the Argentinean Health care system has been a substantial decline in prices, which in the late 1990s were among the highest in Latin America, and in some cases higher than the cost of the same products in rich European Union nations.

The law will affect the following stakeholders:

- Pharma Companies: higher competitiveness among companies, redraw their marketing strategies and even look overseas to make up for shrinking margins at home. Increasing presence of multinational companies
- Consumers: Accessibility to lower drug prices.
- Doctors must list the generic name of medicines on patients' prescriptions.
- Pharmacies: In the past, pharmacists were simply merchants, but now they must be behind the counter to provide advice on the characteristics of each product.
- Public universities and hospitals in Argentina have asked the state for support that would allow them to produce generic drugs only identified by their active ingredient, at lower prices than their brand-name equivalents, and to improve quality controls, in order to offer high-quality products at low prices, or even free of charge.

The law on generics was "an extremely important step" in a country that for years saw consumers' access to pharmaceutical products shrink. Consequently, the main result in the Argentinian Health care system has been an improvement in the access of population to medication at lower prices. People ceased to be captives of a laboratory, and can now seek out cheaper alternatives, which means the number of people with access to medicines has increased.
1. ARGENTINEAN HEALTH CARE SYSTEM

1.1 Overview

By constitutional mandate, the provinces are the technical administrative units responsible for the health care and protection of the population. The municipalities usually administer their own resources and have the authority to program and carry out health actions independently. The Federal Health Council (COFESA) is the institutional forum for consensus-building, setting goals, and adopting common policies and decisions among sectors and jurisdictions. The National Government maintains a presence in the provinces through delegations of the Ministry of Health, the Health Services Authority, the Occupational Hazards Authority, and the Authority of Associations of Retirement and Pension Funds.

The main players in the Argentinean health care are the following:

- The Obras Sociales plans are the entities responsible for the management of social security.
- The Health Services Authority (SSS) under the jurisdiction of the Ministry of Health and Social Welfare (MSAS) is responsible for the oversight of the Obras Sociales plans, compliance with the Compulsory Medical Plan (PMO) by health insurance entities, guaranteeing system quality and coverage, and cost recovery of public hospitals (now called Public Decentralized Hospitals).
- The public hospitals provide coverage to the population on demand and, in fact, act as reinsurance for the Obras Sociales plans, since they maintain a flow of free care for the insured population.

Of the 60% of the population that have some coverage, 17.7% are affiliated to the Obras Sociales plans that belong to the Provincias, public hospitals give assistance to 31.8% of these population and the rest are assisted by the PAMI (Plan de Adultos Mayores Integral).

The health system in Argentina is structured around three principal sectors: a) the public sector, publicly financed and maintained, consisting chiefly of provincial and national administrative structures at the ministerial level and the public hospital network. At present, public sector demand has increased because of growing unemployment, the economic crisis, and the breakdown in the chain of payment in the private and social security sectors. b) a compulsory social security sector based on the Obras Sociales plans (OS) that group workers according to their line of work. c) the private sector, made up of independent health professionals and facilities (private hospitals, clinics, etc.) that provide services to private patients, but especially to OS beneficiaries through individual and group agreements that include different modalities of payment for services.

The principal problems traditionally affecting the health situation or health services delivery have been the poor articulation of the sectors, inequality in the levels of financing and quality of care, and barriers to access (mainly economic) by some population groups to the services.

For instance, those ill people that are admitted to public hospitals for a long term treatments have generally access to drugs free of charged. On the other hand, 80% of the ambulatory expenses (a total of 4.229 million every year) that are related to drugs are paid by patients since there is a lack of health coverage and insurances.

The Argentinean health system inverts 22.000 million pesos annually, of which 95% are dedicated to the medical assistance. Argentina possesses a complex system with sufficient resources but which does not resolve the emerging and basic health problems of the population. As a part of this problem 32% of the health expenditures regard the exaggerated drugs consumption and drugs growing prices (from 1991 to 2000 prices increased about 144% and in 2002 during the devaluation of the peso when inflation was around 20%, drugs increased an average of 60%, reaching 350% in some cases).
2. THE PHARMACEUTICAL INDUSTRY

2.1. Industry overview:
Argentina is one of the largest pharmaceutical markets in the world. It currently occupies the 11th position (accounting for approximately 1.3% of global pharmaceutical sales, ahead of countries such as Belgium, Sweden and Australia), and the 2nd one in Latin America, behind Brazil and followed by Mexico. During the twelve months to July 1999, the Argentine pharmaceutical market sold 403 million units, which represented US$ 4.05 billion.

Its strong development (growing at a compounded annual growth rate of 13% from 1990 to 1998) has been boosted by the existence of health insurance plans (“obras sociales” and HMO’s) that cover an important portion of the country’s population. It has also been shaped by the concept that pharmaceutical products should not be covered by patent monopoly, since “the public health is at stake” (argument strongly endorsed by the local pharmaceutical companies). Consequently, companies have made large investments in brand recognition and in enhancing the goodwill of their commercial names. As a result, Argentina has built a strong domestic industry with a large number of national companies competing with well known multinationals.

The market is mainly dominated by Ethical products (cannot be sold without a prescription) accounting for 92% (US$ 3.6 billion) of the market. OTC (over the counter) products cover the remaining 8% (US$ 0.4 billion). Unlike OTC products, ethical products cannot be advertised massively due to health regulations. In Argentina, the medical profession has always claimed its right - and responsibility - to select not only the prescribed drug, but also the commercial trademark that identifies the manufacturer. This has forced laboratories to concentrate their efforts on the medical profession, utilizing the services of sales representatives, advertising in specialized magazines and sponsoring of medical congresses.

2.2. Industry structure
The pharmaceutical market is composed of over 280 laboratories of national and foreign origin. Approximately 52 are international, representing 47% of the market’s total sales volume and 49% of its revenues (up from 40% in 1990). Following the world’s trend towards concentration, small local laboratories are being purchased by large international players already present in the Argentine market or seeking to enter into it, or by the largest local players seeking to consolidate their position. 75% of the total sales are represented by 25 companies. Foreign capital mainly comes from the US (21%), Germany (11%) and Switzerland (9%).

2.3. Drugs available
In the Argentinean Market pharmaceutical companies offer in year 2000 the following different kinds of drugs except from Generics:
PRODUCTS

<table>
<thead>
<tr>
<th>Products</th>
<th>Definitions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Original or innovative drugs</td>
<td>Drugs that contain new active principles and which went through an exhaustive research and development process</td>
</tr>
<tr>
<td>“Second brands” or Licenses</td>
<td>It is the same drug produced by the innovator but legally branded by other pharmaceutical companies</td>
</tr>
<tr>
<td>Copied products</td>
<td>These products are similar drugs but that are not bioequivalent to the original drug. These drugs have either a fiction name or the drug name followed by the producer name (DCI).</td>
</tr>
</tbody>
</table>

However, it is important to mention that in the future Generics would play an important role in the health care sector.

2.4. Distribution System

Traditionally, laboratories in Argentina have sold most of their products (directly or through distributors) to wholesalers (called “droguerías”), who in turn are the suppliers of around 12,000 pharmacies. In order to reduce costs and increase efficiencies, some of the main laboratories (nationals and foreign) have pooled efforts to outsource the sales, billing, physical delivery and collection functions through the creation of specialised distribution companies (called “distributors”). Distributors act as agents for the laboratories and do not purchase or sell products on their own account. Laboratories (mainly nationals) are the owners of the distributors. Thus, they control a large portion of the distribution and wholesale of pharmaceutical products. For instance, Pharma Star, the biggest distributor in Argentina, is formed by the 25 most important laboratories (national and international) that command 65% of the total distribution of drugs.

Shareholding structure of distributors and main wholesalers is presented in Exhibit 1. In addition to selling to wholesalers, laboratories also sell directly to public and private hospitals, social insurance funds, cooperatives, supermarkets and large pharmacies in the urban areas. Because in the year 2000 there are no Generics, doctors prescribe commercial trademarks, not active ingredients. There is no repackaging: pharmacists cannot sell unpacked products (by the unit). Exhibit 2 illustrates the pharmaceutical distribution system.

2.5. Regulation

When seeking to introduce a new product in Argentina, laboratories must register its therapeutic compounds with the Ministry of Health. In the case of compounds which are similar to already registered ones in Argentina or in a country considered to have stricter approval standards, the testing procedures focus on manufacturing processes and quality control. The whole process will usually last 6 months (12 months in other cases). Since 1995 a new Law (New Patent Law) grants patent protection to new pharmaceutical products. After an initial “grace” period intended to give domestic companies the time to adapt to the new law, patents will become effective after October 2000. Since then, patent holders will have the exclusive right to manufacture, import and distribute their products for a period of 20 years.

1 It is a drug that is a bioequivalent copy of an original product, the patent of which has expired. These drugs can be sold under the name of the active ingredient (unbranded generics) or under a brand-name (branded generics, such as certain store-brand generics).
2.6. Competitive Forces

2.6.1. Rivalry

With still no patent protection for pharmaceutical products, the market is led by Trademarks and not by Products: Products can be easily copied, so marketing of brands is key to gain public approval. In such a branded product market, there are a number of key factors which determine the success of a pharmaceutical product: (i) the laboratory’s image among physicians and pharmacists, (ii) the marketing efforts developed behind each individual product, (iii) consistent product quality and reliability, (iv) professional qualifications of the sale’s force, (v) product prices, (vi) product presentation and packaging and (vii) company’s specialization.

In the market there is not a single player capturing more than 10% of market share, and as mentioned before 25 of the companies account for 75% of the sales. Small companies enjoy considerable strength in some segments of the market, and there is almost no price competition (due to high segmentation of the market). Rivalry is, therefore, basically focused on promotional efforts to get the physicians prescribe their products.

2.6.2. Barriers to Entry

The main barriers in the pharmaceutical industry are research and development costs, manufacturing facilities and development of a sales force. Due to the fact that there was no patent protection before 2000, there was no need to have a R&D department to develop new products, which represents a huge investment. On the other hand, companies in this market invest an important part of their revenues – a 22.5% on average – in marketing (mainly institutional advertising and promotional expenses directed to physicians) in order to build brand image and loyalty.

Despite the fact that investment in manufacturing facilities is considerable, the margins in the industry are high enough to recover the investment in a relatively short period of time (between 4 and 5 years). The high number of players currently competing in this industry proves this fact.

Finally, another important barrier to entry in the Argentine market is the development of the sales force required to reach the physicians, and therefore we would rank the entry barriers as medium.

2.6.4. Power of suppliers

Most of the raw materials are imported from abroad, and therefore there is a high impact of the exchange rate on the final prices of the drugs. However, the supply of molecules and other raw materials (excipients, packaging...) resembles a commodity market where there is not a single supplier concentrating substantial bargaining power.

---


3 Source: Pharmaceutical R&D: Costs, Risks and Rewards.
2.6.5. Power of clients

**Distributors:** Laboratories have taken the control of the distribution – vertical integration. Distributors act as agents for the laboratories and do not purchase or sell products on their own account. Consequently, their power is low.

**Final Customer:** The end consumer of ethical products does not make the purchasing decision. His role is limited to buy what the physician prescribes.

**Payors:** Social security and HMOs\(^4\) try to establish some kind of control to the power of the pharmaceuticals. They aim at putting pressure on prices by giving physicians lists of cheaper products to include in their prescriptions. The fact that payors are very fragmented, and negotiate the confection of these lists independently with the pharmaceutical companies, limits considerably their bargaining power. Pharmaceutical companies are grouped in three strong associations (CAEME, CILFA and Cooperalia) whose main aim is to represent the members when negotiating with the Government (lobbying) and in other circumstances (such as negotiations with payors).

2.6.6. Substitute

The presence of substitutes in this industry is merely testimonial and is referred to homeopathic products, alternative medicines, etc. Pharmacists are not allowed to substitute the physicians’ prescriptions for other alternatives.

---

\(^4\) Health Management Organizations
3. INTERNATIONAL GENERICS MARKET

The factors driving the international generic drug industry include patent expirations of many of the best selling drugs within the next decade, the increasing presence of managed care and other cost-containment efforts. Because of these factors, the average annual growth rate (CAGR) for generic drugs has been nearly double that for the overall retail pharmaceutical market worldwide for the past several years, averaging about 11% between 1992 and 1998. This has caused that generic drugs represents an increasing percentage of the overall pharmaceutical industry sales. Exhibit 4 depicts the evolution of this share.

In 1998, generics represented approximately 9% of the international pharmaceutical market and 12% of the U.S. drug market in dollars. The generic drug market is projected to approach double-digit growth over the next three years, compared to 5% to 6% annual growth projected for branded products. In generic products, there is little (if not none) brand awareness, and the main competition is based on price, thus reducing substantially the margins. For example, whereas the average price for a branded drug in the year 2000 is $65.29, the average for a generic product is $19.33. Exhibit 5 shows the evolution of prices for both markets during the last years. As you can see, this difference has increased importantly these last years. The main beneficiary in the generics market is the final customer, who in the end captures the most of the value when patents expire.

This competition based on prices makes economies of scale very important in order to reduce unit manufacturing costs. Exhibit 6 shows the Income Statement structure for three players in this market. As you may see, unlike the branded-products companies, their main costs are in the manufacturing process, while spending in R&D and marketing is relatively low.

Additionally, as has been mentioned earlier, the decision-making power in the case of generic products is partially shifted to pharmacists and final customers. Therefore, although the sales force may still play an important role in this market, their efforts will have to be directed to pharmacists. Finally, there is an advantage to a first-mover in this market right after the patent has expired (sensibly undercutting the price of the product) but will last only until other generic versions appear in the market (and prices continue to decline).

---

5 Source: IMS Health
4. CONSEQUENCES IN THE HEALTH CARE SYSTEM

Consequence of the Patent law and of the depressed economical situation of Argentina, the Government passed by decree in 2002 the Generics Law. The law obligates doctors to prescribe drugs by their generic name, and allows consumers to choose between all products that contain the active ingredient, based on price and quality considerations and advice from pharmacists. Although medicines are staple products, the severity of Argentina's crisis — the jobless rate was 21.5 percent in 2002 and even now more than half the country still lives below the poverty line, according to the government — meant increasing numbers of people could not afford to buy drugs. Anxious to head off a health — and political — crisis, the government hastily passed the generics law, overruling a powerful lobby of big Argentine laboratories that have traditionally made most of their money on branded drugs. According to some industry leaders, the government was really concerned in adopting the Generic law as soon as possible: "Without the generics law, people would have suffered terribly, so the government rushed through in 18 months what we had been expecting to take three or four years."

The main commercial implications of the enforcement of the Patent Law will be felt when the first drugs patented expire and reach commercial distribution. The relative weight of patent-protected products will then increase rapidly, to achieve the typical share of overall market sales they have in other developed markets.

On the other hand, copy products in Argentina are expected to survive for a few years more, particularly those launched within a year of patent law enforcement, but are expected to lose market share to true generics. Suppliers of copy products are obliged to pay royalties to suppliers of branded originals, which will contribute to the decline of this section of the market.

The patent protection has set the ground for an increasing presence of multinational companies, which had to choose between Greenfield developments and organic growth, or direct acquisition of a domestic company (with its manufacturing capacity and reach to physicians through an established sales force). The local industry is expected to suffer at the hands of enhanced multinational competition. Some local suppliers will be obliged to enter the generics and/or OTC markets as strategies for survival in the light of heightened competition.

The new law is already smashing the monopolies on certain drugs produced by transnational pharmaceutical companies, which must now compete with cheaper nationally produced versions.

As opposed to the Patent Law, the commercial implications of the Generics Law have been affecting rapidly the entire population and the whole Argentinean Health care sector:

- The Generic law shook Argentina's previously cozy pharmaceutical industry to the core. It not only changed consumer buying patterns, but also forced bigger drug companies to lower their prices, redraw their marketing strategies and even look overseas to make up for shrinking margins at home. The drugs market, worth nearly $6 billion in the mid-1990's, shrank to $1.2 billion in 2002.

- For consumers, the immediate effect has been lower drug prices. Although not all drugs are available yet as generics prices have fallen across the board. The law also allows consumers to choose between all products that contain the active ingredient, based on price and quality considerations and advice from pharmacists.

- Under the new law, doctors must list the generic name of medicines on patients' prescriptions, effectively shifting the balance of selling power away from physicians to pharmacists, as they can now recommend unbranded drugs to patients.
Companies, therefore, are starting focusing its promotions on drugstore owners and employees, and companies set up its own postal distribution network, sidestepping traditional wholesale (see Exhibit 7) distributors, most of them owned by larger laboratories.

Public universities and hospitals in Argentina have asked the state for support that would allow them to produce generic drugs only identified by their active ingredient, at lower prices than their brand-name equivalents, and to improve quality controls, in order to offer high-quality products at low prices, or even free of charge. A hospital in the district of Hurlingham, on the outskirts of Buenos Aires, opened a laboratory this month capable of producing 70 pharmaceutical products at a cost 20 times lower than that of commercial versions available on the market. The initial investment in the new laboratory totaled less than $100,000. The medicines will be provided free of charge to patients admitted to the hospital.

At first people were reluctant to buy generics. They were concerned about the drugs' safety. Hurt by dwindling sales, traditional drug companies at first warned consumers against buying generic cocktails produced in the back rooms of smaller pharmacies, saying they contained inadequate amounts of antibiotics or that the quality was inferior. Under the law, generics producers must guarantee that their drugs will have exactly the same clinical outcome on patients as their branded equivalents, though not all are subject to full bio-equivalence tests, which can cost up to $30,000 a drug.

Regarding the generic market, it is growing so rapidly that some traditional manufacturers of branded drugs are considering buying out smaller laboratories to produce no-brand drugs themselves. According to some sector experts: "There has been such a radical change in the market that we've all had to rethink our strategies. We have had to become more flexible in our marketing and realize that customers who used to have 10 pesos in their pocket, now only have 4." More flexible marketing has meant everything from traditional point-of-sale campaigns — two for the price of one — to coupons offering discounts of up to 40 percent to needier families and patients who need long-term treatment. It has also meant making the most of the weak peso to export to markets outside Latin America.

While generics here still account for only a small market share — 10 to 12 percent, compared with nearly 50 percent in the United States — Argentina's continuing economic woes mean potential is huge.
Exhibit 1 - Structure of distributors and main wholesalers

<table>
<thead>
<tr>
<th>Distribution Company</th>
<th>Owner</th>
<th>Wholesale Company</th>
<th>Owner</th>
<th>Market Share</th>
</tr>
</thead>
<tbody>
<tr>
<td>Farmanet S.A.</td>
<td>Boehringer Ingelheim, Bayer, Novartis, Casasco and Gador</td>
<td>Monroe Americana</td>
<td>Farmanet Holding (*), Disprofarma, Rofina and WestSphere, an international private equity group</td>
<td>27%</td>
</tr>
<tr>
<td>Disprofarma S.A.</td>
<td>Bago, Phoenix, Elea and G&amp;M</td>
<td>Drogueira del Sud</td>
<td>Macchiavello family.</td>
<td>27%</td>
</tr>
<tr>
<td>Rofina S.A.</td>
<td>Roemmers</td>
<td>Drogueira Barraca - Suizo</td>
<td>Kovalicker Family</td>
<td>20%</td>
</tr>
<tr>
<td>GlobalFarm SA.</td>
<td>Bristol Myers, Janssen, M.S.D., Schering, Plough, Glaxo, Smithkline and Temis, Lostalo (owned by the Macchiavello Family)</td>
<td></td>
<td>Argentia</td>
<td></td>
</tr>
</tbody>
</table>

(*) Owned by Boehringer Ingelheim, Casasco and Gador.

Exhibit 2 - The pharmaceutical distribution system

- Pharmaceutical Co's
- Distributors
- Wholesalers
- Direct Sales
- Pharmacies
- Hospitals
- Other
- 70% paid by “Obras” and HMO's
- OTC
THE ARGENTINEAN 2000 PATENT LAW AND THE PHARMACEUTICAL SECTOR

Exhibit 3 – Market Share of Generics worldwide

Source: Distribución mundial del mercado de genéricos, Scrip's

Exhibit 4 – Market share evolution of the Generics within the Pharmaceutical Industry

Source: Generic Pharmaceutical Association (web page)

Exhibit 5 – Price evolution

Source: Generic Pharmaceutical Association (web page)
Exhibit 6 - Income Statement of 3 pharma companies

<table>
<thead>
<tr>
<th>Year 2000</th>
<th>Alpharma</th>
<th>Barr Labs</th>
<th>Mylan Labs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Revenues</td>
<td>900,794,000</td>
<td>440,110,000</td>
<td>790,145,000</td>
</tr>
<tr>
<td>COGS</td>
<td>500,033,000</td>
<td>315,652,000</td>
<td>361,818,000</td>
</tr>
<tr>
<td>Gross Profit</td>
<td>400,761,000</td>
<td>124,458,000</td>
<td>428,327,000</td>
</tr>
<tr>
<td>Operating Expenses</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>R&amp;D</td>
<td>N/A</td>
<td>40,451,000</td>
<td>49,121,000</td>
</tr>
<tr>
<td>SG&amp;A</td>
<td>276,464,000</td>
<td>45,000,000</td>
<td>156,247,000</td>
</tr>
<tr>
<td>Operating Income</td>
<td>124,297,000</td>
<td>39,007,000</td>
<td>222,959,000</td>
</tr>
<tr>
<td>Other Net</td>
<td>-3,430,000</td>
<td>33,023,000</td>
<td>19,784,000</td>
</tr>
<tr>
<td>EBIT</td>
<td>120,867,000</td>
<td>72,030,000</td>
<td>242,743,000</td>
</tr>
<tr>
<td>Interest Expense</td>
<td>45,183,000</td>
<td>2,405,000</td>
<td>116,625,000</td>
</tr>
<tr>
<td>Income Before Tax</td>
<td>75,684,000</td>
<td>69,625,000</td>
<td>242,743,000</td>
</tr>
<tr>
<td>Income Tax Expense</td>
<td>20,176,000</td>
<td>25,448,000</td>
<td>88,497,000</td>
</tr>
<tr>
<td>Equity Earnings</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Minority Interest</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Net Income from operations</td>
<td>55,508,000</td>
<td>44,177,000</td>
<td>154,246,000</td>
</tr>
<tr>
<td>Average Product Price</td>
<td>$19.33</td>
<td>$19.33</td>
<td>$19.33</td>
</tr>
<tr>
<td>Products sold</td>
<td>46,600,828</td>
<td>22,768,236</td>
<td>40,876,617</td>
</tr>
<tr>
<td>COGS/product</td>
<td>$10.73</td>
<td>$13.86</td>
<td>$8.85</td>
</tr>
</tbody>
</table>

*Source: Yahoo Finance*
Exhibit 7 - Purchasing Process before and after the 2000-2002 regulation

Source: http://www.boletinfarmacos.org/042002/debate.htm