

MEXICO: The ninth largest pharmaceutical market in the World

Mexico, which has over a hundred million inhabitants, has become the world's ninth biggest pharmaceutical market and the largest in Latin America, surpassing Brazil for the first time in its history. The sector already represents 1.18% of the national GDP, generating US\$9,244 million (source Canifarma). The private sector market is valued at US\$7,394 million, and the governmental market, through social security, is estimated at US\$1,850 million.

After years of protectionism during the 80's, the Mexican market has gradually opened up and liberalized. Unlike in Brazil and Argentina, national laboratories have lost ground to the multinational companies that have now become the country's largest manufacturers, with Pfizer and Roche leading the way. The country's manufacturing infrastructure has also become one of the most modern in the world, with many factories FDA approved. Growth potential remains high with a large chunk of the population not yet integrated, increasing life expectancy resulting in the apparition of 'developed countries' pathologies alongside those traditionally found in developing economies, the introduction of modern medical practices and potential for exports.

Nevertheless there is increasing concern about the future, as growth in recent years has mainly been fuelled by price hikes rather than by increases in unit sales. And the model seems to be reaching its limits, for although Mexico's macro economics have improved, the purchasing power of many Mexicans has decreased, which will directly affect the industry as for many Mexicans, medicines are "out of the pocket" expenditures that they cannot afford. In fact the Secretary of Health indicates that 20% of Mexicans postpone or renounce healthcare because of their inability to afford it.

Financing healthcare protection has



Woman and child by Javier Ramón Vega, September 1956

become a nail biting issue for the Mexican government with an estimated 58 million Mexicans who simply have no social healthcare cover. Historically Mexico's healthcare system has been composed of two programs: the Imss for employees of the private sector and the Isste in the public sector. A third program, the "Seguro Popular de Salud", was launched on a national

have to register and pay a fee to get the health benefits, which is a step towards their integration into the formal economy. He hopes that 14.3% of the uncovered population will be , integrated annually into the Seguro Popular program. At that rate, the whole Mexican population should benefit from a healthcare program by 2010.

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level in January 2004 to solve this issue. According to Dr. Julio Frenk Mora, Secretary of Health, this program aims to "offer financial protection to the 20% poorest Mexican families not included in any other health program." The program will be funded on a tripartite basis, including the federal government, the regional governments, and the beneficiaries. The Seguro Popular de Salud, hopes Dr. Frenk, will lead to "the formalization of those living in the informal economy as they ..

Jorge Lanzagorta, general manager of Canifarma -the Pharmaceutical Industry National Chamber- which brings together almost 95% of the industry's players, sees a growth opportunity if the Government succeeds in funding the Seguro Popular: "since the objective is to reach full coverage of the population, this should result in an important market expansion in order to fulfil the new demand," he says. To Mr. Lanzagorta another source of growth could come

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from Mexico's export potential: *"Another important element is the increase in exports," he says, adding "we are observing an increase in exports of pharmaceutical products not only to our traditional markets but also to new ones."*

The Mexican pharmaceutical industry is becoming proactive so as to become one of the top quality markets reaching OECD's standards. This should allow Mexican products to become recognized worldwide and increase their capacity to be exported to foreign countries. Nevertheless, many improvements still have to be taken care of, and health institutions are working on it. Mr. Lanzagorta points out that the development of proper regulations are at the heart of such a development, *"if we achieve the harmonisation of health issues, the market should become more open and we should increase our exports,"* he says, and concludes, *"credibility is one of our biggest challenges, and you can only achieve that by developing regulations of world class standards."*

Eric Hagsater, President of Canifarma and of Grupo Chinoín adds *"the current challenges for the industry are the agreement of a common agenda with the government as to how to develop the industry's future, the resolution of the problems with the Free Trade Agreement and being able to discuss issues on an equal footing with US, Canadian and European health authorities."* He concludes *"we need a strong regulatory authority such as Cofepris that can speak on the same terms to the FDA, the Canadian and the European authorities and of course to the Latin American ones."*

Cofepris, a newly created Federal Commission in charge of sanitary risk protection, amongst other things, is at the heart of the regulatory process. Cofepris is the highest Mexican authority in terms of production, transformation, distribution, commercialization and advertisement for health related products and services, and acts as an independent body. For Ernesto Enriquez Rubio, general manager of Cofepris, the agency faces various challenges, amongst them are the establishment of a system of authorized suppliers between Mexico and the USA and Canada, to be granted

recognition of mutual trust and ease the relationships between the countries, or the development of electronic transactions within the pharmaceutical industry.

But Cofepris' largest challenge is to introduce the 'product registry', as in Mexico registration is granted indefinitely, resulting in the presence of outdated products on the market, which, as Mr. Enriquez Rubio points out, *"often don't comply with the existing legislation"*.



Jorge Lanzagorta general manager Canifarma

"credibility is one of our biggest challenges, and you can only achieve that by developing regulations of world class standards."



Ernesto Enriquez Rubio
Federal Commissioner Cofepris

"we are working on a reform which would simplify the regulation by at least 70%"

This paradoxical situation reaches its peak, when the government, through the cost conscious social security system often buys these cheaper 'illegal' products.

Product registrations should be limited to five years and renewable only under strict conditions such as process control, certified supplier, bio equivalence and bio availability studies which guarantee that the formulation was not changed, absence of reports on damaging side effects of the drug etc... According to Mr. Enriquez Rubio, *"a direct and immediate consequence of*

registered medicines from 40,000 to 7,000 improving the overall quality of registered medicines."

According to Mr. Enriquez Rubio this should help *"in the short and medium term, to clarify Mexico's pharmaceutical market, and guarantee the improvement of the effectiveness of products available on the market."* Mr. Enriquez Rubio also points out the necessity to simplify the legislation: *"we are currently working with over 3200 law articles, which is hardly manageable, so we are working on a reform which would simplify the regulation by at least 70%, to make it more accurate and transparent,"* he says. This change in the Mexican legislation is seen by many as a major improvement.

No doubt many in the industry will welcome those changes, although many consider that, in Mexico, enforcement of regulations is often more problematic than the lack or quality of regulation. For example, Mexico has by far one of the most modern IP and patent protection legislations in Latin America. As a result international innovators have invested heavily and prospered in Mexico.

On the other hand the lack of enforcement has resulted in a very confusing situation with generic medicines, and so far, withheld the real development of this market. As a result, drugs that have no proven efficiency track records, nor passed bio availability and bio equivalence studies, are available to the public and sold under the term of generic. In 1997 a law stipulating that only drugs that passed strict tests, could receive registration, and would be labelled GI for Generic Intercambiable (inter exchangeable) was voted. To date the law has never been enforced, although its implementation decree is in the process of being voted on this year.

Another field of disappointment in Mexico is absence of fundamental research expenditure in a country that could boast comparative advantages in this field. The creation of the Inmegen - National Institute of Genomic Medicine- in 2004 could help change this situation, and the country's biodiversity could also become a serious asset for companies wishing to invest in biotechnology, if Mexican authorities decide to support the activity.



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First institute of genomic medicines opens up in Latin America

As EU and US regulations become more and more stringent, Mexico could boast growing advantages in order to attract clinical research. "Mexico is also very attractive for companies wanting to develop clinical research centres because international companies can find the large numbers of patients they need in order to invest", explains Manuel Miguelez, president of Amiif - Mexican Pharmaceutical Investigation Industries Association- and general manager of Roche Synthex Mexico. "In the areas of oncology, aids, transplants and many more, we already have world class research centres and highly trained doctors," he adds. This trend should strengthen as every year more new medicines are being launched in the country with the development of the pathology linked to ageing populations and adapted to chronic and degenerative diseases (hypertension, diabetes, heart conditions...).

On the other hand, despite the presence of innovative companies in Mexico, the share of resources dedicated to basic research is fierce. "There is still too little basic research in comparison to the potential of the country", laments Mr. Miguelez who blames the incapacity of the universities to collaborate with corporations: "I believe that we could also develop basic research centres, on the condition that our universities cooperate more with the industry. They have to see how universities in the US and Europe work and fight for grants. We need to have small groups of people working in specialized areas and their networks working between companies and with other institutions and other universities", he says.

The country being so close to the USA where many have their research infrastructures makes it even less probable that these will transfer this activity to Mexico. Hence, so far, only a handful of national companies are involved in basic research activities. For Mexican companies, most research opportunities are within niche products: Laboratorios Silanes one of Mexico's oldest and largest is specialized in fabotherapeutic (anti-venom) vaccine products. Other companies involved in basic research are Aplicaciones Farmaceuticas in gynaecology or Probiomed which specializes in the recombinant DNA protein. Another laboratory, Lemery, part of the Sicor Group which was recently acquired by Teva (Isr.), is about to launch a 100%

Mexican developed molecule for which it spent six years doing basic investigation which proved its effectiveness in the treatment of cervix cancer.

But another pitfall hampering the development of basic research is the lack of attraction to the sector of human resources according to Jaime Uribe de la Mora, General Manager of Probiomed: "although we are much closer to the USA, for each Mexican doing a Master or PhD in the USA, for each Mexican doing a Master or PhD in the USA, there are fifty Indians," he laments. He further denounces the lack of national investment in human resources and highly qualified education. In fact there is no pharmacist university program in Mexico.

Nevertheless a major event in 2004 might mark a stepping stone in the area of research in Mexico with the creation of Inmegen - the National Institute of Genomic Medicine-. "After the discovery of the human genome; our work at the Inmegen is to identify the genes involved in diseases and to understand their molecular mechanisms. The next step is to use this information either to prevent or cure diseases. This is where pharmaceutical companies fit in so well," explains Dr. Gerardo-Jimenez Sanchez, general manager of the Inmegen. He reckons it will take ten to fifteen years before genomic medicine becomes part of routine medical practices.

Genomic medical research could have a tremendous economic impact for developing countries, not only preventing diseases and improving the global health of work forces still affected by common diseases, but also saving costs from diagnosis all the way down to treatment. This initiative is supported by the World Health

Organisation as a step to improve the health through medicine customization making them more efficient. "Apart of all the health improvement potential that can come from this research, the project will permit the development of the infrastructure and of a business incubator within the institute that will allow us to commercialise knowledge produced from our own research and interact with the industry," hopes Dr. Guillermo Soberon, the president of the advisory committee of Inmegen. And concludes: "once a country has the knowledge and the infrastructure regarding Genomic Medicine it will allow it to develop new businesses around it. The last step is that it will create wealth."

For more information log on www.inmegen.org.mex



Dr. Gerardo Jimenez Sanchez
General Manager, Inmegen.

"Our work at Inmegen is to identify the genes involved in diseases and to understand their molecular mechanisms"


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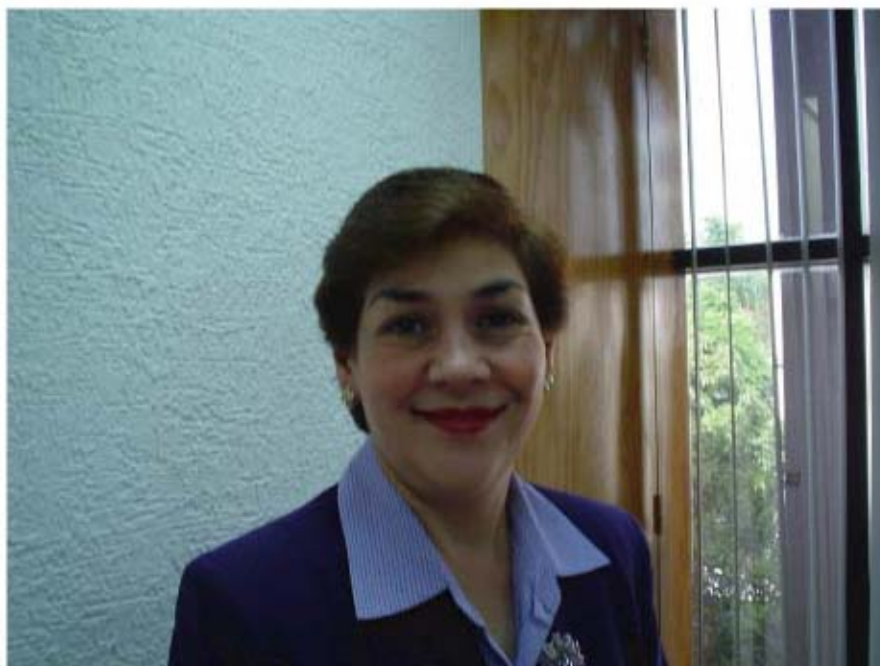
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The Long Road to Generics

In Mexico, the lack of enforcement has left a cloudy situation with regards to generics. The term "generic" still means anything different from an original brand regardless of any scientific proofs of efficiency. As early as 1997, Mexico was the first Latin American country to pass a law in order to stimulate and regulate the development of quality and efficient generics, qualified as *Genericos Intercambiables* or GIs (for *Inter Exchangeable Generic*). The law was very clear in its definition: GIs are efficient products that contain the exact same amount and form of active medication as the brand ones. This needs to be demonstrated, through clinical tests and protocols, called *bioequivalence*, to prove the product works as well as the original and can be switched from one GI to another within a treatment.

But because of lack of enforcement and of customer education and because other products boasting the name generics often offer up to a 75% discount over a GI, in a cost driven market, many patients turned to these low price medicines. This creates unfair competition, which has greatly hampered the development of the GIs and despite Mexico's early regulation, the share of GIs in the pharmaceutical market only just reaches 2.5% which does not compare with that of countries like Brazil where they already account for more than 12% and even less to those of other OECD countries such as the USA where they account for 40% of the market.

Mauro Lara Verde, general manager of Lemery and president of Anafam - National Association of Medicine Manufacturers - an association representing mainly GI manufacturers, strongly condemns this situation: *"The weakness of the GIs in Mexico is a scandal. It is unbelievable that in this market the government has not yet made a stronger stand towards these products, which offer an affordable, effective and safe solution. Everyone has the right to health care in the Mexican Constitution"* he claims. He hopes that the General Law for Health, will further enforce the use of GI



Socorro España Lomeli, Executive Director Anafam

"GIs will be a decisive support for the System Seguro Popular"

medicines, increasing its future share in the public market. At the time of this report the law had already been approved by the Federal Chamber of Deputies and was being studied by the Senate. The costs of shifting to GIs can be high and may partially explain the reluctance of some laboratories to get involved in this trend, as Mr. Lara points out: *"The costs incurred by small national laboratories, a hundred thousand dollars for each test, as well*

Nevertheless some national companies have chosen this trail. Laboratorios Kendrick is one of them. In 1997 it decided to switch all its production to GIs. Fernando Lombardo, the company's president remembers that the investment was important for a middle size laboratory: *"It surely had a big impact, because it involved a lot of investment. Each study costs between US\$60,000 and \$120,000 dollars. We rely on government funds to finance*

Quality Generic market hampered by lack of law enforcement.

as the updating of existing manufacturing equipment, delay their will to get GI approved", he says. Nevertheless, Socorro España, general manager of Anafam hopes that the implementation of the Seguro Popular will benefit the further development of GIs: *"Without a doubt GIs will be a decisive support for the Seguro Popular by providing medical attention and cheap quality medicines to the non-covered population"*, she says.

these projects, but we still fund a big part ourselves," he says.

In order to avoid unfair competition from so called generics which do not comply with the law, Laboratorios Kendrick's strategy was to select about 20 products it believed still had value for the future, being *"highly sensitive and expensive products, which provide an economic option to expensive high tech and often lifetime medical treatments"*, explains Mr. Lombardo.



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Improvements in regulation trigger hikes in R&D Expenditures

Innovators have long had a place in the Mexican pharmaceutical market, and at least 30 companies are now present and active in the country. Strong patent protection legislation was amended in 1991 so as to permit patenting of pharmaceutical products and again in 1994 to align it with that of the most developed countries in the world. Following the 1991 patent protection law, research and development increased five fold in Mexico, according to Amiif, which represents most international companies present in Mexico. As a result, annual investment in production has increased reaching US\$150 million in 2003. These investments are expected to reach US\$200 million in 2004 with the majority going towards the upgrade or expansion of production facilities.

Patents in Mexico are granted for a period of 20 years, during which time companies can conduct the necessary additional studies, launch their product on the market and enjoy exclusivity. Rafael Gual, general manager of Amiif, sees this legal framework as a very serious asset: *"Mexico's growth has been guaranteed by political and economical stability over the past seven years alongside with the establishment of a robust legal framework. Companies are now supplying the national market while*

exports, often to international subsidiaries of companies with operations in Mexico, have increased," he notes. Patent protection also stimulated the development of clinical trials: *"the number of clinical trials has considerably increased: from 400 in 2002 to 1,000 in 2003."* Mr. Gual hopes this figure will reach 2,500 in 2004.

In September 2003 a decree completed the intellectual property law, linking Cofepris's sanitary register to that of the Mexican patent office. This is seen by many as a very important improvement as Enrique Conterno, general manager at Lilly Mexico points out: *"Intellectual Property regulation was improved in Mexico since 2003 with the passing of the regulation linking registration and patenting. Therefore a copy of a product that is patented cannot be registered anymore. This allows for true enforcement."* He adds: *"for the moment 'linkage' applies to compound patents and not to used patents. To be equivalent to the US, these should also be listed. Another area for improvement would be data exclusivity. Nevertheless, there is a national commitment towards IP and the situation will improve,"* he says.

Lilly Mexico was created in 1943 and inaugurated new production facilities in 1999. Mr. Conterno wants to turn

Lilly into "the fastest growing innovative pharmaceutical company in Mexico." *"To achieve this, we expect to keep growing fast in the governmental sector and end the year with a 3.5% market share in value while our target in the private market is 2.3%,"* he explains. Lilly's strategy is clear and based on new products: *"Between 2004 and 2005 we have seven product launches planned, a number equivalent to what we launched between 1985 and 2001,"* explains Mr. Conterno.

"With the launches we carried out since the beginning of the year we already account for 20% of the new products available on the market. And we haven't yet launched Cymbalta or Forteo," he says. Mexico has become a strategic market and location for many pharmaceutical companies as well as for Lilly: *"Mexico is one of the top ten strategic countries deserving full attention and dedicated management,"* explains Mr. Conterno. Mexican operations are at the centre of Lilly's industrial strategy with over 50% of production being exported to over twenty countries, in Latin America and other regions.

Another company using Mexico as a cornerstone within its industrial strategy is Boehringer Ingelheim, through its subsidiary Boehringer Ingelheim Promeco. It is in fact one of the few companies exporting to the US and Canada. The decision was taken to turn Mexico into a production hub for North America following the Nafta agreement in 1994. According to Dr. Carlos Sagasta, president and general manager of Promeco exports to the US and Canada will exceed US\$200 million this year, and should overtake local sales by 2005. *"Our main objective is to increase our exports to the US and Canada, and make them our main markets. Boehringer Promeco now focuses entirely on the production side because we feel Mexico has real manufacturing potential. We see Mexico as a great country and a wonderful platform to North America, where people are well trained and can be very efficient in their jobs,"* he says.



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Mexico is also becoming increasingly important for Altana Pharma, which celebrated 40 years of presence in the country in 2004. In 2000 Altana completed its administrative building and remodelled its production facility. With sales reaching US\$152 million in 2003 according to Clive Cain, president and general manager of Altana Pharma Mexico, the Mexican subsidiary represents about 7% of the group's total turnover. In Latin America Altana Pharma is organized around three countries: Mexico, Brazil and Argentina. Other countries are managed through licenses and/or partnerships, explains Mr. Cain: "We deal with partners that distribute our products in countries where Altana is not present and supply them from Mexico." In return Altana Mexico has licensing agreements in Mexico, "as a result, the portfolio of products Altana Pharma manufactures in Mexico is more extensive than that of our company in other regions. This is explained by the fact that we manufacture or commercialize some products for other companies under licensing agreements, and in addition we have specifically developed some products for the Mexican market," explains Mr. Cain.

"Our reputation is established in particular segments, and within those segments we are considered market leaders or a major player. We are seen as a much bigger player in Mexico and our name recognition maybe stronger than in many other countries," he points out. Altana Mexico actually boasts the 12th biggest sales in the Mexican Ethical market according to IMS but is the market leader in Gastroenterology. The company's single biggest product remains Pantoprazol, which should continue to contribute heavily to the revenue stream as the acid-induced disease market is still growing in Mexico. Altana is also number five in the gynaecology market and should reinforce its position in the airway disease market with Alvesco, which recently received registration from the Mexican authorities for the indication of asthma (both paediatric and adult) and COPD.

Only recently arrived in Mexico, Mr. Cain is still discovering the market and its specificity: "Mexico is very different from most of the markets I have experienced in Europe. The private sector is a cash market; there is a direct link between the size of the wallet and the buying of a medicine. This affects pricing structures, there's a limit imposed by the purchasing ability of the patient and beyond a certain price products become very difficult to sell," he says. Recently appointed in Mexico, he might have arrived at what is the most challenging time: "Although some segments and drugs are still growing, since last year the Mexican market has been very tough. Some colleagues have even told me that this was the toughest they could remember. In terms of units, according to IMS figures, there has been an overall negative trend. There has been a shift in the number of units sold recently, with fewer prescriptions written and less visits to doctors," he explains.

Confronting such a challenging situation, many companies are rethinking their market positioning and strategy. This is the case with Roche Syntex Mexico, one of Roche's five largest subsidiaries worldwide, and the second biggest selling company in Mexico. According to Victor Manuel Miguélez, president of the company, although the bulk of their income still comes from primary care products, Roche Syntex is slowly but steadily shifting its efforts towards speciality care: "We need to make sure that the small businesses of specialities, which are growing at a compounded rate of 30%, compared to the 4 or 5% growth of the primary care, becomes our primary market in the future." He adds: "We have actually managed to become number one in Mexico for oncology, which reflects Roche's position worldwide."

Mexico is dealing with two trends at the same time: a large young population and an ageing population, hence speciality care products are becoming increasingly important as diseases considered exotic in Mexico



Enrique Conterno
General Manager Lilly Mexico

"We want to become the fastest growing innovative company in Mexico"



Clive Cain
President Altana Mexico

"There is a direct link between the size of the wallet and the buying of a medicine"

ago, are becoming a major source of growth for pharma companies. For example, Mexico could boast the world's fifth largest diabetes population estimated at 7 million patients; but many are simply not yet diagnosed. "Diabetes is growing every day in Mexico, and the Ministry of Health has declared it one of the most important health issues," explains Edvard Philipson Morales, general manager of Novo Nordisk Mexico. "Over the long term perspective, Mexico seems to be a very interesting target," he adds. Novo Nordisk, the world's largest insulin manufacturer has recently decided to enter fully the Mexican market: "Mexico is Novo Nordisk's white spot because of its potential and the fact that it is the only large market where we're not correctly represented," concludes Mr. Morales.

Pfizer wants to double its sales by 2008



Jorge Bracero, President and General Manager Pfizer Mexico and Central America

Is Mexico poised and prepared to overtake Puerto Rico as a production hub for the United States? "No", answers Jorge Bracero, President and Regional Manager for Pfizer Mexico and Central America (Costa Rica, El Salvador, Panama, Guatemala, Honduras, Nicaragua), who has been working for Pfizer around the world for more than 29 years. As a Puerto Rican by birth, he could be attacked for bias on this issue, yet he is prompt to highlight the growing importance and potential that Mexico represents for many pharmaceutical companies and for Pfizer in particular.

In fact, Mexico is already Pfizer's largest operation in the region and the New York based firm holds a leading position in the country as the number one seller in Mexico according to IMS surveys, a status Pfizer intends to keep: "Pfizer is N°1 on sales, and we want to consolidate our position by raising our market share from 9.2% to 12%, by launching 23 new products by 2008," explains Mr. Bracero. "We want to double our current sales to reach US\$800 million by 2008 and aim to increase our profitability by 2% a year," he adds.

As for many other companies the threat of expiring patents will make his task harder and is expected to result in changes in the customer's portfolio: "currently 22% of our sales are directed to the institutional and governmental sector. By 2008, this figure should be reduced to 19% mainly because some of our patents will expire," explains Mr. Bracero.

"An opportunity in Mexico is that health culture is still at an embryonic stage."

But he remains quite positive about the prospects offered by the Mexican market: "an opportunity in Mexico is that health culture is still at an embryonic stage. Only 15% of the Mexican population goes for an annual check-up. For example, in therapeutic areas such as cholesterol, which are key for Pfizer, only 25% of the patients have been diagnosed. Thus the

potential for growth is huge," he explains.

Mr. Bracero disagrees with those who denounce high pricing policies in Mexico as a source of problem denting potential growth or threatening national health, rather he identifies lack of availability or accessibility as the biggest issue hampering the further development of the pharmaceutical industry and suggests these are areas where socially responsible companies

23 new products launched before 2008

should and could get involved: "I don't see pricing as a key issue. The critical issue is access to healthcare," he says, and adds: "we identified that the best way to collaborate with the government is to provide access to the population. Last year we built 40 clinics in various states of Mexico, providing them not only with physical facilities, but with free medicine."

Mr. Bracero is also convinced that companies have a role to play in triggering research and development programs in Mexico. "We believe Mexico has huge potential in Research & Development if it can rely on the available talents. We want to promote the development of research in Mexico by exposing local scientists to foreign universities. This is why at the beginning of 2004 we launched a new initiative called The Pfizer Scientific Institute, which is a unique non profitable initiative in Latin America."

Besides, Pfizer Mexico is also becoming a showcase and a reference for the use and implementation of technological solutions. For example a new fully automated warehouse, which required a US\$33 million investment, resumed operations in 2004 in Toluca. And in November 2004 Pfizer Mexico became the first ever Pharmaceutical company in Mexico to receive the National Award for Technology, delivered by Mexico's president Vicente Fox, as a reward for excellence in use and management of technologically advanced solutions.

No Pain no Gain

Understanding pain is still in its infancy in many countries including Mexico. In many cases appropriate medications are available but doctors do not know how to handle them. A standard medication for moderate pain like Tramadol for instance is used 30 times more frequently in Western Europe on a per capita basis than in Mexico. The ratio is even more disparate for substances like Morphine. The reasons are diverse including economic, social and religious issues, but the result is that many patients suffer needlessly.

Hence, the need for educating both physicians and patients about this issue is critical according to Klaus Kuchen, general manager at Grunenthal de Mexico: *"We also believe that being a pharmaceutical company is more than just about selling products. We want to educate physicians about all the options available for treating pain, only then can we claim to add value for patients and physicians and reduce overall costs,"* he says.

Grunenthal is a family owned German company that ranks amongst the top players worldwide in moderate to severe pain. Grunenthal's business model usually focuses on countries that are too small to attract the interest of bigger multinationals. In Latin America Grunenthal is active in several countries

including Ecuador, where it has been present for over 30 years and owns a FDA approved plant.

Grunenthal's products have long been distributed in Mexico, through a commercial agreement it enjoyed with Boehringer Manhein before they were taken over by Roche. After Boehringer Manhein's takeover the decision was taken not to abandon the average US\$4 million pa generated in Mexico was incorporated in 1998 and in 2001 plans for a factory were launched. *"We plan to start production in March 2005, but the most important thing for us is to receive the registration for our products under Grunenthal Mexico's name and to become 100% independent,"* explains Mr. Kuchen.

"Standard medication for moderate pain like Tramadol is used 30 times more frequently in Western Europe on a per capita base than in Mexico"

Positioning is also very clear: *"Grunenthal is amongst the top players worldwide in moderate to severe pain, so we decided on a corporate level that this should be our core business in Mexico too. Our vision is to become the preferred partner in this field in Mexico,"* he explains. Pain should become the company's main growth driver, representing 50% of its turnover, according to Mr. Kuchen. The company will also be active in the fields of gynaecology and paediatrics. It should soon

launch parent friendly medicines with innovative and convenient packaging and with easy administration for children, allowing them to take the drugs through straws. Mexico could become a key driver for Grunenthal's corporate growth. *"We expect that in six to eight years Mexico will generate similar results for Grunenthal as Spain or Italy,"* says Mr. Kuchen, who is targeting sales of US\$80 million within eight to ten years. *"We know this is achievable, because our products are good, our service is excellent and our people well trained and dedicated; this is what it takes to develop your market,"* he says.

But recruitment is part of the challenge, as he points out, *"we need to recruit managers as our company grows. Highly educated Mexican managers are very good at their job, but they are as expensive as expatriates,"* he explains. And concludes, *"we know we can't attract people purely with financial incentives because we are not billing as much as other multinationals. But Grunenthal de Mexico being a young company, it is still possible for an employee to put his 'seal' on it and to influence the future of the company. We can offer responsibilities and empowerment. We try to transmit an open spirit and open minded culture,"* he concludes.



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Keeping an eye out for partners

For mid-sized specialized laboratories partnership is becoming key to international development. Laboratorios Sophia started operations more than sixty years ago with a clear vision: to transform pharmaceutical products to improve the development of ophthalmologic medicine. From a local family-owned company it became an innovative manufacturer, recognized for its quality and is now leader in its market in Mexico. Sophia started in Guadalajara (Mexico) and now it covers Central America, Caribbean and the northern part of South America (Venezuela, Colombia and Ecuador).

With its US\$45 million sales a year, Laboratorios Sophia sees a

"limitation in the Mexican market growth potential" says Eleuterio López, general manager of the company, who adds: *"our objective is to increase our presence with more products in more countries, principally in Europe and the USA."* Today, exports represent around 15% to 20% of Sophia's total sales. But penetrating foreign markets can be problematic for Mexican companies.

"The poor perception of quality and competitiveness of products 'Made in Mexico' is a real problem at the time of export" says Mr López. In order to counter this bad reputation, Sophia implemented different strategies. Participating to international congresses or sharing information with foreign doctors coming to Mexico for their education are the normal ones. But, Laboratorios Sophia also has an original strategy. *"We offer a free trial of our products to our potential customers and until now the results have been more than satisfying as we have had no rejections or critics"* comments Mr López.



Eleuterio López
General manager, Laboratorios Sophia

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"Laboratorios Sophia has been looking for strategic partnerships for the last four or five years. We started to forge commercial and distribution alliances with European companies of our size in order to have joint growth. What we offer are three or four unique products that do not exist anywhere else," tells Mr López.

Another strong point is the company's involvement in research. Sophia is one of the few laboratories that partnered and participated in joint research with Mexican main universities. It developed an eye and tissues databank and offered human resources exchanges in order to strengthen the university's master in ophthalmology with the Tec de Monterrey. This kind of initiative brought Sophia

recognition when in 2003 it received the World Intellectual Property Organisation (WIPO) prize for Research and Development and in 2004 the Canifarma award for leading companies' involved in basic research. On the industrial side, Sophia is building a latest generation manufacturing facility, which will comply with FDA standards.

Other laboratories need partners too, such as Darier for example. Darier

specializes in dermatologic products, and faces the same "perception challenge" as Laboratorios Sophia, says Mr Ahumada, its CEO. Darier's strategy is slightly different that of Sophia's. *"We would like to partner with companies doing research in dermatology; develop licensing and technology agreements so as to bring their products and technology to Mexico."* This has been a pretty successful strategy for Darier, which always tries to complement its products' portfolio to offer a wider choice to its customers.

Services clear the way for faster growth

The very concept of outsourcing is still at an early stage in Mexico. Two reasons explain this situation: *"the lack of human resources who offer both experience of the pharmaceutical industry and entrepreneurial spirit; and, the fear by many laboratories of losing control of their operations, which is still the main obstacle for the development of outsourcing companies,"* explains Mr. De la Torre. But he is confident that as they guarantee integrity to their customers, outsourcing companies will start to flourish and attract more business in Mexico: *"Outsourcing has become a reliable option to grow your business in Mexico. The only consideration is the process of choosing the right outsourcing company,"* he says. Grupo AEFA works in the area of sales force management for innovative laboratories, offering a whole range of services from one shot commercial actions to the integration of the whole commercial process. The group recently launched a new service called AEFA Total, which Mr De La Torres describes as the most innovative and complete way of outsourcing, handling the entire commercial process. They have already

sold this service to Productos Medix, a mid-sized company with turnover of US\$27 million. Volaos, a new company, was created for that purpose and the entire commercial staff was transferred from Medix. Results are striking with a 35% commercial cost decrease and a 50% productivity improvement. And since they work on percentage, Grupo AEFA is committed to increasing need for qualified and flexible services throughout the pharmaceutical industry is reaching Mexico and has driven the recent creation of services for the industry. As a consequence, outsourcing services are developing in Mexico to allow pharmaceutical laboratories to sustain their rapid portfolio growth - often a consequence of mergers and acquisitions - and to permit them to focus on their core activities: research and development of new products, monitoring of product distribution and drug pricing.

"Innovative companies realize that market-share gains become too expensive to obtain by themselves and they need a reliable and trusted partner to gain share on a less expensive basis. From our perspective outsourcing is a good way to

help pharmaceutical companies grow much more rapidly than they could by their own means," explains Alejandro De La Torre, general manager of Grupo AEFA, a company that specialises in Business Process Outsourcing with offices in Mexico City, Monterrey, Puebla, Guadalajara, Merida, Leon and Tijuana. *"Grupo AEFA is the leading outsourcing company in Mexico with regards to turnover. We estimate that we will have sales of about US\$13 million this year, while other agencies will probably be in the region of US\$5-6 million. We are targeting a rate of growth of 25% for 2005,"* he says and adds, *"our staff enjoy large accumulated experience of success. We offer our customers the benefit of this experience while only paying for a part of it."*

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With over twenty five years servicing the pharmaceutical industry, Fabiola Trigueros is probably one of the best placed to talk about evolution in the need for services in the industry. Now part of the French-based Cegedim group, the company she heads boasts over 25 years servicing the pharmaceutical industry in Mexico with tools to monitor and understand sales performances. She is also he one the industry consistently turns to for accurate and up-to-date market information: *"we are the leaders in providing market information and analysis and the best database for our clients,"* she claims, which is confirmed

by most of top pharmaceutical executives in Mexico.

When she took over Marketing Services Mexicana in 1987, in her own words, the company was 'a mess' with only one client left. She relates that her first initiative was to invest in computers and to upload all the information gathered over the years into a digital database. A few years later Marketing Services Mexicana had regained its position as market leader and created 'Infomed', a benchmark database that includes all the clearance files for 'doctors, pharmacists and hospitals' for the pharmaceutical companies. A shrewd



"Outsourcing has become a reliable option to grow your business in Mexico"

Alejandro De La Torre
General manager Grupo AEFA



"We have the most modern and up to date database of pharmaceutical and healthcare professionals"

Fabiola Trigueros
General Cegedim Mexico

businesswoman, Mrs. Trigueros understood that survival in a sector where decisions were increasingly taken at headquarters' level would come from integrating into a larger group. In 1996 Thomson Group (US) took over the company before selling it to Cegedim in 2002, when Marketing Services Mexicana became Cegedim Mexico.

"We are now part of a global network with state of the art technology. Our people received training by Cegedim who spent millions of dollars for that purpose," she says. And adds *"We are able to offer*

and assist companies which are restructuring their sales force or the territory alignment, by re-providing them analysis on the productivity of each rep. Besides, we have the most modern and up to date database of pharmaceutical and healthcare professionals. For more than a year we have had a call centre that specializes in contacting doctors and pharmacists around the country in order to collect, check and update information name, address, speciality etc." She adds *"we offer Cegedim's three most innovative and efficient software: TEAMS, a sales force automation tool, ATLAS, a complete customer relationship management solution and ONEKEY, the industry's most comprehensive database and customer master,"* explains Mrs. Trigueros.

Close relationships and trust are at the heart of her success: *"One of our secrets is that we never compete with our clients, we learn from them. We enjoy close and strong relationships with our clients and have always refused to work for those whom we consider unfair competition to them,"* she says and notes: *"Our strength remains in the quality and the quantity of the information we provide. Nowadays, even companies which have decided to implement software different from the ones offered by Cegedim, turn to Cegedim Mexico to acquire accurate and intelligent information about the Mexican market."* Today Cegedim Mexico's client portfolio consists of not only the international companies but also with many local companies, and Mrs. Trigueros manages not only Mexico and Central America, but also most of Latin America (excluding Brazil) with offices in Colombia, Ecuador, Guatemala, and Costa Rica and already has clients in Chile and in the Dominican Republic. *"We plan to open offices in other Latin countries. We are always on the look out for companies to takeover. The most important thing for us is to ensure that these companies share our ethical principles and practices,"* concludes Mrs. Trigueros.

Demystifying drug distribution

Considering Mexico's size of nearly 2 million square kilometres, distribution is a key issue. The majority of pharmaceutical companies cannot afford to maintain their own logistics fleets. Most drug manufacturers, as well as state institutions, lack distribution networks of their own to distribute their products to hospitals and the more than 20,000 pharmacies nationwide. As a result, the importance of wholesalers and distributors has risen in Mexico.

The Mexican drug distribution system is very similar to that of its northern neighbour, with three channels: pharmacy chains (lead by Farmacias del Ahorro, Farmacias Benavides, Farmacias Fénix, Farmacias ABC and Farmacias Guadalajara), independent

pharmacies (which are present everywhere), and Over-the-counter (OTC) products distributed in retail stores (Wal-Mart, Gigante, Soriana), drugstores and groceries. Physical access to medicines is now at its optimum as it is possible to find a pharmacy on every

corner in Mexico. Large retail stores in Mexico like Wal-Mart, Gigante or Carrefour have their own pharmacy inside the store and are becoming heavy weights in the distribution process, sometimes causing harsh competition with more

Three wholesalers control above 80% of the drug distribution market.

traditional networks.

While the efficiency of distribution is not at stake, there is rising tension in the system as the distribution of Mexican medicine and wholesaling has evolved into an oligopolistic system with three



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companies (Casa Saba, Nadro and Casa Marzam) controlling around 80% of the distribution of pharmaceutical products.

The weight and concentration of the main distributors leave no choice for laboratories other than to increase the discounts they offer to wholesalers if they want to have their products distributed," laments Sergio Chavoya, General Director of the Anadim, an association of mid-size pharmacy chains and distributors. "If the laboratory does not agree on those discounts, they no longer have the possibility of having their products distributed and sold," he adds. Anadim is currently focused on improving its members' negotiating position. Thus it tries to get a consensus on discount policies and asks for "the homogenisation of discounts so as to all get the same access price to medicines," explains Mr Chavoya.

The country's fourth largest distributor is part of the Farmacos Especializados group of companies. The group is composed of eight companies. Amongst them are Farmacos Especializados, Farmacos Nacionales, Farmacias Especializadas (a countrywide pharmacy chain), Equimed, which manages vaccines and a selected portfolio of medicines, Selecciones Medicas which is dedicated to medical equipment, and Proimune, a distributor of biological products to the private and public sector and vaccines transportation.

Farmacos Especializados started with a single pharmacy in 1978 with the idea of distributing speciality medicines nobody else wanted to distribute because of their scarce volume and low profit margins. "We were born with the development of modern medicine and the rise of new very specific medicines," says José Antonio Pérez Pérez, President of Farmacos Especializados. This family owned company is a pioneer in "all products considered of high speciality that cannot be produced or directly distributed in Mexico and are imported as finished products," he adds.

Farmacos Especializados now manages more than twenty specialized medicinal fields via close contact with the major Medical Societies and participates to over fifty medical congresses a year, mainly in oncology, infectiology, haematology, nephrology, cardiology and urology. "We are identified by the pharmaceutical industry as a warehouse for their speciality products because of their limited availability," comments Mr Pérez Pérez. Because of their scarce volume and the unpredictability of the needs, no laboratory can afford to maintain a transportation fleet in order to supply a few boxes of very specialized products from time to time to remote areas of Mexico. Farmacos Especializados has spent more than 20 years handling this kind of logistics.

"Supplying one or two boxes of a specific medicine to a remote area of the country is five times more expensive for a laboratory to do on its own than going through our distribution network in which we manage over a hundred and fifty products, diluting the distribution costs," says Mr Pérez Pérez.

They became one of the major distributors in Mexico through its subsidiary, Farmacos Nacionales, which is a chain of more than 60 pharmacies located around the country. They recently entered the medical equipment market, still in the highly specialized niche, for example they now represent Medtronic in Mexico, which is a leader in the research and manufacturing of pacemakers. And they recently launched a new telemarketing sales service, Telefarmacos, dedicated to receiving customers' orders on a toll-free number in order to increase their efficiency as well as to gather inventory information. It is aimed at servicing patients living in towns, which have less than 50,000 inhabitants, which often lack specialized medicine distribution services.

Many pharmaceutical companies also relied on Consupharma, a company with 300 employees, to get their Over the Counter (OTC) drugs on supermarkets shelves. When in the 1990's government price control was gradually abandoned, the government allowed an



Perez y Perez Family: Founders of Farmacos Especializados

average price hike of 10% per company that could be distributed in anyway between the products. Most pharmaceutical companies decided to apply much of the hike to prescription and new products rather than to OTC drugs, mainly because of the lack of experience pharmaceuticals companies had in dealing with untraditional distribution networks such as supermarkets or drugstores. With experience in the mass distribution industry, as a former president of Procter and Gamble Mexico, Consupharma's president and founder, Francisco Cortina, offered to assist companies like Smith Kline & French, Promeco, Abbott or Schering Plough to "obtain presence in supermarkets and reclassify some products from prescription to OTC and to find a way to improve their products' promotion."

"We are a good option for companies which have too many products to commercialize in the country, and aren't able to devote the necessary time to all of them. We are also a good option for companies which already exist in Mexico, but are not devoting efforts to our own market, like enough time to customers we know very well, such as supermarkets, drug and grocery wholesalers and drugstores or for those who have a very limited sales force or limited geographical coverage. Finally we are a very good option for companies out of Mexico, which are not willing to spend money in establishing themselves in Mexico. They can benefit from our distribution network in Mexico City, Guadalajara and Monterrey. And we are opening a new facility in the south east of the country, probably Villa Hermosa," explains Mr. Cortina.

Consupharma can be considered as "an entry key to the Mexican market for companies established or not in Mexico, becoming their 'brain and muscles' when it comes to the distribution of their products; we can manage the whole process of distribution for a pharmaceutical company." What distinguishes the company from a wholesaler is that it actually often invests and partners in such projects, "we can act as a distribution consultant or become a true commercial partner sharing financial risks within a long term relationship. We devote all of our efforts to specific brands and products, this allows us to better analyse the distribution and sales results and suggest new ways to improve our mutual business," explains Mr Cortina. He adds, "behind the sales force and the merchandising we also have a marketing group working together with our commercial partners to develop the correct strategies for the market."

The group diversified and now offers its services for personal care and food products. For example it carries Mexico's leading condoms line, Sico, which has a market share of over 60%, far ahead of its competitors. The next step is the development of customized marketing strategies as to offer its 'partners' ad hoc solutions for a better commercialization of their products ■

New networks cause harsh competition

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stones across the way.
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You will find Bridges.



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