

# Interview with Hernán Lpez Bernab, President, HLB Pharma Group

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Your entry into the Argentinean pharmaceutical market in 2004 was very unconventional, with your ‘holistic solution’ that had not been seen before in Argentina. Why was the time right in 2004 to start HLB Pharma?

Hernn Lpez Bernab: We saw a special moment in Argentina to start a new company that was focused on providing services to international companies. HLB Pharma combines: a national company, with international reach. We have a strong position in the market because of our years of experience. We created a team that includes people with local and international experience.

At first we offered production services, this side of our business is very strong. We produce more than 50 million units. Our first client was Sanofi Aventis: now we work with around twenty international companies, many of them are top ten leaders worldwide. That was the first aspect of our model. The second was to develop our own pharmaceutical division. It is essential to our business that we do this in a way that does not cause conflict with the companies we work with. We have branded generic products, and will never launch products that have the potential to cause differences with multinational companies. We respect intellectual property in all senses.

Roberto de Len Snchez: For this reason we are members of CAEMe, the international chamber. The first step is to consolidate our position in the Argentinean market, and the second step is the Latin American market, whilst always trying to offer the best services, and maintaining strong partnerships with international companies.

You’ve been very successful: you gone from one hundred employees in 2004 to over five hundred. What have been the main growth drivers for HLB Pharma in this time?

Roberto de Len Snchez: Many international companies no longer manufacture many of their own products in Argentina, and are looking for strong partners to work with in the country. This was the case when we signed with Sanofi Aventis, who selected HLB Pharma Group as their partner in production in Argentina. Today we manufacture for Pfizer, Bayer-Schering, Bauch & Lomb , Nycomed, Merck, Serono , Intendis, and help companies such as AstraZeneca with clinical trials for Europe.

One reason we are so well respected is the level of international authorisations that we have. We are fully certified to produce for the whole of Latin America. We have the approval of INVIMA, who are notoriously tough, and ANVISA, and today we export inter-company throughout the whole of Latin America.

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Hernán Lázpez Bernabé: We believe we are the first choice for production amongst the international companies operating in Argentina. A high level of quality is very important in our world. For example, we constructed a manufacturing site specifically for ophthalmology, which was built in compliance with FDA specifications.

Roberto de León Sánchez: The FDA approves products rather than manufacturing sites, but our site was created so that every product that is manufactured there fully respects their guidelines. This is the main difference between the FDA, who approves products, and EMEA, who approves manufacturing sites.

Although we don't intend to produce products for the United States, we built our facility to FDA standards, to show our international clients our high level of manufacturing quality. We bought the Schering AG manufacturing site here in Argentina three years ago for this same reason.

The difference between us and other national companies is international compliance. We are a member of CAEME; we signed the IFPMA ethical code, and we are not only internationally compliant in our marketing, but in technical matters too. We receive a different audit every week from our international partners, and we maintain not only GMP, but cGMP, Current Good Manufacturing Practices.

Your outlook and strategy places you in a unique position in Argentina. How do you feel as a company you fit into the Argentinean market?

Hernán Lázpez Bernabé: It's a new and innovative business model, 5-6 years in advance of the rest of the market. Reliability, high quality, and protection of international property are our first principles.

Roberto de León Sánchez: This approach is very important with the national sanitary authorities, which encourage good manufacturing sites in order to avoid problems.

Hernán Lázpez Bernabé: HLB provides a "holistic solution". We try to provide everything in one place. We can provide expert knowledge of both the Argentinean and Latin American markets. Companies see that local knowledge is important in order to compete here, and we are often their first choice.

You have two big parts to your business, the service side and your own pharmaceutical division. How do you balance these two aspects of your business?

Roberto de León Sánchez: In the first stages of the business, HLB Pharma provided manufacturing services. Today we are split at roughly 60% production and 40% pharmaceutical division products. Our own pharmaceutical division was started two years later, beginning in 2006.

Hernán Lázpez Bernabé: Both parts are essential to HLB Pharma's business. We want to grow both areas in an independent way, not to give priority to one or the other. The balance is constantly shifting as the two sides grow, and we buy new manufacturing facilities, or take over other companies, but it is the growth that is important to see. We are also growing the scale of the business we do with our existing partners.

Roberto de León Sánchez: With Pfizer for example, the first step was industrial agreements, now we have marketing agreements. Their top ophthalmology products are in our hands, for both promotion and sales. The same is true with AstraZeneca, and we recently signed an agreement with Lundbeck for their psychiatry line. We also have the Diagnostic Medical Division with GE, with whom we launched a revolutionary product last month: Visipaque. NeoStrata is very important in our

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Dermatology Business Unit.

How do you prioritise therapeutic areas? Are you looking to expand and eventually cover all areas?

Roberto De León Sánchez: Today, we manage dermatology, diagnostics, ophthalmology, CNS and gastroenterology. The idea is to eventually include every business unit. We are in negotiations with two or three international companies in order to close new agreements. The idea is to acquire local companies or mature products in order to increase our critical mass. We are able to do this due to our flexibility, which allows us to take full advantage of the Argentinean market needs.

From your trade balance, how much would you say goes to the local market, and how much goes to your export market?

Roberto de León Sánchez: Around 40% of our production is exported. Our expansion as pharmaceutical division started six months ago. We are opening Uruguay, Chile, and Paraguay, and our objectives for the next six months are Peru, Colombia, Venezuela, Guatemala, the Dominican Republic, Panama and Belize. We are under negotiations with Asian companies too, because we are interested in the big markets: China, Russia, and the new Europe. We have plans for Brazil and Mexico too, but that is a second step because the moment is not quite right yet.

You've obviously seen that the future of Latin America is going to be regional production. How do you intend to expand on that regional production?

Roberto de León Sánchez: Hernan plans to invite EMEA authorities to visit our plant and receive EMEA approvals. Once we have EMEA approvals, and ANVISA agreements, HLB will be able to produce not only for Latin American countries, European markets, but for the majority of Asian and African markets.

Hernán López Bernabé: If the business opportunity presents itself, we would be interested in buying another production site close to Mexico, in order to gain the best coverage of Latin America.

For a company like HLB, manufacturing to international standards, getting the right ingredients is very important. How big an issue is this in Argentina at the moment? Do you think that Argentina needs to vertically integrate?

Hernán López Bernabé: During the 1960s and 1970s, there were companies in Argentina that produced raw materials. The problem with Argentina is not the human capacity; the local expertise is the best in Latin America. The problem was the economic rules. Producing raw materials involves high local costs, and the logistics are very difficult to manage. It's hard to say what will happen in the future. Profitability in API manufacture is very short, and you need to have large stocks to increase this profitability, which is difficult in a country like Argentina, given current legislation. Argentina was the first country in Latin America to produce raw materials, but the industry all but disappeared due to its low profitability: in the end, it is much easier to get APIs from another company. There are still companies that produce specific ingredients. In the future, strong intellectual property regulation in Argentina means that some companies might start to develop in the next ten years to offer materials, but not under current legislation.

You've already mentioned some of the problems that the multinationals face in terms of management. What do you think are your key management skills here at HLB Pharma?

Roberto de León Sánchez: We have a great combination of strong local expertise, people who were born in the industry, and people who have worked in multinational companies and different markets for many years. Our model is MNC packaging, MNC quality, MNC compliance, with

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Argentinean flexibility and speed in our decisions. This is the key to our business.

Hernán López Bernabé: The HLB Pharma management works as a team. The team wants to win, and we work 12 hours a day to do the best that we can. I think that is the reason for our success. Our team works the same way as the best companies in the world. We work happy.

Is there a final message you would like to send about HLB Pharma and about Argentina?

Roberto de León Sánchez: Our objective is to operate as an integral and trusted partner to multinational companies in Latin America, and hopefully soon we will be able to extend this success to new regions and markets.

Hernán López Bernabé: When you start a new company in the 21st century, you have to think globally. Today, we have a lot of potential projects, and our success will be based on choosing the right ones. We are confident we can do this.

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