Interview with Jose Manuel Cousiño Lagarrigue, , Camara de la Industria Farmaceutica de Chile, A.G. (CIF)

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What was the vision behind the creation of the Camara de la Industria Farmaceutica de Chile (CIF) and what have been the main milestones and achievements?

CIF was created in 1953 and was originally composed of all the pharmaceutical laboratories operating in the country. Today CIF is a chamber that groups the innovative pharmaceutical companies of American and European origin. We base our work on three pillars to develop our activities. These are the notion of free-trade and the respect for intellectual property, as well as the code of ethics of the International Federation of Pharmaceutical Manufacturers Associations (IFPMA) that is essential to our work. In general, our main objective is to defend the interests of our members and to create a regulatory, legal and general business environment that is favourable to develop our business in Chile.

Secondary to this there are other issues of our concern, such as the quality of pharmaceutical products. In Chile, unfortunately, medicaments are heterogeneous due to the fact that the local authorities are very tolerant of manufacturing practices by the local industry. In this country 66% of local pharmaceutical producers do not abide by GMP guidelines and this is listed by the Instituto de Salud Publica (ISP) on their website. There is a general failure to deliver the GMP on behalf of the local companies. Chile's pharmaceutical products also lack bioequivalence and studies of bioequivalence are stalled in the country. Products are distributed without verifying their therapeutic equivalence and there is a practice of interchanging one product for another and therefore not respecting medical prescriptions. This is a very serious issue that harms and places in jeopardy

Chile's population. There are a number of other issues as well, such as the lack of a regulatory framework to control the quality of the active ingredients and raw materials used in pharmaceutical products. There are also concerns with stability studies being very weak and basic, and finally the lack of vigilance of the pharmaceutical industry as whole which allows for delayed reactions to events that affect the industry at a global level.

What are the main challenges that the innovative industry is facing in Chile? What specific actions is CIF taking to address these challenges?

Intellectual property rights are by far the most important challenger. Unfortunately, Chile has not properly implemented the directives of the FTA with the US. More specifically the problem lies with the linkage between the official body that issues patents and the Instituto de Salud Publica (ISP) that provides the license for commercialization of a product. This is a clear violation of the directives of the FTA, because under its obligations Chile should deny any request to commercialize a product that is protected by a patent unless previously authorized by the owner of the patent.

These violations are explicit and clear to everyone, as this is the fourth consecutive year that the country is listed under the U.S. Trade Representative's Priority Watch List. The country has remained on this list because the government's response to this issue has been mute. There is an inter-ministerial commission that was formed to address these concerns but the problem is that there is no agreement within the government itself. The Ministries of the Economy and the Ministry of Foreign Relations have much interest in having this issue resolved. We are awaiting for news in the next weeks.

What specific actions is CIF taking to address this challenge of patent violations?

We have met with the Ministries of Economy and Health and with all the figures in the government that are related to this debate. We have submitted documents as evidence of the violations, which is what lead to the creation of the inter-ministerial commission. Unfortunately, the commission has failed in its mandate because the Minister of Health has blocked any further action. This might have to be raised to the presidential level because the pressure from the United States will most definitely continue to mount.

We have also organized seminars and a variety of events in coordination with AmCham, with whom we have also made public statements condemning the violation of IP. Here in Chile the infringement of IP is not specific to the pharmaceutical industry and can also be seen with other products, such as software, movies, books and music. Sadly there is a culture of imitation rather than innovation and this is the larger problem which is more cultural than anything else.

What is the relationship between CIF and ASILFA?

Our relationship is divided because of the issue of IP rights. They maintain that they respect product patents but not the patents of procedures, even though legally both of them are protected under the patents. Essentially what they want is that our members invent products so that they can be launched to the market by anyone who wishes to produce them. They don't understand that pharmaceutical products don't simply emerge and fall from the sky as raindrops. There is a huge investment into developing and marketing a new product these days; a cost which is estimated at US$1.3 billion for biopharmaceuticals and US$1.1 billion for a chemical-based pharmaceutical.

What ASILFA generally objects to is the duration of patent protection, which they don't realized is governed by international standards that are dictated by the WTO. The patent registration entity of Chile takes about 8 years to provide a patent for a product, so out of the 20 years of exclusivity mandated by a patent, you have to subtract this time as well. Once a product has been launched, usually there is another innovative product from the loyal competition that is marketed within 4 years. Here in Chile, however, you find that the generic imitation of a product is available in the market even before the innovative competitor. ASILFA's position is truly unreasonable and they will probably tell you that we are abusive in our practices. There are very few instances where we do cooperate.

How have innovators dealt with the predominance of generics in the market?

If it wasn't for the patent we wouldn't be here today. We have 73 products protected under patents, which represents a 1.3% of all pharmaceutical products in the market. Out of these 73 patents, 50 of them have been respected by the local industry and the other 23 have been copied by more than one company. In some cases there are up to 8 or 10 different versions of the same product because it is copied by several local producers. When you have this scenario it is impossible for us to take legal action because it is too costly to target 10 different companies in a courtroom. It is very simple; this situation needs to be fixed and this is the only way forward because this situation is very much damaging the country.

How have international treaties played a role in regulating the Chilean pharmaceutical industry?

In the case of the Europeans, they are only concerned with data protection from the clinical trials. They don't pay much attention to the linkage, as does the US, because for the Europeans the notion of linkage is natural and doesn't even have to be discussed. For them it is inconceivable that within the same government you would have opposing positions from two different entities in regards to the same product. They don't understand how the health authorities could contradict what has been stipulated by the patent authorities. We have continuous meetings with the patent regulation entity, the ministry of the economy, the American embassy and with other organizations in the US to try and bring a solution to this issue.

What opportunities exist for innovators to license their products in order to limit patent infringement while still making a profit?

The Chilean market is very complex and competitive with several challenges. The first challenge is the issue of concentration of distribution channels which are dominated by the three main pharmacy chains in the country. This concentration limits the agility of the market as whole. The second challenge to licensing is that now that the large pharmaceutical companies are globalized, they have production facilities in other countries and only have marketing and distribution operations here in Chile. None of our members have production facilities here in Chile because it is not cost-effective and there are more favourable manufacturing conditions in other countries like Argentina, Puerto Rico and Colombia. They all used produce here but it was no longer cost-effective.

Characteristically, the pharmaceutical market in Chile is dictated by the government's public spending in healthcare and what we find today is that the country has the largest debt in healthcare that has ever been seen in the world. I have been in the pharmaceutical industry for 44 years and I have never seen something similar in the past. The government today owes our members an estimated US$ 52 million.

Could you tell us about the opportunity for the growth in the clinical trials market of the country?

This is definitely an interesting opportunity. Out of our 19 members 14 of them finance between 150-160 Phase II and Phase III studies annually. Many of these studies are done simultaneously in several countries. Chile has great research centers and universities and a very good scientific community, which makes it attractive for this kind of studies. There are also established guidelines in the country to perform this kind of study to ensure the protection of the patients and to clearly determine the responsibility of those conducting the studies. Today there is an estimated US$ 24 million invested in clinical trials annually, and this could easily double in a couple of years if regulations were updated by the government to become more advanced and agile in their allowances.

What steps is the government taking to develop the biotechnology sector?

I wish the government understood the importance of this, but there is no sign that the Ministry of Health is ready to take the necessary steps to exploit these opportunities. There is a worldwide trend of increasing discoveries of biopharmaceuticals and decreasing findings of new chemical molecules for pharmaceutical use. EMEA is at the forefront in developing guidelines for new biopharmaceuticals, and amongst their main principles is the idea that there cannot be a generic version of a biopharmaceutical. CIF has lobbied the government for the creation of a differentiated regulatory process for biopharmaceuticals so that their exclusivity, therapeutic efficacy and safety are ensured, but this has not happened yet. There is a draft document that we developed back in

2008 to address these issues, but it has not been approved. This then allows for the copy and imitation of biopharmaceuticals which is extremely dangerous to the health and safety of the Chilean population.

What other opportunities exists within the Chilean pharmaceutical industry?

Chile has the advantage that it is an economy that is truly based on the notion of free trade and competition. Prices are not regulated and therefore customers are given the opportunity to buy products at the lowest prices. Unfortunately some of these products are not equivalent and cannot be compared, but nevertheless competition is the driving force of the market. The only thing that CIF wants is that patents are respected to improve market conditions.

Additionally, the political environment of the country overall is quite healthy. We do not suffer from corruption and favouritism as in other countries. As I mentioned before, our research centres and education is also quite advanced and is very useful for studies and clinical trials to be conducted in the country.

You have 44 years of experience in the pharmaceutical industry, what is the most important lesson that you have learned?

What I have enjoyed the most working in this industry is the professionalism of the environment, particularly when it comes to human resources management that is based entirely on merit rather than on existing relationships. Many local companies, for example, have a history of hiring managers within the family rather than the most qualified professionals. The advancement of my career, from my days at Parke Davis and SmithKline Beecham until today, has occurred because of my achievements, and this is something that I truly value and respect within the pharmaceutical industry. When I first accepted this post I thought it would only be for a couple of years, but now, it has been 14 years at CIF and this is the evidence of how much I enjoy doing what I do.

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