Interview: Jean Jacques Duhart, Executive Vice President, Cámara de la Innovación Farmacéutica de Chile (CIF)

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“70 percent of products on the Chilean market cannot demonstrate quality, safety and efficacy through bioequivalence studies”, explains Jean Jacques Duhart,

Vicepresidente Ejecutivo of the association that represents the innovative pharmaceutical companies in Chile (CIF). Jean Jacques Duhart discusses the main challenges that his member are facing.

Mr. Duhart, you took the reins of the Camara de la Innovación Farmaceutica de Chile, A.G. (CIF) last year. What has surprised you most?

There is a distinct difference regarding generic drugs in Chile that you will not find in developed markets: generics in Chile are not ,in a large proportion, therapeutically equivalents, that is they have not demonstrate their efficacy and safety, as it is the case in the developed countries. This has been recognized not only by the health authorities but also by Fiscalia Nacional Economica – the national agency responsible for safeguarding fair competition. This is not merely a concern in terms of health and risk for patients but it also introduces an important market distortion—different actors are competing with different standards.

Patented brand name drugs only represent a small percentage of the Chilean pharmaceutical market. The rest of the market is split between ‘similar’ drugs produced by laboratories without a patent, private label drugs produced by a pharmacy’s own laboratory and generic drugs. Similar drugs are a peculiar category that only exists in Chile; these products are neither generics nor originals and have not demonstrate their quality, efficacy and safety.

According to IMS Health statistics, out of all registered medicines in the country by 2013, only about 20 percent are original products. Bioequivalent products represent a small 10 per cent of market penetration in Chile. The original and generic bioequivalent are the only ones certified in terms of quality, safety and efficacy, as recommended by the World Trade Organization. The remaining 70 percent of products cannot demonstrate quality, safety and efficacy through bioequivalence studies. This, naturally, is a huge concern for CIF because it creates unfair competition and also implies a huge risk for patients health.

In early 2014 the Ministry of Health passed a new law on the handling of medicine, which politicians had been pushing for almost five years to put into effect. What is your uptake of the new medicine law and what impact will it have on you members?

The changes introduced will make mandatory for physicians to include onto the prescription, beyond the brand name of a medicine, the generic name in case there is a bioequivalent available.

Unfortunately, the former Minister of Health communicated a wrong interpretation of that article of the law, saying that the mandatory inclusion of the generic name was in all cases, no matter if it was a bioequivalent or not. This misinterpretation contradicts directly the content of the bill, introduced a lot of confusion and uncertainity among actors in the health system, and put a serious threat to the policy of bioequivalence, promoted for many years in Chile, as it becomes irrelevant for interchangeability!

Through constitutional studies we have demonstrated that the state cannot force physicians to change their recommendation without ensuring therapeutic equivalence suitable for substitution. We have succeeded in that debate and are currently in the process of monitoring the implementation of the medicine law, especially in the wording of Article 101, which seeks to establish the mandatory generic prescribing.

For that reason we are in discussion with the recent appointed Minister of Health, Ms. Helia Molina, and her team in order to clarify the purpose and scope of the new medicine law. Because if the law would allow physicians to prescribe any generic drug including non-bioequivalent all efforts done by the previous governments would be for nothing.

What are the main market trends you have identified?

Beyond the need of closing the gap in terms of efficacy and safety for a large part of drugs commercialized in Chile (nearly 70% of them in units), another topic of debate in Chile is Quality Standards and Good Manufacturing Practices (GMP). There are still many old laboratories that need to comply with these standards. Data of Instituto de Salud Pública de Chile (ISP) report published last year revealed that a third of national laboratories do not fully comply with GMP standards. There has been a lot of secrecy around what is the real situation in this important matter as it not revealed the laboratories that are not complying.

As CIF, we are supporting bioequivalence studies as we strongly believe that this is the way forward to normalize to Chilean pharmaceutical market, creating a more equal playing field, and been in line with WHO guidelines. As a matter of fact, currently international companies are responsible for more than half of bioequivalent products available on the Chilean market. It is important to bear in mind that our members compete worldwide in both segments: original products and generics. People often forget that international companies such as our members are also the main producers of real generics at an international level.

Another critical challenge is that Chile has one of the highest citizen out-of-pocket expenditure on health and pharmaceutical products among Organization for Economic Cooperation and Development (OECD) nations. This has to do with the structure of financing the drugs cost. Opposed to many countries in the region, health coverage in Chile excludes medicines for a large part. As a result Chilean families spend more on health than the average in the region.

Logically there is a positive correlation between the level of development of a country and the level of health. Moreover, due to a rapidly aging population the country will have to increase the investment in health and medicines. This development requires immediate attention and in order to be efficient we will have to broaden the coverage of health insurance.

We were told in 2010 that Intellectual property rights were by far the most important challenge…

Intellectual property rights are important issues but not our main concern. Increasingly, companies are moving from patenting to data protection. Patenting is becoming increasingly difficult as the process lacks flexibility. Data protection is more related to the essence of the development of products. Currently we are in the process of improving the regulatory framework for data protection in Chile.

Are there any initiatives CIF is supporting to in increase the access of added value medicines?

CIF is supporting the activities of International Society for Pharmacoeconomics and Outcomes Research (ISPOR) in Chile. This international organization promotes the pharmacoeconomics concepts and tools for health care decision makers to increase the efficiency, effectiveness, and fairness of health care to improve health.

The Chilean pharmaceutical market must move to more institutional ways of evaluating and buying medicines. Developed pharmaceutical markets have become increasingly deeper where buyers are mainly institutions, not individuals. It is a basic economy lesson that buying larger quantities you pay less. Chile needs to move into that direction as well. The health system in Chile can be described as a two-tier system with two major types of health insurance – public and private but we still lack of good coverage for drugs cost.

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

This is definitely an interesting opportunity. Chile has great potential to become a regional leader in clinical trials, due to its qualified human capital base and the reasonable good regulatory framework, and have many important competitive advantages for developing such a cluster. Currently, Chile lead the per capita rate of clinical trials in Latin America (0.34 per 10 000 inhabitants, threefold of that of Brazil or Mexico).

Up until today the clinical trial environment has been seen as a matter for international companies. We are working on involving more local partners in clinical trials and research and development. It is our ambition to establish Chile as a leader for clinical trials and research in medicines.

With the goal of making Chile an innovation hub in the world, the Chilean Ministry of Economy and CORFO announced last year four multinational companies that will set up shop in Chile with their new research and development centres. One of these centres is built by pharmaceutical company Pfizer, which will invest in a precision medical centre studying new genome-based diagnostic technologies for cancer. These initiatives will have a tremendous impact on the Chilean market but also on Pfizer’s internal organization.

As CIF, do you believe you will actually have success in introducing member suggestions into ratified legislation?

Naturally we cannot work alone. We must improve our capacity to engage other partners in our discussions regarding quality, efficacy and safety. As CIF, we must engage all healthcare stakeholders, including insurers, pharmaceutical companies, providers, governments and others in order to provide the best healthcare to Chileans while at the same time ensuring an efficient regulatory environment for pharmaceutical companies.

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