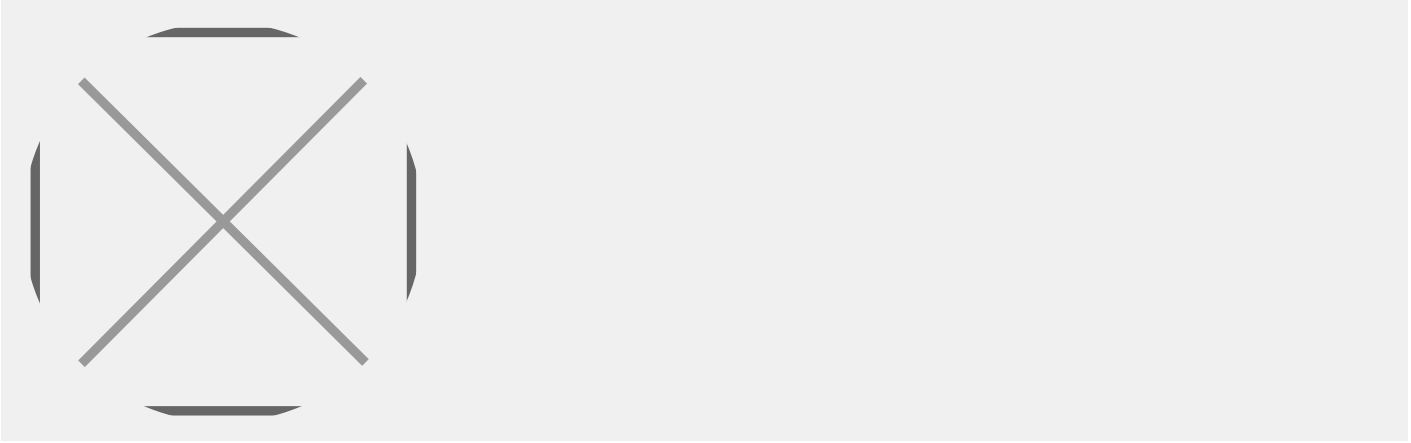
Interview with Renê Delsin, General Manager, Roche Chile



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How would you assess Roche's performance in Chile since its establishment and how has your portfolio developed in the Chilean market?

Next year marks Roche's 40th anniversary in Chile, which makes this affiliate younger than most of the other Latin American ones. This is mainly because from the beginning the Chilean market was dominated by local players and the government. To give you an example, Laboratorio Chile was a public enterprise at the genesis of the pharmaceutical industry in Chile, and this has impacted the way the market is managed until today. Multinationals came to the country at a later stage. Roche Chile at the beginning started with the traditional primary care business offering chemical compounds.

Today, Roche is fostering its position in Chile with innovative products for more complexes unmet medical needs (Oncology, Arthritis, etc) and working closer with government to incorporate new technologies in the public system,. As a matter of fact, we are currently growing above the market, mainly driven by our biotech drugs.

In spite of all the restrictions, we have succeeded in including some of our medicines in the Chilean system: the first one was a monoclonal antibody for lymphoma. Recently we also included another biotech drug for breast cancer. It has been clear for us that in order to develop our presence in this market we needed to improve the access to our products in the public system given that 80% of Chilean population is in this segment. Oncology has been a key business for Roche as it represents over 50% of our portfolio in Chile.. Furthermore, we are also using our diagnostics area to leverage our presence and deliver personalized healthcare.

Based on your experience in the industry, what would you say are the main challenges for Roche in the Chilean market today?

A first challenge for Roche today is to migrate faster from more basic primary care drugs to high-tech medicines, especially in an environment like Chile where the government's overall investment into the healthcare system is low.

The country has very good health indicators, life expectancy and quality of life when comparing with other countries in Latin America. Nevertheless, this is not totally related to direct investment into healthcare, but rather it is more due to basic homework that was done before in terms of developing the adequate sanitarian infrastructure and education. The public investment into the healthcare system reaches approximately 3% of the GDP while another 3% is invested by the private sector. When compared to other countries in our region, this 6% ratio is much lower than the average. Not to mention that half of this 3% of GDP invested by the government is composed by employees' contribution (7% of our salaries), thus the real contribution is approximately 1.5% – an astonishingly low figure indeed.

Therefore, our main challenge has been how to incorporate the new technologies, especially biological drugs, into the Chilean public system with such low investments.

Another key challenge is the regulatory framework for pharmaceuticals. Chile has signed on many international agreements, and we could expect that local standards and regulations would be in line with the international ones, including WHO, EMA and FDA. However, if we analyze into details the current situation the regulation is still very weak. If we consider the regulatory environment for pharmaceutical products in terms of a timeline, I would say that Chile lags behind ten years as compared to Brazil for example. Talking about generics, only very, very few copies have bioequivalence today in Chile. In the case of biotechnological products, intended copies have been approved using the same pathway of generics (against WHO recommendation). This is a challenge for the industry and health authorities to guarantee the quality of pharmaceutical products aiming to protect patients.

Specific to biotechnology, there are certain steps that the Chilean government must take in order to develop this sector. What do you think can be done in Chile to improve the legislation and foster biomedical innovation?

It depends on which kind of innovation we are talking about: local innovation is one aspect and another one is innovation brought to the country by multinationals through R&D and clinical trials. In the second case there is also a need to update the existing regulations, especially the point about ethical committees in line with international standards. In Chile, we have good investigators, good patient pool and a well-established infrastructure. Centers of reference are concentrated in Santiago and some other few cities what can facilitate the implementation of clinical trials. By developing the regulation, structuring approval processes in line with international standards, more

clinical trials could easily come to Chile.
Local companies have innovated in some industries, like wine and salmon. In the case of pharmaceuticals, Chilean companies have acted more as followers, launching copies or representing some international companies that are not present in Chile. The development of a new molecule requires big investments and a global scale. This is even more critical for biotechnological products, where complexity is much higher when compared with chemical products. By fostering collaboration with world class institutions, Chile could be more active in this field. Any way, it would require substantial investments and a new mindset, really focused on innovation.

What enhancements do you believe need to be made to the ISP in order to optimize the system and insure that patents are better enforced and procedures are improved?

From the structural point of view ISP needs to change its model. It should be an agency much more focused on core activities to guarantee the quality of pharmaceutical products to protect patients. For instance, even though GMP is an old concept, in Chile only a small percentage of companies have GMP and only very few products have bioequivalence studies. These facts alone are basic reasons why the regulations need to be improved and the public health institute needs to be better structured to enforce them.

What is Roche's opinion of the debate regarding patent violations in Chile? How has this affected your operations in the country?

Patents are crucial for innovation. Chile is improving in this field, but it still has some pendent issues like linkage. We are alert and defending actively all our rights. .

Chile seems to be a good clinical trial environment for its access to qualified technicians and a population with favorable characteristics. How has Roche been exploiting this opportunity? What do you believe is needed to expand the Chilean clinical activities?

Roche is currently starting to bring more international clinical trials to Chile. This is a very new development because they were not part of our national operations until now. We recently received the green light from our regional headquarters to start new Phase III trials next year in the Chilean market. Prior to this we had Phase IV trials in Chile. Our objective now is to bring to Chile new molecules that we have in our global portfolio, specifically for Oncology and CNS mainly.

Does Roche have any partnerships with universities in Chile as a means to foster biotechnological research in the country?

Roche is working close together with universities worldwide. In Chile, as I mentioned before, we have clinical trials in place and we intend to expand them. We also have some projects leaded by our Diagnostics Division like gene sequencers. I believe we can do more, and our intention is to

establish further partnerships. The universities are key players and a strong reference for innovation.

What is your vision for Roche in Chile for the next 3 to 5 years, and what is your final message to our readers of Pharmaceutical Executive about Roche's commitment to Chile?

We want to strengthen our position in the biotech field, where we are the leader today. We are number one in biotechnology but we are not yet recognized as such, so this is what we aim for the future years. Furthermore, we want to be seen as a partner for the government to improve patients' outcomes. As a source of new technologies, we want to work with them to improve patients' access to the new generation of biological products.

My final message is totally linked with this point. I would like to stress that our long term commitment to Chile is to bring innovation, personalized healthcare that can really improve patients' lives, and work together with all stakeholders to make it available to the largest number of Chileans.

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