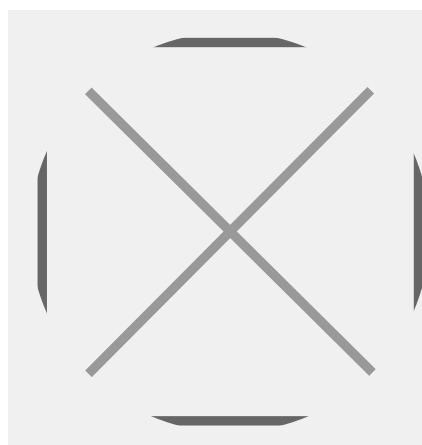


Interview: Sandra Sánchez y Oldenhage - General Manager, PROBIOMED, Mexico



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Sandra Sánchez, General Manager at PROBIOMED, explains the crucial role that biosimilars will play in the future healthcare system as well as the importance of complying with COFEPRIS' regulations to expand PROBIOMED's business within the region.

Last time we met with you, you explained that PROBIOMED was following a three tier-strategy: first, meeting the new COFEPRIS' requirements, second, establishing corporate governance, third, global expansion, and fourth, accelerating the development of the five products you had in your pipeline. Two years later, what would highlight as your main achievements?

During the last couple of years we have been highly focused on ensuring that PROBIOMED complies with the new COFEPRIS' Biotechnology / Biosimilars regulation and I am proud to confirm that we are well underway and on course to meet all stricter requirements. The entire company is committed to achieve this goal. We are working closely with COFEPRIS to make sure we meet every single requirement by the end of 2017.

COFEPRIS has done a remarkable job in becoming a reference regulatory agency not only within the region, but globally, at the time it aims for highest regulatory harmonization standards. To date, COFEPRIS has achieved PAHO certification (*Pan American Health Organization*), WHO certification for vaccines (*World Health Organization*) and PICs Certification for GMP standards and

quality systems (*Pharmaceutical Inspection Co-operation Scheme*).

PROBIOMED is vertically integrated, which has helped us control our costs, ensure high quality biosimilars, and deliver a better value proposition. However, the new regulation has significantly affected our business all throughout the manufacturing process – from the gene to the finished product. It has represented a colossal investment of time, money, and resources, but we are positive that once we are compliant, we will unlock incredible opportunities and markets as the new standards are perceived to be the benchmark within the region and at par with highest global standards. Therefore, it will give us quick access to other countries.

PROBIOMED is in the right place and at the right time to start exporting products. With local approval under the new regulation, plus, COFEPRIS' continued expansion of international recognition, it will come a day in the near future that Mexican market approvals (MAs) will be recognized on a "fast track review" thus accelerating market entry within Latin American countries. As a result of COFEPRIS' PAHO certification, Mexico MAs are now already recognized (*one-way recognition, e.d.*) by seven countries: Ecuador, El Salvador, Colombia, Chile, Costa Rica, Panama and Belize.

[Featured_in]

PROBIOMED's value proposition—to provide high quality products at a lower cost—is exactly what governments and patients are looking for: significant savings while expanding access and treatment. We are currently exporting to 14 countries located in four continents and we are planning to further expand to countries that really need these products and make our products available and accessible.

Regarding our internal affairs, specifically corporate governance, we have advanced significantly too. We have defined processes through which our company objectives are set and pursued in the context of our social, regulatory and market environment. We have identified the distribution of rights and responsibilities among different participants in the corporation, as well as defining the rules and procedures for making decisions in our corporate affairs. We have delineated and implemented the right policies, procedures, levels of authority, and the organization we need based on our mission, vision, and values. This goes hand in hand with balancing the interests of key stakeholders, such as the shareholders, financiers, customers, internal management, and the government; so I would say we have put together a holistic approach to achieve solid corporate governance.

PROBIOMED's value proposition is offering high quality biosimilars at a low cost. Considering you are the only vertically integrated company in Mexico for Biotechnology medicines, the new regulation impacts the company along its entire processes. As general manager, what have been your strategic priorities to ensure meeting these new requirements didn't impact your value proposition?

Correct, the fact that PROBIOMED is the only vertically integrated company in Mexico for biotechnology medicines, has helped us control our costs, ensure high quality, and deliver a robust value proposition. This gives us our competitive edge.

Today, all of the biotechnology companies (national or multinational) in Mexico either import API (Active Pharmaceutical Ingredient) or finished product, making cost control more complex for them as they are subject to import and cost variations from abroad. On the contrary, PROBIOMED produces biosimilar drugs from the gene to the final product, all in Mexican territory, and our value proposition will continue to be provisioning high quality biosimilars at a lower cost, resulting in significant savings; a dire need all institutions and patients across the world are in search of fulfilling. This gives them the capability of increasing access and treating more patients.

Indeed the new regulation has been a challenge; not an easy feat, in comparison to the rest of our competitors, our integration has given us full control on our costs and quality, thus a solid bar-none value proposition. We see this challenge as a huge opportunity.

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Our mission is to provide high technology medicines to the world in order to improve human health and patients' quality of life. We focus on serious chronic degenerative diseases that have a high social impact and economic burden; offering high-quality biosimilars at a lower cost, increasing access and treatment reach. We offer products for grievous illnesses such as cancer, rheumatoid arthritis, chronic renal failure, diabetes and multiple sclerosis, among others. PROBIOMED is a healthcare ally for Mexico and the world, as it has been able to address many challenges for both health institutions and patients that today have become a burden for many countries.

PROBIOMED has been marketing biotechnology products for more than 18 years, and have been pioneers within this growing field, a competitive advantage bar to none in the country. Our company is a benchmark in biotechnology; our history, our knowledge, and our experience in the field speak for themselves. Key to mention is the fact that we are the only company in Mexico that produces from gene to finished medicine, to which innovation has played a critical role within our development. Chemically synthesized drugs are relatively easy to manufacture and develop;

however, in the case of biosimilars, the development and manufacturing process is much more complex, since it is created from living cells. Today we have 16 registered biotech drugs and several in development, which is the largest portfolio of any company in Mexico. Our trajectory, solid experience, know-how, and a first-class team (in development, manufacturing, regulatory approval and commercialization), all together make us a leader within the market.

What is the rationale behind such structural change?

As market dynamics, regulation and competitors change, resources (financial and human), time and effort become more and more pressured and considerably higher. We see that new regulation requirements have been significantly increased, while current competition is becoming fiercer and more aggressive; with more incumbents entering the Mexican market. Finally time to market overstretched, and the country's economic context strengthens the importance of finding the right balance of quality and cost to address cost containment issues.

For this reason, PROBIOMED is undergoing a process of evaluating strategic alternatives to ensure we have the adequate resources to face all these challenges and guarantee time to market and accessibility of our products that many countries are in dire need to rely on.

Having the right partner would help us to accelerate time to market which would allow us to hold a stronger position among actual and future incumbents. For years we have relied on one sole team fully dedicated to developing new biosimilar products one after the other, with no real pressure on time to market as there were not enough players in the market. Today, this has changed significantly, making it difficult to stay on top of the game unless we further invest in R&D and develop biosimilars in parallel and be first or second to market in order to actually reap the benefits of that target segment. So finding the right partner / ally(ies) will definitely accelerate this process and help improve capabilities to develop more products in parallel like big pharma does.

The company is very proud of what we have accomplished in 46 years; competing with big pharma companies is not an easy feat and today we are a strong player and a threat to most incumbents. We plan to continue growing our share and value, and position PROBIOMED as global player and benchmark, whether that requires going at it alone, partnering or else.

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What do you see as your remaining plans to further grasp the biosimilars opportunity and enhance PROBIOMED's commercial performance in Mexico?

Mexico is facing very severe challenges in terms of: demographic and epidemiological change; increasing of diseases and number of patients; smaller number of tax payers; reduction of public budgets dedicated to acquiring new treatments. Because of these reasons, we have to visualize opportunities and contribute in an efficient and opportune way, in the following fields. First, research for treatments that can become a solution for Mexican patients. Second, biosimilars will continue representing a great business opportunity given that the biotechnology market is expected to continue growing at a double digit pace (est. 25% annually) as the patent cliff gets closer, with aggregate sales close to USD90 billion. Third, being an active player and fostering circumstances that favour the development of pharmaceutical biotechnology in Mexico as they represent high added value products. Fourth, the biotechnology market represents a great opportunity, not only in Mexico. Government agencies in many countries are looking for savings in their health budgets. At PROBIOMED, we see it as an opportunity to continue growing by means of supplying quality products at a reasonable price worldwide.

The biosimilar industry is in a very rapid pace of development, maturation and harmonization. As the certainty to enter markets throughout the world becomes clearer, with a harmonized regulatory framework further evolving, the penetration of PROBIOMED's products will follow.

PROBIOMED is dedicated to the development and commercialization of high quality biosimilars that can offer value through unquestionable quality and improvement in access to medications. In order to accomplish this, we have to be extremely responsible in the investments we make into demonstrating the quality of our products. We believe that an over investment in studies that are not scientifically or regulatory sound will defeat the value of a biosimilar, challenging their cost offering. Some country regulators are still struggling with these requests, due in part to the novelty of the industry.

As the industry matures so will the requirements throughout the world to demonstrate that manufactured products are of high quality, safe and effective, placing more emphasis on the chemical and physical composition of the medicinal product and less emphasis on the redundant, expensive, and sometimes un-ethical, clinical trials.

PROBIOMED manufactures to the highest quality in the biopharmaceutical industry, we have valuable products that can be shared with the world that is in need of them. Additionally, we continue to grow our pipeline of products in development. Currently, we have 5 products under

development.

Our goal, is to develop biosimilar medicines that will rank in the top tier patient treatments globally. For this to become true, we intend to keep working on offering products that will help patients in developing economies, where they are the most needed, thus focusing on chronic degenerative diseases that have the highest social and economic burden.

One of COFEPRIS' strategic pillars has been to open the door to generics to make more complex expensive treatments available to a larger number of patients. Do you think this can be duplicated for biosimilars as well?

The highest prices payers and patients are currently spending are for biotechnology products as a result of their high effectiveness in the growing chronic disease areas. Biosimilars, however, offer a solution to this situation, drastically lowering the costs that payers have to spend while offering up-to-par effectiveness and safety.

Biosimilars contribute to institutions' savings and cost containment initiatives, reduce patient out-of-pocket, increase access and patient treatment. A good example of this, in Mexico, is actually represented by the entrance of one of our products to the market: erythropoietin. For this medicine, used to treat anaemia in patients undergoing dialysis and/or chemotherapy, price dropped 90% since the entry of the biosimilar in 2000, while patients treated rose from 3500 before 2000 to more than 80,000 patients in 2007. Finally, estimated savings in health sector from 2000 to 2015 amount to more than 7.470 billion pesos [around USD511 million], which represent the budget needed to build 10 regional hospitals with 250 beds, 10,000 ambulances and 122 clinics with 10 consulting rooms each.

PROBIOMED has always had the goal of offering high quality biosimilars at a lower price, allowing patient out-of-pocket savings, as well as institutional budget savings. We will continue to offer this, given it is one of our main differentials.

In summary, the value proposition of biosimilars is well aligned to COFEPRIS' objectives. Indeed, companies like PROBIOMED offer high quality lower cost biosimilars, which clearly translate into economic savings as well as better market access and treatment reach.

The TPP would open and strengthen new export potential for PROBIOMED while in the meantime heighten regulation around data exclusivity. As a result, what is your assessment of the impact it could have on PROBIOMED?

We are convinced the agreement will provide the pharmaceutical industry with much needed impulse, towards the patient's benefit and the health institutions of the country.

We recognize the work of the former Commissioner of Cofepris Mikel Arriola *[now General director of IMSS, Mexico main social security institution, e.d.]* in having positioned COFEPRIS as a leader and a benchmark for regulatory agencies from countries participating in the TPP. As well as their prominent role in the negotiations of this agreement that will, without a doubt, promote economic growth and pharmaceutical innovation in Mexico. It will also impact positively in terms of the capacity to treat a larger number of patients in our country and become crucial for the health sector in the region.

However, Mexico needs to foster and enhance its local manufacturing of Biotechnology medicines in order to take advantage of the export potential. Local manufacturing, both for API's and biotech products, has drastically dropped and currently 97 percent of the API's consumed in Mexico are imported.

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What is your vision for the company and the objectives that you will like to have accomplished in the following three years?

I see PROBIOMED as the vanguard of a new life sciences growth model centered on the unmet health needs of emerging country markets, one built on low-cost, high-quality "frugal" innovation. PROBIOMED is unique in Mexico for our strategy that begins with knowledge of the gene, developing cell lines, and progressing to an end-product based on the underlying biology of a specific condition. In Mexico we can do that efficiently because we are the only company vertically integrated, and for less than what it would cost in the US or Europe, thus making life-saving medicines available to vulnerable populations – expanding access and treatment, lowering costs and demonstrating savings. This value proposition is what any country in the world, especially emerging markets are in dire need of.

PROBIMED's business model is consistent with a key public health objective for all countries, rich or poor—to find savings from the substitution of off-patent innovator biotech products for safe, high quality, low-cost biosimilars. These savings can then be applied to investment in the next generation of innovative biologic therapies or infrastructure, both critical in any healthcare system.

The next step is making PROBIOMED a true global player in biotech. This means approaching business as a community-building effort. We have to do a better job at the politics of working with all stakeholders to secure that 'win-win' outcome.

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