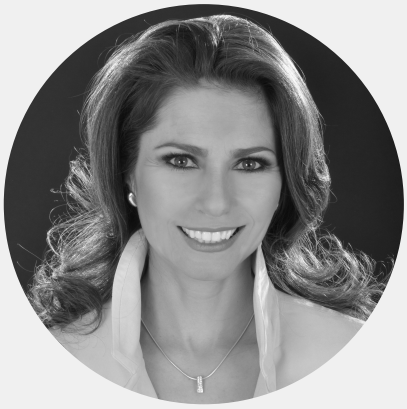
Probiomed – Sandra Sanchez Y Oldenhage, General Director – Mexico



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Probiomed wants to move to the next level. The recently appointed general director discusses her plans to grow the business and expand internationally, leveraging the company's in-house developed biotech products and vigorous pipeline to become a reference company for biotechnology worldwide, without forgetting work-life balance.

You have been appointed as general director of Probiomed in May 2014 as part of the company's 10-year strategic plan to grow the business and expand internationally. What mission were you entrusted with when you were appointed?

Probiomed has been in the industry for 45 years and has been a family business all the way, moving from selling APIs to generics and finally entering the segment of biotech drugs. The founder and current president of the company, Jaime Uribe de la Mora, realized that to take the company to the next level, he needed to bring external expertise and he was sure I would be the right person 'for the job'. I am convinced that my 26 years of experience in the industry will help to further build on this endeavor.

In my position as general director I have a three-fold mission: institutionalize the company (establishing and enabling corporate governance), expand it internationally and drive organic growth with in-market products and the development of new drugs. This strategy will allow the family business to accelerate growth in a disciplined manner, maintain competitiveness and

ultimately become a strong global player in a rapidly changing external environment. An environment where you need to reinvent yourself to ensure you can endure the challenges and boldly harness the opportunities. The pharma industry is facing a critical patent cliff, consolidation and drying pipelines at the time that regulatory frameworks are becoming more and more stringent and scrutinized, demographics and epidemiology are shifting to older patients with costly chronic degenerative diseases and public healthcare budgets are shrinking, thus establishing cost containment programs.

All these dynamics are significantly changing the landscape and are forcing mid-sized companies to adapt, reinvent themselves and move to the next level.

Everyone we have met has told us that Mexico is at the forefront in Latin America in terms of regulation for biotech and biosimilar drugs. How would you assess the current regulatory framework and what needs to be improved?

Commissioner Mikel Arriola has worked very hard to transform COFEPRIS (the Federal Commission for the Protection against Sanitary Risk) into a Regulatory body of regional reference, not only within Latin America, but positioning it globally. Among other successes, under his leadership, his team was able to achieve the Pan-American Health Organization certification for both pharmachemicals and biologics / biotech and the WHO certification for vaccines. Mexico's regulatory framework for biotech and biosimilar drugs is now one of the best regulations in the world; I would dare to say that probably at the level of the FDA and EMA.

The biotech regulation was only one of Commissioner Arriola's agenda items, and as with many other achievements, he was able to deliver on this. The Mexican official standard NOM 257 is expected to be published by the end of this year. Despite tough and heated discussions with industry players, he was able to shape a solid proposal, integrating different opinions and positions, with the patient's benefit at the center of everything.

The challenge and focus now, for any company playing or wanting to play in this biotech / biosimilar sector, is to ensure it meets the new regulation. This will not be an easy feat, as it will entail additional work burden, lengthy timelines, precise planning and "deep pockets". All of this in a country context where infrastructure in this sector is still lagging. As an example, one of the tests needed for a biosimilar to demonstrate biocomparability is a characterization testing. However, depending on the magnitude of the test very few companies in the country have this capability, if at all; hence you need to outsource it from other countries, increasing costs and timelines. So at the end, Mexico still needs to develop the necessary infrastructure to make sure we can meet the

regulation without relying on outside suppliers; and all players will need to promote and foster this development. There is still a gap, but at the end, the only way to ensure this is developed, is by placing the bar high enough, as the new regulation has done.

For Pobiomed this has a huge implication as we are the only company that is fully integrated – we manufacture from the gene to the end product medicine. The new regulation impacts us along the entire process, so the challenge becomes even more defiant.

COFEPRIS will soon publish the revised official Mexican standard NOM 257 to regulate biotech drugs and biosimilars. How do you think it will impact the industry?

The regulation approved in 2012 was crucial, but it did not go into by law specifics, so the next “to be published” NOM 257 (expected December 2014) will be critical to clearly understand and eliminate any ambiguity on what the specific requirements will be to obtain approval for a biosimilar (“biocomparable” as named in Mexico). I truly believe the NOM as it stands in the discussions and draft we saw, represents a reasonable intermediate position between AMIIF’s (the Mexican Association of Pharmaceutical Research Industries) stance and the one of ANAFAM (the National Association of Pharmaceutical Manufacturers). The approval of the standard now implies a successive two-step process: as a biosimilar company we first need to move on with the renovation process of the biotech products which were approved under the former regulation (approved as generics as they have been in the market for up to 17 years), and then prepare for the new products / products in development, guaranteeing we fully comply. COFEPRIS has offered the industry support to “shepherd” companies in the process to warrant a smooth transition.

The current challenge for Probiomed is the amount of biosimilars we carry in our in-market portfolio and those in development – we are the only company with 16 products in the market and five in development. Hence, the implications are huge while we need to continue operating. We need to make sure that in the process, we do not compromise time-to-market of biosimilar products. We are fully committed to expand our reach and guarantee access to more patients that are in dire need of our products – high quality biosimilars at a lower cost.

Nonetheless, the opportunities are great: the fact that COFEPRIS has been recognized by the World Health Organization and by the Pan-American Health Organization makes Mexico a country of reference, which can accelerate our entrance to those countries which have started to recognize Mexico’s MA’s (marketing approvals) as well as seize the prospect of exporting vaccines worldwide. This will definitely accelerate our global expansion strategy, once we meet the new standards.

Probiomed has always been one step ahead of the market. It first entered the API segment, then generics and today is pioneer in biotechnology here in Mexico. What is going to be the company's next step?

Our focus in the short term is a three-tier strategy: first, we need to ensure we meet the new regulation requirements. This does not only have an impact on product approval, but since we are fully integrated, it has implications on GMP's (good manufacturing practices), on the manufacturing process, product itself as well as products under development.

The second thing we need to do is build our new state-of-the-art plant for biotechnology products to ensure we have the capacity to meet unmet biosimilar needs and reach more patients. We are currently deciding where we are going to build our plant, given the investment required for a biotech plant compared to a pharma-chemical one can range from five-to-ten times higher depending on the dimension and technology needed. As you have probably already seen in the news, we are also looking at other countries, because of the incentives they offer to attract such an investment. We obviously want to keep the investment in Mexico, but at the end of the day we need to assess what is the best option for the company in the short, mid and long term; considering time and complexity to access markets and patients.

The third pillar is accelerating the development of the five products we have in our pipeline. Albeit, we need to meet the former two priorities I just mentioned. We plan to be at the forefront and need to be strong enough to move to new product launches.

Our vision is becoming the global biosimilar company from Mexico to the world. We are already in four continents and are exporting to fourteen countries, with a differentiated premise. What distinguishes Probiomed is its value proposition: we have quality biosimilars at a low cost. There are companies, which have biosimilars but not at a low cost and some which have cost but not the quality. We have the best of both worlds to offer patients worldwide.

Some weeks ago we were with Dr Francisco Bolivar talking about how Probiomed is an excellent example that partnerships among private companies and academia can create success stories. What do you think needs to be done in Mexico in order to have more of such success stories?

Probiomed is the only company in Mexico, which produces from gene to product. No other company does that in-country. This is the reason why the company has been able to keep high quality at low costs, while most of the local and international companies import either API and/or finished goods. Under this promise there is a huge opportunity for strong partnerships. However, in

order to make such partnerships materialize, the government needs to help by declaring and fomenting the biotech sector as one they want to develop, as it was the case of aerospace technology and wind energy. Otherwise we are alone against this challenge, and it will really become a colossal one.

Three factors drive country competitiveness: a healthy population, innovation and investment in breakthrough sectors that are critical to drive growth. Today Probiomed is alone in the development and manufacturing of biotechnology medicines arena in Mexico – as the industry does not seem very interested in relying on local manufacturing – fostering such partnerships between private industry, government and academia to develop biotech products or infrastructure will be tough. Nonetheless, Probiomed does work very closely with UNAM (the National Autonomous University of Mexico) and CONACyT (the National Council for Science and Technology), among others. We create 1,300 direct jobs in Mexico and rely on some of the best researchers in the country. Many of these positions are highly qualified jobs.

Looking at the epidemiological profile of Mexico, which therapeutic areas do you see growth coming from?

I see growth coming from diseases such as diabetes, cancer, chronic kidney disease, cardiovascular diseases and autoimmune diseases such as rheumatoid arthritis, multiple sclerosis; those which have an incredible impact on budgets and society. These are the areas with high unmet medical needs world-wide, and of course Probiomed is focusing on them. We are here to make a difference and our mission is to focus on enhancing patient's quality of life and human health.

Let me give you an example of the potential health problems I foresee and how Mexico's future health projections look grim. Currently Mexico has 75,000 patients on dialysis as a result of chronic kidney disease (CKD); additionally 6 million more have diabetes, which is the main cause of CKD and will end up in dialysis. Moreover, obesity is a key risk factor for diabetes and cardiovascular diseases, adding to the problem. Mexico is the 1st country worldwide with children obesity and the 2nd in adults. Imagine the trickling chain effect of diseases and it is scary.

Furthermore, if we look at the impact this demographic and epidemiology shift will have on budgets, it doesn´t look good at all. As it is they are already pressured. And what about out-of-pocket expenditures? Mexico has the second highest out-of-pocket drug expenditure among the OECD countries, only surpassed by Hungary. Hence, the only way to target this issue and make payers and patients budgets allocation more efficient is for biosimilar and innovative biotech drugs

to coexist. Once the patent expires, biosimilars need to come to market to ensure government savings, which could only then be reinvested in innovation. If you don't create this virtuous cycle, there is no way to properly address the budget issue.

Picture the following context: older patients, with more chronic degenerative diseases, with more diseases, where the better options are biotech treatments, for longer periods of time and with less young people paying for retirement funds. Biosimilars of course present a solid alternative to the growing demand of biotechnology products.

So where are we going to see Probiomed in five years from now?

Probiomed will be a reference company for biotechnology worldwide. We plan to be a major player – that's where we want to be and that is what we are focused on. And with a value proposition – high quality at low cost – which any healthcare institution in the world is looking for, I only see success.

You have been working at international multinational companies such as Pfizer and Amgen for a long time. What attracted you to a national company such as Probiomed?

There were two reasons behind my decision, a personal and a professional one. I'll start with the business one, which is unquestionable. From a professional standpoint, biosimilars are going to be the growth drivers moving forward. If I had to choose a company in Mexico, which has the best opportunity for growth, it would definitely be Probiomed. I truly believe Probiomed is one of the few companies poised for success worldwide.

There was also a personal reason. In September 2013 I had the opportunity to move to Germany. Unfortunately, two weeks after my decision, my mother was hospitalized and everything in my life changed. My priorities had to shift. For years I have been focused on my career, enjoying it and very passionate about it. However, seeing my mother in the hospital for many months, made me challenge my status quo and I realized that I wanted to spend more time with my family in Mexico. I had to rebalance my life and make tough decisions. As a result, I decided to stay in Mexico – my family needed me and I wanted to spend more time with them. So I needed to be in harmony with what I wanted, and the best opportunity I had to match professional challenge and personal aspirations was Probiomed. And after almost one year in the position, I can attest – I made the right decision. I am thrilled with the opportunity, passionate about the challenge and I am walking my personal-life talk.

What would be your piece of advice to female executives that would like to have management positions in the healthcare sector?

One of the most important barriers I especially see in Latin American women is ourselves. We think we cannot do it, we think that our second role as mothers and caretakers is the most important one and that matching professional and personal objectives is impossible. My word of advice is that work-life balance is not a noun, it's a verb and it is possible. You need to live this as an active balancing act – walk the talk. This means that depending on the stage in your life, your priorities at the time and what success looks like for you – you actively need to reflect that with actions; and these will differ as you evolve. If you are 20 years old, not married and want to become a top executive, you need to ensure you are getting all the experience you want, you might need to stay late hours, work hard, travel a lot, and so on. If your actions reflect your priorities and aspirations at that time, then you are achieving work-life balance. But if you are 32 years old, want to be a mom, then you can't work long hours, stay late and travel – if you are doing this, then you are not achieving work life balance.

A further advice I would like to convey to women is – be visible. Since we usually have second roles, you often make the best of 9am – 5pm jobs to also be able to spend time with your family and children, but if you stay in your office, have lunch at your desk and are not out there talking to people, networking, no one sees you, nobody knows who you are. Try to balance visibility with privacy. Nobody will think of you when making a choice for a promotion if they don't see you or people don't talk about you. Visibility is critical, and you need to be out there. I truly believe women should be bold, take risks, lift their hand up and follow their dreams. You can do it all, it is a matter of balancing priorities and aspirations with your stage in life.

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