Interview: Maarten Pouw – BU Director Mexico & Latin America, DSM Sinochem Pharmaceuticals

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Maarten Pouw, business unit director of Mexico and Latin America at DSM Sinochem Pharmaceuticals, explains the crucial role that sustainable antibiotics play in combating antimicrobial resistance and showcases the company's region-wide commitment to offering

reliable, compliant and sustainable APIs.

Could you please introduce to our international audience the key activities and operations of DSM Sinochem in Mexico and in the region?

In Mexico and Latin America, DSM Sinochem commercializes its full range of anti-infective, cardiovascular and anti-fungal products. We market the same portfolio as in our other global markets. There are however strong local differences on which APIs are preferred between countries. The company is running a global business but it is structured in four geographic regions.

Within our global manufacturing network, Mexico is an important hub for DSM Sinochem Pharmaceuticals. We produce a full range of semi-synthetic penicillins that we are commercializing globally. A unique factor is also that we are the only penicillin manufacturing facility located outside of China, which has critical approval from all leading worldwide regulatory agencies such as the FDA. Mexico, in this sense, plays a very strategic role in supplying not only Mexico and Latin America but also the rest of the markets we are stepping into such as Europe and the USA.

You were appointed business unit director of Mexico and Latin America in 2014. What is your assigned mission?

My mission is to strengthen our operations in Mexico and the rest of the countries within the region. DSM Sinochem Pharmaceuticals has a long history in the country but we have perceived a lot of competition coming from Asia. We want to be successful in this market and, for that, we need to have the best resources in terms of facilities, technology and human capital.

The core message that the management board gave me when I was appointed as business unit director of this region was to build up a sustainable and profitable business across the territory. DSM Sinochem Pharmaceuticals enjoys a leading position within the region since all our products commercialized in Latin America have a large market share. However, we are fully aware about the high dynamism of the industry and this is why we are continuously finding new ways to bring more value to our customers.

How strategically important is the Mexican affiliate within the regional and global operations of DSM Sinochem Pharmaceuticals?

We have a long history in the country and last year we celebrated 45 years of local penicillin production in Mexico. I would say that this alone demonstrates that we are really active in this country and gives you a fair impression of how strategic Mexico is for us.

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In terms of size, Mexico is the second largest market within Latin America after Brazil, followed by countries such as Colombia and Argentina.

We truly believe in the strong potential of the Mexican pharmaceutical industry being positioned as the 11^{th} market globally. From the perspective of the API sector, the Mexican market has gained a lot of competition due to the fierce entrance of Chinese and Indian competitors. In addition, it is important to mention that Mexico is considered a gateway for the rest of the countries in Latin America and the USA from a geographical perspective. Such factors position the company in a strategic spot to distribute the products to neighboring countries.

“Think global, act local” permits DSM Sinochem Pharmaceuticals to align the strategy of each BU to the global guidelines while implementing actions targeted to local needs. As the leader within the region, could you explain to our international readers how this is translated to your region?

The implementation of our strategy in the region is driven to a large extent by our ambition and ability to be with our clients here. Through face to face interaction, relying on local employees, we are able to get a better understanding of client needs. We combine this with strong internal guidelines, strategies and principles.

These strategic guidelines help us to really extrapolate from one region to another any best practices. We enjoy a very dynamic and active communication with the rest of the regions to ensure such synergies; we reap the benefits from our global knowledge which we can then implement according to local particularities.

DSM Sinochem Pharmaceuticals has quite a comprehensive product portfolio sorted into six business lines: penicillins, intermediates, SSPs (Semi Syntethic Penicillins), SSCs (Semi-Synthetic Cephalosporins), anti-fungals and cardiovascular. Where do you foresee the most growth coming from?

On one hand, we have products in our portfolio that are well established in the market that have been commercialized for a long time. Such products have quite a stable and steady sales performance as a consequence of their mature stage.

On the other hand, if you look at the corporate business development strategy we are expecting to experience strong growth coming from cardiovascular and anti-fungal products. Such products are quite innovative solutions and we are enlarging our product portfolio in these areas.

Additionally, I also foresee growth coming from our integration into drug products. I think that it is also going to be an important driver of expansion for DSM Sinochem Pharmaceuticals in the future.

The WHO classifies antimicrobial resistance as one of the top threats to humanity. 700,000 people fall victim to antibiotic-resistant bacteria annually and according to the AMR Review headed by Jim O’Neill, 10 million people will die annually due to antimicrobial resistance by 2050. This obviously affects humanity but also your business. How is DSM Sinochem Pharmaceuticals approaching this challenge in Latin America?

Antimicrobial resistance (AMR) is a major global health and wealth threat. There is increasing evidence that irresponsible manufacturing accelerates AMR due to the uncontrolled release of antibiotics into the environment. In particular, water courses downstream of production facilities may contain significant concentrations of antimicrobial activity, and risk becoming breeding grounds for resistance. With the increased movement of people – including those carrying resistant

bacteria – AMR can spread widely.

At DSM Sinochem Pharmaceuticals we strongly believe in producing essential life-saving antibiotics in the most responsible and sustainable way possible. This can help conserve the effectiveness of existing antibiotics today, and for generations to come.

Regulation is definitely needed, but it can take several years until it is implemented. DSP doesn't want to wait for regulation and firmly believes that the industry should take responsibility now. The industry and the entire value chain have to act responsibly and stop buying, using and selling irresponsibly produced antibiotics.

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We have also been one of the driving forces in establishing the UNGA Roadmap for Progress on Combating AMR, signed by 13 leading global pharmaceutical companies, including DSP. We call on other antibiotic manufacturers to show leadership and join the UNGA Roadmap too.

In October 2014, we launched our Sustainable Antibiotics program, initially targeting our own in-house waste water treatment process. We have already implemented the basic requirements for clean and sustainable antibiotics production at all sites, including using the cleanest production technology available for our products and operating dedicated wastewater treatment plants 24/7/365 as an integral part of the manufacturing process at all sites in combination with antimicrobial activity testing.

How are you partnering with stakeholders in Mexico and within the region to advance towards a solution and what has been the response so far?

DSM Sinochem Pharmaceuticals is the only antibiotics producer in Mexico and, therefore, we are in the spotlight of Mexican regulation in this area. Obviously, the sense of urgency in Mexico is completely different from the existing one in other countries with a more active industry in antibiotics manufacturing such as India and China.

However, the commitment is there and there is still a lot of debate going on nationally and regionally. In Latin America we are trying to communicate to public and private stakeholders all the health issues related to antimicrobial resistance. We are fully aware that we cannot solve such challenge as a sole company and we are therefore actively dialoguing together with the sector. I am proud to say that the response has been quite positive so far and we are glad to be leading such process in the region; it ensures that DSM Sinochem Pharmaceuticals will be able to anticipate any regulation change in this area.

DSM Sinochem Pharmaceuticals' Mexico site is the only remaining FDA approved site that can produce Penicillin G in the American continent. What makes Mexico attractive as a manufacturing center for pharmaceutical products?

Mexico is a very attractive country in terms of its broad pool of highly educated professionals, its easy entry to the rest of the countries within the region, and the access to raw materials, among many others. Notwithstanding, the aforementioned factors need to be encompassed with top-notch technology in order to maximize its potential. Such reasons lead to DSM Sinochem Pharmaceuticals' strategic decision to strongly invest in developing the manufacturing capabilities in Mexico and now we enjoy the only remaining FDA approved site that can produce Penicillin within the entire continent.

Cofepris aspires to be the standard of quality in the region, meeting the standards set by the EMA and FDA. What are your conclusions on that and how can it be a lever to continue driving the internationalization process of DSM Sinochem within the region?

Harmonization of regulation is a global trend and other countries such as Brazil are also following it. In my opinion, this is the right direction because it ensures that all the players within the industry are following the same rules. Even though DSM Sinochem Pharmaceuticals is already applying the strictest regulatory standards to all its manufacturing capabilities, such dynamism needs to be encompassed with a continuous update of our operations; it is a non-stop challenge.

Obviously, the fact that Cofepris is currently in the spotlight of regional health regulation positively affects our business and makes it much easier to export our health solutions to other countries within Latin America.

What are your competitive advantages that make you the provider and partner of choice for the industry?

What sets DSM Sinochem Pharmaceuticals apart is our full backward integration and control of our supply chain. In all of our APIs we strive to bring the highest quality product produced with the latest and most sustainable technologies. For example, the PureActives®, our sustainable antibiotics and next generation statins, deliver unique quality and performance in the finished dosage formulation. They are also a very sustainable alternative to chemically produced antibiotics.

Due to our extensive experience in many of the worlds markets including those with the toughest regulatory requirements our customers enjoy the confidence that we meet the latest regulatory

requirements. Our focus and drive for continuous improvements allow us to stay ahead of the dynamics that shape our markets.

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What are the key objectives that you would like to achieve in the upcoming three years?

One of my main objectives is to maintain the commitment that DSM Sinochem Pharmaceuticals has always had with the regional healthcare sector in terms of delivering the right health solutions with long-term values. In this sense, we want to expand our product portfolio, our manufacturing capabilities and our footprint in Mexico and Latin America. This means that we will continue to focus on developing our people and capabilities to match the market requirements across the value chain.

On a more personal note, with the lack of new antibiotics in the pipeline we have a joint responsibility to keep the existing antibiotics effective: we all have to play a role to take, use and make antibiotics responsibly!

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