Interview: Gurulinga Konanur – General Manager, Hetero Mexico

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Hetero, the global API leader, has consolidated its position as the partner of choice of the pharmaceutical industry in Mexico, with a portfolio of more than 300 APIs. GM Gurulinga Konanuris is piloting entry into the B2C market, with upcoming launches of biosimilars, oncology and HIV treatments. Hetero is also investing more than USD 50 million in the country to develop its manufacturing capacity of high-specialty products.

You were recently appointed GM of Hetero Mexico. What attracted you to embark on this new challenge?

As a vertically integrated company, Hetero holds a width of portfolio that is absolutely unique for an Indian company, but also from an international standpoint. We manufacture and market high-quality products through the entire pharma value chain, from Intermediate to Active Pharmaceutical Ingredients (API) and Finished Formulations. Holding such a range is particularly attractive in terms of growth opportunities, but also with regards to the stimulating challenges it brings to my daily responsibilities as general manager. While I had previously held general manager positions in the B2C segment, Hetero's entry strategy in Mexico was centered on our API segment, the company's core segment at a global level. This specificity was particularly exciting for me, as it offered me the opportunity to strengthen my understanding of the B2B sector, while I can now leverage my industry experience as we are entering the specialty B2C segment.

Furthermore, the growth trajectory of Hetero, which was only founded in 1993, is absolutely mind-blowing. After only two decades in the market, the group displayed global sales of USD 1.5 billion in 2015. Hetero definitely stands as a very ambitious company, whose aggressive growth strategy has proven being extremely successful.

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Finally the Biotech, since my post grad in biotechnology at the university, this field has always been of great interest to me. Over the past few years, Hetero has been able to tremendously develop its biotech competences, while our biosimilar division now stands as a strategic priority within the group's development plan. Although we decided to venture in this promising segment only in 2009, the group was able to rapidly gather a multi-disciplinary team of over 200 specialists to start related research and development projects. In 2011, Hetero's state-of-the-art R&D and biotech-manufacturing facility was officially opened. In India, we already brought three different biosimilars to the market, and we currently have four promising biosimilars in our development pipeline.

Hetero entered the Mexican market in 2011, but the Indian company has been growing extremely fast to reach around 20 million sales in 2015. What were the strategic priorities you set yourself when you took over the helm of the affiliate?

In Mexico, we want to leverage our leadership position in the B2B business (API & Finished Formulations) to enter the B2C segment through our high-specialty generics and biosimilars. In the United States, our entry in the B2C segment has been extremely successful, and we decided to build manufacturing plants to sustain the development of our products. Considering our remarkable success in American market, we decided to replicate a similar approach in Mexico, with a focus on highly specialized treatments, such as Biotech, Oncology and Anti-retroviral (ARV) for HIV/AIDS.

To provide Mexican patients with these life-changing but affordable treatments, we also decided to bring our technology & manufacturing expertise from India to Mexico and to set up a substantial manufacturing facility in the country – only four years after having initially entered the Mexican market. The rapidity at which we decided to develop our manufacturing arm in Mexico clearly illustrates the aggressive growth philosophy that truly characterizes Hetero.

Overall, this manufacturing facility represents an investment of more than USD50 million over the next five years. This plant will follow the most stringent manufacturing regulations, including FDA / EU standards, which will ensure we can swiftly start supplying the Mexican market. Furthermore,

by leveraging COFEPRIS' international recognition, we also expect to start exporting our treatments to Central and South America.

Hetero clearly stands as a company that considers Mexico a regional hub for its development in Latin America. As general manager, what has been your experience in setting up the company's manufacturing footprint in the country?

Mexico is a country where new market entrants can expect to receive an extremely valuable support from the government and other public and regulatory authorities. Government agencies dedicated to foreign investments as well as key regulatory partners have been particularly helpful since we entered the market, by closely accompanying us through all the regulatory and legal steps we had to reach.

Furthermore, Mexican stakeholders are indisputably committed to bring more foreign investments to the country, and healthcare-related and innovation-driven companies are evermore warmly welcomed. Mexican public partners are very sensitive to the employment opportunities that foreign companies can bring to the economy, which rendered our manufacturing facility project particularly appealing to them. In comparison to other parts of the world, setting up a healthcare business in general and a manufacturing facility in particular are not so difficult in Mexico, where key stakeholders strive to make your life easier and ramp up the maturation phase to help you be operational as soon as possible.

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Looking at your biosimilar portfolio, Hetero recently launched Bevacizumab (angiogenesis inhibitor) in India, after Darbepoetin alfa (to treat anemia) and Rituximab. How are you progressing in brining these treatments to Mexican patients?

As COFEPRIS' expectations and requirements are aligned with the best international standards, bringing biosimilars to the Mexican market remains an exigent process. Although market approval timelines displayed by COFEPRIS have been tremendously reduced over the past years, biosimilars follow a different and specific approval pathway that remains particularly lengthy. First, our biosimilar plants have to be approved by COFEPRIS, and then have to gothrough pre-clinical studies followed by local clinical studies before reaching submitting dossier stage.

In Mexico, we managed to successfully pass 1st phase for Rituximab, and we are now progressing in a right direction to finish the 2nd phase very soon. In the meantime, we are closely liaising with COFEPRIS to ensure we constantly meet their expectations and requirements, as we want to bring

our biosimilars to Mexican patients as swiftly as possible. Considering the others biosimilars in our portfolio and the very promising R&D pipeline we hold in this field, we can expect that bringing Rituximab to Mexico will only stand as a first step in our ambitious biosimilar development strategy for the country.

As you are developing your manufacturing capacity in the country and working to bring your first biosimilar treatment in Mexico, what remains the importance of the API segment in this development strategy?

The API division stands out as our major business division both in Mexico and globally, and we expect that despite our upcoming developments in the B2C field, it will remain our main source of revenues in Mexico in the upcoming years. In Mexico, we have been able to substantially increase our client base, while the number of our APIs approved by COFEPRIS has been following the same upward trend.

As a matter of fact, Hetero now proudly stands as the company offering the largest portfolio of COFEPRIS-approved APIs in Mexico. With the upcoming market approvals that should be released within the few months, our total portfolio will comprise more than 150 approved products. In Mexico, we consider both local and multinationals hold very interesting growth perspectives, and we remain open to any new partnership with pharma manufacturers implanted in the country.

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Some observers highlighted that developing local API manufacturing in Mexico would stand as an indisputable condition to sustain the further growth of the pharma manufacturing sector in the country. So far, pharma manufacturers mainly rely on API imports, which are then particularly exposed to currency moves, while APIs can amount to 80 percent of the production cost of a pill (according to ANAFAM). As the leading player in the API segment in Mexico, what is your assessment of the situation?

First, the share of the API price within the total production cost of a treatment is highly related to its therapeutic area, its level of manufacturing complexity, segment in with you are selling and final cost of the treatment. For branded products, for example, API only represents a negligible share of the total production cost of the treatment.

In Mexico, we focus on developing our manufacturing facility for high-specialty finished products, but we do not envisage bringing API manufacturing to Mexico. Our API manufacturing footprint is

uniquely concentrated in India, where we notably hold one of the biggest API plants in the world, covering more than 500+ hectares, a thousand API manufacturing reactors and employing around 6000 people.

The impressive size of this cutting-edge and unique API manufacturing facility allows us to easily supply the increasing needs of our international clients and further enrich our portfolio, while the substantial quality & economy of scale it generates helps us to be extremely competitive, even in comparison to our Chinese competitors. By relocating a part of our manufacturing capacity to Mexico, we will then lose the cost-efficiency that the size of this manufacturing facility offers, which will in turn substantially hinder our competitiveness in the Mexican market.

In the HIV segment, Hetero is one of the largest manufacturers and suppliers of antiretroviral formulations and APIs with a 30 percent market share worldwide, while it actively participates in institutional programs with WHO, UNICEF, and PAHO, among others. What opportunities do you see for Hetero to contribute to improve treatments in the HIV space in Mexico?

This segment stands out as a strategic priority within the development path we want to follow in Mexico. We notably plan to move forward on the local manufacturing of finished products in this therapeutic area, as soon as our Mexican manufacturing plant will be up and running. The HIV segment is extremely important to Hetero globally, it stands as a fundamental part of our company’s DNA to provide HIV patients with high quality treatments that are extremely affordable. Furthermore, the HIV field perfectly illustrates the competitive advantage brought by our vertically integrated structure, as we are able to offer a comprehensive set of solutions through the entire value chain, from APIs to ARVs.

> We want to establish Hetero as a leading pharma manufacturer in Mexico, which should help us to fulfill our fundamental mission to provide Mexican patients with high-specialty, outstanding quality treatments at an affordable price.

Dr. BPS Reddy, Founder and Chief Managing Director of Hetero Group of Companies, recently highlighted that Hetero will continuously and tirelessly increase its commitment to HIV patients in the upcoming years – although we already stand as a pioneer and a leader in this field, with one out of three HIV patients in the world using our treatments. In the upcoming years, bringing more therapeutic solutions to the Mexican market will be one of our key priorities to ensure Mexican patients can fully benefit from the remarkable width of expertise that Hetero has been accumulating in this field.

What would stand as the fundamental objective you want to achieve with Hetero in Mexico?

First, we want to establish Hetero as a leading pharma manufacturer in Mexico, which should help us to fulfill our fundamental mission to provide Mexican patients with high-specialty, outstanding quality treatments at an affordable price. Finally, my personal objective is to ensure we maintain our leadership position in the API segment while successfully entering the B2C market, where we have a big role to play in Mexico.

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