Interview: Samuel Mauricio – Vice-President, Octapharma Brazil



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Samuel Mauricio, vice-president for Brazil at Octapharma, one of the largest human protein manufacturers in the world, provides an insightful analysis of the Brazilian plasma market, demonstrating Octapharma's remarkable willingness to further position itself as the partner of choice for the country's public healthcare system.

As the head of the Brazilian operations of Octapharma – one of the world's largest producers of plasma products – since 2009, you are in a privileged position to identify the latest and most significant trends shaping the Brazilian ecosystem in this specific segment. Which specificities of the Brazilian market would you highlight to our international readers?

When it comes to plasma products, the Brazilian market has not radically changed over the past five years, but it is worth mentioning that some of its main specificities have truly gained in importance.

The retail market still accounts for a small share (28 percent) of the overall demand, and local distributors continue to make up the essential part of the frontline business. In this regard, some large, US-based distributors have tried over the past few years to enter and rapidly gain market share in Brazil, but the country's operational complexity had a major impact in the fulfillment of their endeavors. As a matter of fact, the sheer size of the Brazilian territory *[Brazil is the fifth*

largest country in the world – Ed.] renders logistics management extremely challenging, especially when it comes to sensitive plasma products that must comply with stringent temperature and quality controls. To give you an idea, moving products from coastal hubs like Rio de Janeiro or Sao Paulo to more isolated cities like Manaus, typically takes more than a week – through various transport modes. Thus, when you combine this specificity with Brazil's state-based tax system, which probably stands as one of the most complex and demanding systems of its kind in the world, you hold a better idea of the challenges faced by market entrants in the country.

Overall, one of the key specificities of the Brazilian plasma market relates to the huge and ever-increasing importance held by the Ministry of Health (MoH) and by public sector's centralized tenders. As a matter of fact, several new large-scale, price-oriented tenders were opened over the past five years, which prompted companies to follow extremely aggressive pricing strategies and therefore contributed to further lowering margins. As a result, current prices in the public tender market for plasma products are among the lowest ones in the world. When products prices decrease below a certain level, it also becomes extremely difficult for companies to invest in the country. In this context, we see that most plasma companies have been favoring a strict, lean, and transactional approach in Brazil, where they limit themselves to bringing products to the market at the lowest cost possible, without promotion, share of voice, segmentation, or development of therapeutic indication.

In this regard, the Brazilian public market for plasma products has truly no equivalent in the world, as we do not see such a radical, price-oriented policy being replicated in other strategic markets globally. For the years to come, the big challenge for pharmaceutical companies will be to provide affordable drugs with health-economics without losing focus on a very specific medicine market.

Given this difficult context, did you see the demand for plasma products increasing in the meantime and – to some extent – heightened volume offsetting decreasing prices?

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It truly depends; for some plasma products, there is still a huge gap between Brazil's average consumption per capita and that of other advanced countries. For example, Brazil's average consumption of IVIG products per capita is extremely low, even by Latin American standards.

On the other hand, the MoH has truly aimed to meet WHO minimum standards for hemophilia products over the past six years, which led Brazil's average consumption per capita to soar from around one International Unit (IU) in 2011 to almost 3.5 IUs per capita in 2017 in this area *[while the WHO's minimum threshold is at three IUs per capita – Ed.]*.

Despite this rapidly growing demand from the public sector, we however did not see plasma companies developing their footprints accordingly, as their key priority is to maintain the leanest structure possible in Brazil. In this challenging context, Octapharma has however decided to choose a different market approach and it is now ready to partner more broadly with the MoH and the overall Brazilian healthcare system.

Octapharma was indeed invited by a Brazilian public enterprise concerning medicine innovation – Tecpar – to design a new Productive Development Partnership (PDP) with the MoH for the supply and technology transfer of recombinant Factor VIII in Brazil – after two previous agreements failed to deliver on their premises. Could you provide insights into the context that led to the submission of this innovative PDP by Octapharma?

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The PDP recently submitted by our company stands as a large-scale investment project that required a dense and complex design phase, as our objective is to ultimately provide the MoH with the most efficient supply platform possible and avoid the setbacks faced by the previous projects.

Considering the information publicly released by the MoH, we understand that a first agreement was signed between the Brazilian Hemoderivative and Biotechnology Company (Hemobrás) and LFB. This agreement unfortunately did not bring the expected outcomes, which prompted the government to sign in 2012 a similar PDP with Baxter *[before the spin-off of Baxalta and its acquisition by Shire in 2016 – Ed]*. Again, looking at the latest developments publicly released by the MoH, it seems that this complex PDP did not deliver neither the expected results in terms of technology transfer nor the production outputs *[signed in 2012, the PDP notably stipulated that the technology transfer should have effectively started within five years, which did not happened – Ed].*

In this context, Octapharma and other plasma companies were invited by Public enterprises to suggest new PDP projects for recombinant factor VIII. Octapharma decided to seize this exciting opportunity and submitted in June 2017 a new, holistic project, whose fundamental approach is to develop a more integrated and complete partnership model, which would allow the government to fully maximize the investment conducted by our company.

What specificities set the PDP submitted by Octapharma apart from those previously implemented?

Given the sheer size of the Brazilian market, we decided to broaden and expand our PDP's integrated approach beyond Hemobras' productive capacity. In this regard, Octapharma's technology transfer would also include the Butantan Institute *[one of the largest centers of biomedical research in the world, located in the state of Sao Paulo – Ed.]*, whose plasma plant was initially set up in 2011 but has remained unused since then.

Furthermore, one of the key specificities of this PDP relates to the outstanding product covered by the technology transfer: Octapharma antihemophilic factor VIII. This fourth-generation recombinant – proudly stands as the latest frontier reached by science – is derived from a human cell-line; hence it is not chemically modified nor fused with another protein. In this regard, it is extremely similar to the factor VIII contained in the human plasma, which minimizes issues typically faced by other recombinants already in the market.

With this PDP, we truly looked at leveraging Octapharma's technical leadership to develop a tailor-made solution adapted to the specific needs of the Brazilian ecosystem, including the risks posed by the high prevalence of infectious and tropical diseases in the country. In this regard, we integrated in our PDP project a proprietary technology that enables the virus inactivation of the plasma for all relevant viruses from a transfusional point of view including the Zika, Dengue and Chikungunya virus, which will provide clinics and hospitals with a heightened transfusion safety.

What makes Octapharma the partner of choice of the aforementioned Brazilian Public enterprise – Tecpar – for such a long-term and strategic project?

Octapharma's differentiator in Brazil is twofold. First, it relates to our readiness to invest huge, long-term resources in the country; as a matter of fact, the aforementioned PDP would entail an investment of USD 500 million from our side, and – according to the information publicly released by the PDP department of the MoH – no other plasma companies have demonstrated their willingness to engage in such a long-term investment project in Brazil.

Second, Octapharma holds a leadership position in the Brazilian market from both technical and regulatory standpoints. Looking at the current competitive landscape, Octapharma proudly stands as the only company holding a fourth generation recombinant factor VIII of unmodified human cell line registered by ANVISA. Additionally, we are also the only company in the country offering the full portfolio of products for the fractionation of plasma, as well as the only company worldwide that invested the required resources to develop a unique plasma virus inactivation technology. Furthermore, we are currently the only company both developing recombinants from human cell lines and fractionating proteins from human plasma in the therapeutic areas of Hematology,

Immunohemotherapy and Intensive Care Medicine.

In the grand scheme of things, this PDP would truly allow Brazil to move up to a new dimension, as only a very limited number of countries have managed to become independent for the production of plasma proteins and recombinant factor VIII. In the case of Brazil, this aspect is even more crucial as the country holds the third largest hemophilic population in the world. As the average consumption of recombinant per capita in Brazil is steadily getting closer to the global average *[five IUs per capita – Ed],* Brazil's annual consumption of recombinant should overcome one billion IUs per year in the coming years.

Octapharma Brazil will celebrate its 25th anniversary in 2018. What will be your strategic priorities moving forward to ensure the company continues to successfully develop its activities in this strategic market?

Our overarching objective is to be recognized as the best company in our area and a frontrunner when it comes to the quality of our processes. Over the past 25 years, our company has managed to build a remarkable track record of successful projects in Brazil, while we have always met our partners' expectations in all projects we engaged in, whether they related to the public or the private sector. When it comes to such sensitive, life-changing products, we believe that being recognized as a reliable partner is absolutely critical and we will continue prioritizing this aspect moving forward.

At the end of the day, Octapharma's main client is the patient; this philosophy is fully part of our corporate DNA and it truly trickles down to the local level. Advancing Human Lives is in our blood, our passion drives us to provide new health solutions. As a matter fact, we built an outstanding reputation among Brazilian patient organizations, while the great relationship we hold with these critical partners empower us to receive extremely valuable feedback and tirelessly improve our delivery.

As a company, our fundamental vision is to consolidate Octapharma's leadership position in Brazil, which will be no easy task given the country's persisting instability on the political side and some of the market trends that I mentioned earlier. Operating in Brazil also entails a heavy responsibility weighing on companies' shoulders: once a product is registered in the country, pharmaceutical companies are held liable during the entire product life cycle – from the moment a given product lands on the Brazilian soil to the transfusion, without forgetting logistics, cold chain storage, and medical & scientific support.

At the global level, Octapharma emerges as a fast growing, financially sound company, and we must ensure that the Brazilian activities deliver results aligned with the overall performance of the group. Moreover, we are committed to develop new solutions to address the unmet needs of patients, which we do intend to achieve by accelerating the development of new products in both our plasma and recombinant products pipeline.

What will be your final message to our international readers?

Brazil stands out as a tremendous learning curve for any business leaders and general managers operating in the country. As the world's sixth largest pharmaceutical market overall, affiliates' heads have to look at the bigger picture in order to design their organizations' winning strategies.

On the other hand, Brazil's complexity requires companies and business leaders to also pay the utmost attention to details – and this is the tricky part. In Brazil, the consequences of small mistakes can lead organizations to critical, disruptive situations which could compromise their long-term development. In a nutshell, my message is clear: think big, but do not neglect the details.

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