Pascal Brière – President, Biogaran, France

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Pascal Brière, president of Biogaran, the leading French domestic player in generics, reflects on the development of the generic market since the 1999 Generic Substitution Act. Brière goes on to comment on Biogaran's unique strategy of leveraging added solutions, international expansion, and biosimilars. He concludes with his thoughts on the changing dynamics of the pharmaceutical industry and a call for realism regarding the future of the French healthcare system.

It has been 20 years since the passing of the Generic Substitution Act in 1999. Do you feel that today's generic market in France has evolved at an appropriate pace?

Although the French generic market has absolutely matured over the past two decades, there is still a huge potential for growth in the coming years. France has a very specific nature given that 53 percent of prescriptions written are for new or innovative products which are not accessible as generics. Unlike many other European countries, French doctors have no constraints on the prescriptions they write which results in a high partiality to novelty drugs. Furthermore, mature products are no longer detailed to physicians by the industry in the same manner as innovative drugs, which also explains this trend.

However, this creates an opportunity for generics players because there still remains one-third of the market to explore. Through GEMME (L'association *Générique Même Medicament,* France's generics and biosimilars association), we are all advocating to incentivize prescribing within the

repertoire. The drugs within the repertoire cover over 75 percent of primary care medicines. By broadening the prescription within the repertoire from 46 percent to 70 in volumes, the penetration of generics can be increased from 37 to more than 55 percent overall.

What are your thoughts regarding the healthcare reforms which have recently been enacted by the Macron administration?

I must admittedly say that the generics industry is not being heard as well as we may expect by the government. During events like the Strategic Council of Health Industries (CSIS), where stakeholders gather to discuss the importance of innovation and so on, there is not an opportunity for real exchange between the industry and health authorities. The administration goes to these meetings – which I must recognize are very well prepared in advance, then they make decisions, and create healthcare policies on their own. This has been going on for quite a long time, as the CSIS gatherings have been in existence since 2009. However, what we have noticed with the 8th edition that took place in July 2018, is that within Minister of Health & Solidarity Agnès Buzyn's first two years in office, the consultation process has changed quite a bit.

Whether you are a generic or innovative player, the entire industry agrees that there is a gap between what has been said by the administration during the 8th edition of the CSIS and the reality of the decision, especially on pricing issues. After the CSIS, the administration continued to create policies and regulations on their own, without consulting the industry. For example, last year we advocated for the expansion of the prescription in the repertoire and to implement incentives for doctors to prescribe within it. We have seen this methodology to be proven successful with biosimilars for rheumatology within the hospital sector when the incentive model directly benefited the doctors. However, the management of the Social Security (DSS) has decided to go a different direction which was never discussed with the industry and have reimbursed on generic prices starting from 2020 – not solving the fundamental issue of the repertoire where substitution is already about 80 percent. As a response, the originators will imply lower their price to the level of generics, dissipating the interest of prescribing a generic.

Biogaran boasts a 28.5 percent market share in France and a remarkable brand reputation as the French people's favorite generics pharmaceutical company. What are your priorities to strengthen Biogaran's position in the French market?

It is very difficult to surpass 30 percent market share, but in fact, Biogaran is not focused on solely chancing share. Our strategy is to continue being the preferred brand of patients by looking at our products through their own eyes. Our competitors take a more commercial stance on their business while Biogaran's approach is on the patient and pharmacist side. We work to provide services for patients and pharmacists and provide new solutions to answer the needs of our stakeholders through an added value service offering.

Furthermore, to be a market leader for generics in France, being a one-stop-shop is crucial. Biogaran's strategy is to have all products that have gone off patent within our portfolio which is why we cover so many therapeutic areas and have over 800 generic specialties. Biogaran is only one of two players in France who are big enough to do this – all the others must focus their attention on profitability and positioning. This allows us to be the premier partner of choice for patients and pharmacies in France.

How are biosimilars positioned to be a long-term growth driver of Biogaran's portfolio?

Biogaran has been a pioneer for biosimilar products at the retail level. In France, a law which allowed for substitution at the pharmacy level was passed in 2014, but the decree was never published. We launched our first biosimilar in first position in the hospital and became the market leader in 2018 in the pharmacy, claiming that the law is, "per se", self-explanatory. This has been very disruptive within the industry, but now we see other companies moving to this position very recently. Since then, we have entered into the hospital market as well with trastuzumab, rituximab, and infliximab taking first positions in the sector. In fact, seven out of ten patients being treated with rituximab in France are treated with our product Truxima®.

Given the high development and manufacturing costs of biosimilars, many generics players have chosen to join forces in order to advance their biosimilar strategy as fast and as efficiently as possible. What is your vision to balance strategic alliances on the one hand, and the advancement of Biogaran's own biosimilar development and manufacturing capabilities on the other?

That is a very good question. There is a debate in the industry regarding whether companies should have fully integrated, internal capabilities to develop, manufacture, and market biosimilars, or if it is best to create collaborations to share these burdens among partners. The level of

investment needed to enter the biosimilar space is, as you mentioned, enormous. The business model is completely different from tradition generics and the risk is extremely high. What Biogaran has chosen to do it is enter into licensing partnerships like what have done with our first three products from Celltrion from Korea and hopefully a fourth with Rovi in Spain. We are not linked exclusively to any company and we hope to continue building new collaborations throughout the industry. We are picking up assets on a product by product basis, which is increasing our chances to be a first mover in the biosimilars market.

Companies like Sandoz manage biosimilars entirely in-house and on their own, but because of that, they may not be the first to reach the market. When it comes to biosimilars, when a product is not first line its value plummets terribly. I trust that flexibility, adaptability, and capability are key assets to be a leader in biosimilars, hence why we chose the path of partnerships at Biogaran.

How would you describe Biogaran's internationalization strategy and what opportunities do you identify to further develop Biogaran's international footprint moving forward?

We have had a very successful operation in France, which we had predicted since 2004. This was a great time for Biogaran to develop internationally and there were already plans in place for expansion. However, for several internal reasons the decision was made to push back our international strategy. It was not until the early 2010s that there was an interest to internationalize once again.

However, most generic markets around the world were mature by that time. This left us with two options: enter a market and build from scratch, or from a limited cash acquisition in countries where we could expect a fast and intense growth. This led us to countries like Brazil and Nigeria where there is still a lot of work to do in the market. These countries –which are not comparable- are going through a fundamental paradigm shift in the quality of generics compared to their first wave of products. Our first step outside of France was subsequently in 2012 through the acquisition of Pharlab in Brazil, and in 2017, we entered Nigeria.

In Nigeria, there are very few pharmaceutical players in the market and large quantities of fake medicines. We entered the market through the acquisition of Swipha which was a former Roche factory in the 1990s, run by individuals after the company had left the country. We have fully restructured the company, applying compliance practices, improved manufacturing processes, and marketing strategies to reach the most patients as possible at a moderate price. Currently, we are

exporting some products to Nigeria and producing some locally, but once we scale up the operations, we will increase the local production. Interestingly enough, Biogaran is the only French, let alone European, player in the generic arena in the country. From Nigeria, we plan on expanding to West Africa and have already entered the Ivory Coast.

In the 2000s, there was an industry-wide trend among Big Pharma to acquire or set up generics arms (Novartis & Sandoz, Sanofi & Zentiva as just two examples). Today there seems to be a reversing trend materializing. What is your assessment of the situation?

At the time, the fashion was to be present in the generic market because the industry still had a mindset of promoting large-molecule, blockbuster drugs. And the idea was related to mitigating risk when drugs were close to facing the patent cliff. Once the industry realized this was insufficient, they dropped generics and ran to high-level R&D for breakthrough science – as we see materialized today with several big pharma, who are for example developing cell & gene therapies and immune-oncology products. Pharmaceutical companies are no longer interested in large products for which volumes are high and rewards are low, but instead high risk, high reward niche products for a smaller patient pool.

Today’s model is a lean and lucrative one. Blockbuster drugs require huge teams and facilities and in the end, are sold for very low prices. To a regulator, there is very little difference between the generic and originator for these products, and they are valued very similarly. Therefore, pharma companies have elected to divest their R&D and manufacturing, investing into external R&D partnership clinical trials and focused on the highest innovation in precision medicines. There is, therefore, a perfect room out there for focused and specialty players such as Biogaran in the generics field.

What final thoughts do you have on the future of the French health system?

Truthfully, I am not so optimistic about the French healthcare system. We are still in the religion of free access to everyone for everything, and there is a resistance to make choices. This mindset is absolutely unsustainable. The pressure is being put back on the pharmaceutical industry, for both originator and generic players, through mature products. Moreover, overly stringent regulatory requirements like serialization are pushing up costs. The only way to resolve this issue is to prioritize what can be covered by the Social Security. In the 30 years I have been in the industry, France has never made a choice, and this has to change.

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