Franck Puget â?? Managing Director, CSL Behring France

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Franck Puget, managing director for CSL Behring in France, discusses the blood plasma specialistâ??s commitment to France, building bridges with public authorities, and regulatory attitudes towards rare disease treatments.

CSL Behringâ??s French affiliate was created back in 2004 and is now the 4th largest within the group. How strategic is France within CSL Behringâ??s overall operations?

First, letâ??s remember that France is the 5th largest economy in the world and the 2nd in Europe. It is absolutely essential for CSL Behring to be present in France. CSL Limited entered the French market with the acquisition of Aventis Behring in 2004. Since then, this presence has been reinforced through local investments in the existing structure. These investments have paid off handsomely: our revenues have increased tenfold between 2004 and 2018. This fact alone clearly shows how strategic France is for the group.

What were the key milestones that enabled CSL Behring to achieve such an outstanding performance?

Before its acquisition by CSL, the portfolio of Aventis Behring was extremely focused on certain therapeutic areas, mainly coagulation disorders. On the other hand, CSL Limited, through its affiliate ZLB, had developed an expertise in therapeutic plasma proteins for immunodeficiency. After the acquisition, the combination of these two complementary expertise domains enabled the new entity, CSL Behring, to accelerate its growth in France and abroad.

How would you describe CSL Behringâ??s performance in recent years?

In terms of business performance, as I said we increased revenues tenfold in the last 15 years. But for us, the most important performance target, the one that makes us go to work every morning, is giving patients access to the treatments they desperately need in a reliable, regular and prompt manner. This patient-centric mindset is shared by all our employees, not only in France but throughout the group. I can assure you that if you go to our offices and question our employees, in whichever department or role, they will talk to you about patients. They will also tell you how proud they are about our treatmentsâ?? quality and clinical efficacy. In practice, the way we strive to better

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serve patients is by working in close collaboration with hospitals and healthcare professionals by providing them with knowledge and support. We also listen to patientsâ?? needs by constantly keeping in touch with patientsâ?? associations such as IRIS, the association for primary immunodeficiency, and AFH, the haemophilia patientsâ?? association. Through these efforts, we are proud to have attained our goals to reach as many patients as possible.

CSL Behring has manufacturing and R&D capabilities in Germany, Switzerland but not in France. Is there a reason for this and is it something that could change in the future?

This state of affairs is due to historical reasons. Our blood plasma fractionation plants are located in Switzerland because CSL Limited acquired ZLB, a Swiss company previously part of the Swiss Red Cross, back in the 1980s. Our manufacturing and R&D presence in Germany stems from the acquisition of Aventis Behring, a company that finds its roots all the way back to 1901, when German physiologist Emil Adolf von Behring received the very first Nobel Prize in Medicine. He founded the Behringwerke company that built a sera and vaccines manufacturing plant in Marburg, Germany still in operation today. As a result, CSL Behring has high-quality production and R&D facilities in both countries.

What are your strategic priorities for the coming years?

In my opinion, companies should focus on a few strategic considerations. Deciding what not to do is just as important as deciding what to do. In France, we have two different strategic priorities. The first, as mentioned, is to enable patients to gain better access to treatments by working more closely with public healthcare authorities. Our role is not just to provide a desired quantity of products to hospitals. Our strategic priority is to provide treatment access in a sustainable way in the medium to long term. In order to achieve that, we must make sure that our manufacturing plants have the capacity to deliver the required volumes. But more importantly, we must ensure that we develop a strong partnership with public authorities so that treatment access is made easier in every way possible. Last, but not least, we must continue to nurture a patient-centric company culture.

The second is to deepen our partnerships with university hospitalsâ?? research teams. In that regard, I am very proud of the fact that we are the first affiliate in Europe to have created in 2016 an Endowment Fund dedicated to supporting French research and supervised by an independent scientific committee. CSL Behring understands that France has incredible assets in that domain and has decided to endorse several projects, mostly in clinical rather than fundamental research. Supporting local research can create exciting new opportunities for the group, as it has in the past. For instance, seven years ago, we started collaborating with a research team that demonstrated the usefulness of immunoglobulin in solid organ transplant. Today, transplantation has become a very important therapeutic area for CSL Behring. I am pleased to say that this emanated from our fruitful partnership in France.

When looking at your therapeutic areas, are there specific ones that are driving your growth in France?

It depends on the year. As a rule, we want to be present everywhere we can make a difference. Our main therapeutic areas are haematology and immunology, but we also have specialty treatments in very specific rare diseases such as hereditary angioedema. All of these therapeutic areas contribute

to our growth, and I donâ??t consider one to be more important than the other. Letâ??s take haematology as an example, and more specifically haemophilia A and B for which we have very innovative and efficient treatments that are life-changing for patients. As a result, we play a very important role in the treatment of these diseases and this is whatâ??s important for us.

You repeatedly emphasized the strategic need to build a strong bridge between CSL Behring and the French healthcare authorities. How would you assess the Macronâ??s administration willingness to work with industry?

As a pharmaceutical company focused on treating rare diseases, we have a public healthcare duty. As a result, we have a responsibility to make ourselves heard and communicate on our challenges in a constructive and positive way. In that regard, I think things are moving in the right direction. The current administration has adopted a welcome approach to listening and understanding. However, things are never black or white and major changes is always too slow.

Franceâ??s Minister of Health AgnÃ¨s Buzyn, has introduced the 3rd iteration of the Rare Disease Plan (*Plan National des Maladies Rares*). What are the merits of this plan in your opinion?

The Rare Disease Plan is the result of collaboration between healthcare authorities, patient groups, researchers and healthcare professionals. This plan is well-crafted, and we welcome it with open arms. So do healthcare professionals who are very involved and sacrifice their lives to combat these rare diseases. The first merit of the plan is to recognize the fact that it can be difficult for patients afflicted by rare diseases to get access to effective treatments. Second, it gives structure to the provision of medical care to these patients. Lastly, it raises awareness among the larger population about the fact that there are a lot of different and serious rare diseases, more than 7000 in fact.

How do you assess the ease of market access in France for innovative treatments targeting rare diseases?

Our neighbours envy the Temporary Authorization of Use (*Autorisation Temporaire dâ??Utilisation / ATU)* system that we have in France, and I think they have good reason to! Itâ??s a fantastic system that enables patients to get access quickly to innovative treatments, and certainly, this system has saved a lot of lives. Further improvements to this system were announced last year at the 8th Strategic Council of Healthcare Industries (*Conseil stratÃ©gique des industries de santÃ© / CSIS),* by extending it to other indications. This system is clearly here to stay which provides a reliable regulatory environment. Regarding the normal authorization process, we were able to make our concerns heard during the CSIS, particularly in terms of authorization timelines. Iâ??m optimistic that market access will become easier in the future, and that the time it takes to get an innovative drug into the hands of patients will be reduced.

Apart from your responsibilities at CSL Behring, you are also President of the French branch of the Plasma Protein Therapeutics Association (PPTA). Could you describe this organization and its mission statement?

PPTA brings together the key global actors in blood plasma fractionation. The French branch is comprised of Biotest, Shire, Grifols and of course CSL Behring. There are more members at the European, North American and global levels. All the members of this association develop and provide blood plasma proteins designed to cure particular rare diseases that are complex and relatively unknown by the public at large. As a result, there is a need to communicate about these rare diseases and the treatments available to different stakeholders: the government, public authorities, healthcare professionals and patients associations. The objective, in the end, is to improve the medical care of patients suffering from these diseases. By unifying our forces in this association, we can speak in unison and deliver a more coherent message that will reach a wider audience.

To conclude, what final message would you like to deliver to our international audience?

Doing this interview has been a great opportunity to look back on the last 15 years of CSL Behring in France. What have we accomplished? First, we have grown our operations significantly and created 50 new jobs. At the outset, we were only 15, and we now have 65 colleagues, all of them focused and motivated by a sincere desire to serve patients. Second, we have made major investments in research which has allowed us to create new opportunities for the company. Third, we have built a trusting, transparent, strong and constructive relationship with government and healthcare authorities.

And last but not least, we have increased and improved patientsâ?? access to innovative treatments that make their lives better, especially in underserved therapeutic areas. This last accomplishment brings me the most pride. Over the years, we were faced with some situations that, to be perfectly honest, were extremely difficult to deal with, but, in the end, we always managed to deliver treatments to our patients who were in desperate situations waiting to receive them. So my final message to other industry leaders is to keep focused on delivering our promises to better serve patients.

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