

# Interview with Laurent de Narbonne, General Manager of Octapharma France, Belgium, Luxembourg,

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**ed in 1983 and entered decisively in the French market in 1999, when it acquired a plasma facility in Lingolsheim, Alsace. Since then, what have been the main milestones of the company, especially since you took the reins of the local operations five years ago?**

Until 2005 Octapharma France had only two marketed products; the original one – the liquid IV immunoglobulin named octagam® (human albumin), approved in 1999 – and a second product named octalbine® (human albumin). By then we had two new marketed products approved: the Gammanorm, a subcutaneous immunoglobulin for primary immunodeficiency; and Octaplex, Octapharma’s state-of-the-art human prothrombin complex concentrate (PCC) which represented a new generation of the product to the market at that time, since it was developed based on the guidelines coming from EMA (European Medicines Agency).

As for 2010 Octapharma has two products to be launched. Octagam 100mg/ml high concentration; and Rhesonativ, an anti-D IG for the treatment of Rhesus incompatibility between the mother and the fetus. The first product should be launched in Q2/Q3 and the second one should be launched by Q3/Q4.

There were also two important products which were approved but not launched and could not enter the market yet: octanate®, a high purity Factor VIII – von Willebrand Factor (VWF) concentrate for prophylaxis and treatment of bleeding in Haemophilia A; and octanine® (octafix® in France), a high purity SD treated and nano-filtered Factor IX concentrate for the prophylaxis and treatment of Haemophilia B.

This increased portfolio was naturally reflected in the turnover of the French affiliate, which increased over 100% in only five years. Octapharma France came from –21 million revenues and this year we will be above the –40 million mark.

**Last year Octapharma AG group had revenues of more than –1 billion, with facilities in five different countries and France as home to a 600.000 liters per year plasma process facility in Lingolsheim (67 Alsace). Hence, how would you describe the role the French operations play for the Octapharma group?**

Historically, Octapharma was founded in France by our chairman Mr. Wolfgang Marguerre in 1983. Therefore, there is a very strong history of Octapharma in France. For instance, our first manufactured product plasma derived factor VIII called octavi® was the first FVIII product to be manufactured with the solvent detergent process, which ever since has had a spread use in the industry worldwide.

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## **How is the local legal environment affecting Octapharma's activities in France and how would you compare the French model to the ones of its bigger neighbors?**

If you look at the map of Europe you will see a set of countries which are very open markets for plasma derived products; these are mainly Germany, Austria, Czech Republic, Switzerland, and potentially Sweden.

In recent years it has been clear that the French market is not self-sufficient for some types of drugs, notably IVIG, albumin, or fibrinogen. Our estimate is, with respect to plasma collection the market is self-sufficient up to 70% for finished products. 30% of the plasma products being sold in France are coming from external providers, which are CSLBehring, Baxter and Octapharma.

What you have seen in the past years is that is that, for a set of reasons, there have been shortages of some products like FVIII, fibrinogen, immunoglobulins, and so on. Hence, the need for more players in the market became more obvious. In terms of general health care policy, you should definitely have more than one provider in one market, since it is very dangerous to depend upon only one source, especially in the field of biologics.

We do think that room is available for all commercial companies.

Nowadays, when you have a product registered in a national procedure or in a multi-recognition procedure you have to comply with the French law which prohibits the use of plasma-derived products coming from compensation while products coming from a central marketing authorization in London are allowed to have compensated donation. Therefore, there is a huge discrepancy because the laws with which you have to comply with in order to offer your product are not set on an equal basis.

## **Even with all these obstacles, Octapharma positioned one of its main facilities in France. How competitive is it to manufacture in the midst of such environment?**

First of all, it is important to understand that in our facility of Lingolsheim we process plasma from Germany, Austria, Sweden, and export the final products to various markets such as Mexico, Ireland, Brazil. Only a fraction of it, from 5% to 10%, is directed to the French market. For France our plasma is coming mainly from Sweden, Germany, Austria and the USA - naturally only non-compensated plasma since Octapharma complies entirely with the French laws.

Regarding the competitiveness of France's manufacturing, the main asset offered by France is the unique knowledge and skills of its employees, especially in the environment of Strasbourg (Alsace), where you have a very famous chemistry University with former Nobel Prizes teaching there. Besides, you have Alsace's Biovalley cluster and important manufacturing sites and laboratories that employ thousands of engineers, scientists and so on.

When you are talking about biologic products as Octapharma does it in Lingolsheim (67) close to Strasbourg, you need a highly qualified population. This is where France can make a difference. However, even though France is a top exporter of pharmaceutical products, when talking about biologic & biotech products France is lacking more manufacturing sites. Companies with help of the French government (Invest in France, Ministry of Finances & Industry, Regions) are working on it but still my estimate is, there are only 10 biologics manufacturing sites in France, and at least 3 of them are located in Alsace, one to a Swiss, one to a US company and another one to Octapharma.

In the last 10 years Octapharma has invested more than -100 millions (including acquisition) in our French operations and now the speed of investments has increased, so you can expect considerably more investments for the next ten years. Three years ago we use to process 400.000

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liters and Octapharma aims to increase it to 800.000-1.000.000 liters per year being fractionated in Lingolsheim in the next 2/3 years. We actually just did the acquisition of further land in order to dedicate the current site only to the fractionation part and the new site will be dedicated to the incoming raw materials and the out-going finished products which will be packed in Germany.

### **When you look towards the future, what are your main ambitions for Octapharma France's operations?**

Over the past ten years Octapharma as a group had an average growth of 20%, a unique situation if you benchmark it in the pharmaceutical industry. As another good example, when I joined Octapharma in 2005 the group had 1200 hundred employees, now we are 4000. Hence, our main ambition and challenge for the future is to continue to grow with the same conviction and speed we have grown recently.

This performance could only be achieved because Octapharma is a privately owned company, what allow us to have a long-term vision for the company and to reinvest 85% of our profits into the company, something rather unique in the pharmaceutical & biotechnology industry.

Part of this long vision can be seen in your ~600 million investments for the next 5 years, from 2009, in collection centers for plasma as well as into the manufacturing and R&D development of our portfolio. These are two global factors that are linked to Octapharma as a group.

Since Octapharma is specialized in new biotech products (we have currently in clinical development, entering phase II/III in EU/US, a recombinant FVIII product processed from human cell lines. , we are somehow protected against possible competition from biosimilars, guaranteeing the long-term success the company.

The potential of the French market is unquestionable. Octapharma believes on it and we are working hard to deliver all our unique products and solutions in order to better serve the French population.

For example, we aim to introduce in the next coming years, on top of the above rhFVIII, a vW-FVIII product, wilate® for both indications haemophilia A and treatment of von Willebrand disease, which is already approved in the rest of EU.

We also have an innovative technology called LG (for prion removal) which is applied to our plasma for transfusion ,octoplas® and soon to be to our universal plasma, uniplas®, then an universal lyophilized plasma, lyoplas® . We wish to make them available to the French patients and caregivers.

Finally with respect to our employees in France, I believe we have been able to raise the level of compensation to a normal range with respect to other companies.

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