Interview: Jean-Charles Rousset – Head of Aspen Sterile Operations and Managing Director, Aspen Notre Dame de Bondeville (NDB), France



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The head of Aspen sterile operations and managing director of Aspen NDB, reveals how their facility in France acts as the main platform for the group´s sterile business, a market with tremendous potential at the world level; how the factory has a particularly strong international exposure, exporting 75

percent of production; and why the ambition is to become a key leader in the global pharmaceutical industry when it comes to thrombosis.

Aspen is a leading pharmaceutical manufacturer in the southern hemisphere and is Africa's largest pharmaceutical manufacturer. What is Aspen's commitment to Europe and in particular France?

Aspen is committed to making high quality, effective and affordable medicine accessible to everyone. In Europe, Aspen specializes in the production of medicines known as antithrombotics. In 2014 Aspen bought 100 percent of GSK´s thrombosis portfolio, both the low molecular weight heparin, Fraxiparine, and the first Xa inhibitor, Arixtra, in a deal worth USD 1.1 billion. As part of the deal Aspen took control of GSK´s former manufacturing site in Notre-Dame-de-Bondeville in France.

On October 19th 2015, Aspen's CEO, Stephen Saad, and Lorraine Hill, Group Operating Officer, came to France to inaugurate a new high speed sterile syringe filling line, a project named Stromboli, representing an investment of 38 million euros (USD 41.79 million). Mr Saad also laid the first stone of a new control laboratory in which Aspen has invested 6.5 million euros (USD 7.15 million). Such an investment should be seen as part of Aspen´s broader objective to increase the site´s competitiveness. The level of knowledge, quality and technical expertise on offer here is world class. The site was previously run by Sanofi and then GSK, who ensured that the standard of quality on offer remained exceptional. An example of this would be the United States' FDA which made no comments during the last audit they performed, and the same was true in July 2015 when we were inspected by the ANSM (the French National Agency for Medicines and Health Products Safety). For a sterile plant of our size, such a track record is exceptional.

With a portfolio of valued anti-thrombotic medicines and focused expertise in the thrombotic therapeutic category, Aspen Europe is set to become a leader in this field. Can you tell us more about your thrombosis strategy?

In 2015 Aspen entered into an agreement with Novartis to acquire the rights to Mono-Embolex, an injectable anti-coagulant, for USD 142.3 million. Mono-Embolex is a heparin-based anti-coagulant sold in the same therapeutic category as Aspen's Arixtra and Fraxiparine. This product is, however, the only low molecular weight heparin that offers patients weight-independent dosing, thereby combining ease of administration with proven efficacy in the prophylaxis and therapy of deep vein thrombosis. The product presents an excellent strategic fit with the Group's recent acquisitions in this therapeutic area and will be positioned as a simple-to-use once daily prophylaxis treatment supporting Aspen's other current anti-coagulant offerings. As the product is to date only on the market in Germany, Switzerland and Austria, Aspen has the opportunity to launch it in other countries. Through these acquisitions, helping us to build a complete portfolio, our ambition is to become the number two in the world in thrombosis treatment, recognised world wide for our quality products

What does France offer to a company like Aspen? What can France deliver for the business on a global scale?

We have built a strong level of confidence in France within the Aspen group. Given its central location in Europe, France is a convenient location for Aspen to have its thrombosis base. Our site at Notre-Dame-de-Bondeville acts as a key hub and is the main platform for the group's sterile activities. The sterile business is a market with tremendous growth potential at the world level, in particular when it comes to vaccines. As I mentioned earlier, we are audited by all of the world's

major health agencies and go through these audits without any major issues. Our factory has a particularly strong international exposure. We export 75 percent of production: 25 percent of production goes to the French market, with 40 to 50 percent of the balance destined for Europe and the remaining 50 percent for the rest of the world. At the global level, numerous sterile factories are closing down due to the high level of quality demanded by the various agencies. This means there is an under-capacity in a market where global demand is growing. While Europe has over-capacity for solid doses, there is insufficient capacity for sterile liquid doses. Aspen is willing to offer big pharmaceutical companies products from our NDB site in order to develop additional capacity.

When we met with Philippe Lamoureux, President of LEEM (The French Pharmaceutical Companies Association), he was telling us how he is worried that France is losing its attraction as a country of production. Is this competitiveness issue a concern when it comes to the sterile business?

It is true that the working environment is difficult in France, where the cost of labour is very high. For this reason Aspen's aim is to run the French site at full capacity. We are currently producing 150 million units per year of sterile pre-filled syringes, with a total capacity of around 215 million units. We need to run the site at full capacity, if we want to be economically sustainable in the long term. There is potential to further grow our Fraxiparine and Arixtra brands as well as the possibility of delivering extra volume through partnering with other laboratories. Around the world there are not many pre-filled syringe facilities with a capacity of over 200 million units. Scale is key when it comes to global manufacturing. This is particularly true when it comes to the area of pre-filled syringes, where the fixed costs and direct and indirect structures are particularly high.

What are the particularities of working for a South African company?

Aspen is a very entrepreneurial company. There is a limited amount of bureaucracy within the organization, where the emphasis is very much on direct communication. We are a results-driven business. This is not usually the case for a company with a European mind-set, where the focus is more on short term challenges, a glass half-empty perspective. The emerging market mind-set, on the contrary, is all about taking every available opportunity. With Aspen, I have the feeling that anything everything is possible.

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