Interview: Oliver Schmitt â?? General Manager, Italy & Greece, CSL Behring Spa

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Following regulatory changes, CSL Behring is now able to offer plasma fractionation and purification services to Italyâ??s public healthcare sector for the first time. General manager Oliver Schmitt discusses the added value and savings CSL Behring can offer in this service segment and the benefits its newest generation of innovative therapies can bring to patients.

Given your 16 yearsâ?? experience working in the plasma derivatives industry, what would you identify as the defining characteristics of the Italian plasma market?

First, I would highlight the excellent quality of the Italian national health care system and the life sciences sector, which are both among the very best in the world. In Italy, while we may in theory have one national healthcare system, each of the countryâ??s 21 different regions interprets this system differently, which means we face 21 different realities in terms of pricing and reimbursement decisions. This structure and heterogeneity has a significant impact on our daily work, and provides enough challenges for my team and I that we never get bored.

The second characteristic pertains to Italyâ??s approach to plasma self-sufficiency. While there are many different angles to plasma self-sufficiency around the world, Italy aims to achieve the most extensive interpretation, meaning self-sufficiency for plasma and all plasma-derivative products. This is a very challenging objective to meet in an efficient manner, as demand for certain plasma derived proteins is rapidly outgrowing others, not corresponding to the proteins proportions in donor plasma.

Expanding on the second point, what role can recombinant proteins play in reducing the discrepancies in demand for different plasma-derivatives?

You can extract and fractionate different kinds of proteins out of a liter of plasma. On the one side you have the relatively simple proteins that can be used for hemophilia products, i.e. factor VIII and factor VIX recombinants. For these simpler proteins, recombinant versions have been available since the 1990â??s, while current recombinant platforms are not yet able to produce more complex proteins such as immunoglobulins.

Thus, at present all demand for immunoglobulin must be met through plasma collection and fractionation. At the same time, demand for immunoglobulins is growing rapidly, due to increased use of immunoglobulin therapies in classical indications such as primary immunodeficiency, as well as new indications for certain neurological diseases.

What advantages can recombinant products offer over their plasma-derived counterparts?

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Within the area of hemophilia, the first wave of recombinant products were launched at a time when the problem of HIV was very present; for countries like the UK, this was a factor in the decision to switch completely from plasma-derived factor VIII to recombinant factor VIII. While there are different schools of thought on both products, everyone unanimously agrees that today plasma-derived products are safe. The industry invested heavily to improve all processes within the collection and fractionation of plasma to ensure the absolute safety of these products. Nevertheless, we also have to take into account the emotions of patients and more specifically, those of patientâ??s parents who often take the choice of treatment. Based on the idea that recombinant products are produced using biotechnology and do not come from a human donor, some patients or guardians feel that they are safer than plasma-derived products and go for the recombinant options. However, in countries like Germany, 50 percent of patients are treated with plasma derived products; Italy tends to be more inclined towards recombinant products.

Our newer recombinant products offer patients incredible advantages in terms of frequency of treatment. For example, our newest product Idelvion, an albumin fused factor IX protein, only needs to be administered once every two weeks, versus a standard factor IX treatment, either plasma derived or recombinant, which must be administered twice per week. Indeed, Idelvion has recently been registered at EMA level and we are currently in pricing and reimbursement negotiations with AIFA.

Could you give us an overview of the structural changes that took place in the Italian plasma market over the last few years and how this has impacted CSL Behring Italy?

When the idea of self-sufficiency was born in the early 90â??s there was a law that clearly stated that production sites had to be in Italy. Therefore, only one company was able to provide fractionation and contract toll manufacturing to the Italian regions. As a consequence of increasing discussions around this law, the parliament took action and approved a new law in 2005, which opened up the market to allow production sites in other European countries to supply Italy with plasma derived products. Unfortunately, it took another ten years until this law was implemented. Since last year, the world has been changing for us at a rapid speed, namely for the first time we had the opportunity to participate in the first interregional tender for toll manufacturing which was led by the Veneto region. This tender was published in November 2015 and in March 2016 CSL Behring was announced as the winner of this tender. This was a wonderful moment for us as we had laid all the groundwork over the last 15 years to achieve this goal. As the worldâ??s leader in the world of plasma-derivatives we have the broadest portfolio and centers of excellence in several areas, both in

terms of therapeutic and geographic areas. We are excited to finally be able to offer the Italian regions access to our products at a great price level, which is crucial in times of limited resources.

Given the complexity of the fragmented Italian market and the opportunities for CSL arising from the participation in regional tenders â?? what is on your agenda to further support the NHS in self-sufficiency?

This is a very complex environment primarily driven by the authorities. For example, all plasma collection centers have to be audited and validated by the state â?? a prerequisite for the Italian state to open up the toll manufacturing towards other European countries. Italy is following the European GMP guidelines, which allows us to include the Italian collection centers in our centralized plasma master file. We have to audit and validate all our collection centers in order to ensure that the quality corresponds to our expectations. Only once EMA has approved this plasma master file we are actually able to collect and fractionate plasma in these plants. This is really illustrates the complexity of our business environment. A lot of challenges lie ahead, but being one of the service providers helping the Italian National Health System to achieve self-sufficiency is an important strategic move for us; moreover, by doing so we are now able to offer the regional health authorities a portfolio and economic yields which they did not have access to previously.

As a result, what kind of structural changes did you have to make to the Italian organization?

The Italian affiliate used to be a commercial branch, investing in medical affairs and running clinical studies, such as phase IV and post market surveillance studies. For the first time we are now competing in a new area, that is as a service provider, and this deviates somewhat from our core competency. Consequently, we are currently setting up a new department within CSL Italy that will be able to cater to the demands of the Italian regions in the best way possible, in order to continue our reputation as a reliable company.

In addition, toll manufacturing is a part of CSLâ??s origin. We just celebrated our 100-year anniversary and we stand as a USD 5.5 billion company, present in more than 30 countries worldwide, fractionating more than 12 million liters of plasma and offering the broadest product portfolio within the plasma derivate field. We are continuously improving efficiencies, both in production and research activities in order to introduce new products year-on-year, and have the global goal of reaching USD 10 billion in turnover by 2020.

For example, we are currently launching Respreeza, a maintenance treatment for severe Alpha-1 Antitrypsin Deficiency patients. It is a very exciting time for us, launching at least one new product per year in addition to new indications and formulations. At present, we are negotiating with AIFA for four new products. This engagement has positively translated into sales, with additional revenues coming from self-sufficiency.

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How does the Italian clinical research community feature within CSLâ??s global R&D activities?

The answer is two-fold. In terms of basic research, CSL has eight research centers around the globe in Australia, Japan, US and Europe. We are a classic multinational company in that sense where research nowadays is brought forward very closely working in collaboration with universities for example. This is an area in which Italy still has room for improvement. Recognizing this, we have taken initiative to improve, for example during the phase II and III studies for Idelvion, the principal investigator was Dr. Elena Santagostino from the Biancho Bonomi hemophilia center in Milan.

We want to further facilitate these kinds of collaborations between between Italian centers of excellence and research groups around the world. Another good example is the PATH trial evaluating the use of Hizentra to treat Chronic Inflammatory Demyelinating Polyneuropathy. We are currently in the final phase of the biggest phase III study in this specific field and the most successful patient recruitment took place in Milan and Turin. Despite the fact that we do not have any basic research in Italy, we have a strong presence in the Italian clinical research community.

What will be your main priorities as you seek to drive growth and build market share over the next few years?

In order to successfully launch products, we need to have the right staff on board. Last year, CSL Behring was awarded the title â??great place to workâ?•. The participation was actually initiated by my colleagues and employees, which have recognized our investment in education and personal as well as professional development. We are trying to develop our organization in a way to face future challenges in the best possible way. An example of this effort is evident in the launch of Hizentra, the first 20 percent subcutaneous immunoglobulin unit in the market. It was a very small market and the research available at the time predicted minimal chances of success with this product. Today, subcutaneous immunoglobulin is the biggest growth driver in the area of immunoglobulins because it tremendously improves the quality of lives of patients and as a result saves the national health system a great amount of costs. We are 100 years old but we are just getting started. We have a lot of opportunities in front of us and we are excited to embrace them.

Where would you like to see CSL Behring Italy in five years?

The Italian market is certainly a challenging one and we have experienced different changes in the area of cost-containment measures and healthcare expenditure. Nevertheless, AIFA is well-known for revolutionary ideas, such as the risk-payment approach, which is unparalleled to a lot of other countries. It will be interesting to see how Italy will develop in the area of cost containment while maintain the ability to maintain and support innovative therapies. We as CSL see ourselves as a business leader and we want to our customers, our commercial clients and patients, to be satisfied with our reliability in delivery, supply, support both from a commercial as well as R&D point of view.

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