Lourdes Pla – General Manager, Lundbeck France & Benelux

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Lundbeck France and Benelux's Lourdes Pla discusses Europe-wide restructuring, the importance of the French affiliate to the global group and the government's attitude towards healthcare and neuroscience.

These are exciting times for Lundbeck – the European operations undertook a major restructuring two years ago and now you have a brand-new CEO in place. How have all of these developments been trickling down to the local affiliate level?

The French affiliate has actually been through no less than three restructurings within the past five years as part of a Europe-wide reorganization. Essentially, Lundbeck, globally, had been facing some headwinds arising from strong generic competition for some of our star products. Equally much of our drug development pipeline remains still in the early phases, so there was an imperative to generate some cost savings and optimize the business model. One decision was, therefore, to consolidate around our core CNS strengths and assets.

The arrival of Deborah Dunsire as global CEO heralds the next stage of our development trajectory. With her considerable track record in biopharma and first-hand experiences on both the research and commercial sides, she should be well placed to help us partner with other industries and labs with a view to developing and acquiring new molecules for the coming years.

Within the French organization, we have returned to a leaner, more efficient organizational size commensurate with the market performance, and one that is now well structured for being able to grow the business. One noticeable change has been that we are now organized along business area lines with France grouped with the Benelux when it comes to coordinating sales strategies.

How would you describe the legacy and strategic importance of the French affiliate?

Lundbeck first established a presence in France back in 1992 and subsequently, in 2009, acquired a pharmaceutical production unit, Elaiapharm, located in the Sophia-Antipolis technopole of the Alpes-Maritimes. Over the years, we have been steadily investing in upgrading and enhancing the capacity of this site with close to EUR 60 million euros being expended during the period 2010-17. The facility remains of key strategic importance to the company and indeed manufactures a range of products for export all around the globe. In all, some 65 percent of its total production is designated for export

Among the employees of Lundbeck France, 95 work for the subsidiary of which 58 comprise sales representatives. We have five personnel dedicated to research and development of new drugs who report directly to Denmark and then a further 184 involved in production at the Elaiapharm site.

What would you say have been your main achievements and priorities since your appointment as general manager of France and the Benelux in March last year?

My first priority has been to return the affiliate back to an upward growth path and I am very proud to be able to reveal that this year we are back to growth for the first time in seven years. This is testament to our ongoing efforts and the effectiveness of the new streamlined business structure in place that emphasizes agility, flexibility and timeliness. My second big objective has been to instil a new spirit and drive within the team. When there has been a lot of internal upheaval in the form of personnel changes, it is always a good opportunity to reinforce the team identity and sense of mission and purpose.

One of the differentiating characteristics of Lundbeck is how passionate we are about furthering the discipline of neuroscience. We are, indeed, the only specialty pharma player exclusively dedicated to this branch of medical science and it is important that this shines through in our dealings with patients, practitioners and the state.

Which areas are currently driving growth and generating the most revenue in France? What would you say are your star performance products right now?

Lundbeck France has always proposed innovative medicines to meet the needs of our patients. These treatments have become references such as Seroplex® for the treatment of depression or Ebixa® for the treatment of Alzheimer's disease. The best performance is undoubtedly coming from new products such as Brintellix® which was introduced to the market one and a half years ago for the treatment of major depressive episodes. Many of the more mature products, meanwhile, have been registering declines not just owing to their maturity, but also due to overall price erosion within the French market.

What, then, is your assessment of the ease of market access in France?

France is a difficult country to introduce new innovation compared to some other West European markets. By way of example, in Spain everything is relatively straightforward. Average prices are moderately high, so it is easy to arrive at a floor price that is acceptable. EMA decisions are reflected at the national level. Moreover, every Spanish region possesses its own pricing criteria so, whenever negotiations are going tough with one particular province, then you still have other options available.

In France, by contrast, there is a single negotiation process to go through for application across the entire territory, so if an agreement cannot be reached then you are effectively locked out of the market. There are head-to-head adjudications on the value of different molecules, and the average prices are lower.

The resulting impact of all of this is that we can experience noticeable delays bringing a product to market and sometimes we find ourselves unable to launch a particular molecule at all! For example, we have a new Schizophrenia therapy, in conjunction with Otsuka, that we rolled out this year in the Nordics and will imminently arrive in the Dutch, Italian and Spanish markets, but we are still trying to figure out how and when to get it to France.

Are you expecting any improvement now that with the Macron presidency there is a staunchly pro-business government in Matignon?

President Macron and Prime Minister Edouard Philippe made strong commitments to increasing the attractiveness of France for the health industry sector during the CSIS meeting early July. There are however difficulties when it comes to translating the political intentions into actions. The Social security budget for 2019 is currently being reviewed at parliament and senate level and the savings requested on the drug budget (in particular through price cuts and taxation) are extremely high.

In August, a decision was taken to no longer reimburse Alzheimer's therapies on the grounds that they don't demonstrate sufficient proof of efficacy during clinical trials and that instead that the government should channel the money saved towards funding the palliative side of Alzheimer's care. We believe that this is an unsound decision that effectively abandons an entire stratum of patients and the people caring for them. It sends out completely the wrong message at a time when these patients require reassurance and hope.

Nor does this decision take into account the complexities of neuroscience. The pathways of psychiatric and neurodegenerative disease are still relatively poorly understood, but what we are beginning to discover is that they manifest themselves in very individualized ways. It nowadays makes sense, for instance, to talk about multiple schizophrenias because each sufferer of the disease registers a distinctive set of symptoms and will display different responses to treatment. Our therapies therefore lend themselves to the new era of personalized medicine but will not necessarily generate the same clarity of clinical trial results as traditional, classic molecules in other more clear-cut therapeutic areas like hypertension. Our view is that the authorities need to start taking these realities into account.

Our current political classes seem intent on taking steps to improve mental health, but psychiatry and neurodegenerative disease tend to be the poor relations when it comes to receiving investment and material support.

How does Lundbeck go about managing the additional risks inherent to the neurosciences realm?

The niche in which we specialize is especially risky. In recent years we have seen heavyweight players such as Pfizer and Lilly drawing in their horns and scaling back their R&D programs in this therapeutic area after some high-profile phase III blowouts. As I mentioned before, it is notoriously difficult to generate comprehensive clinical trials evidence for studies on conditions like Alzheimer's or Schizophrenia and that is because of the heterogeneity of the diseases and the fact

that we maybe don’t yet have the proper tools to measure their true impact across all these variations.

One way that we go about mitigating the risks is to open our doors to external partners. Otsuka, for example, has brought a lot to our collaboration at the global level especially when it comes to pre-clinical and phase one knowhow and the relationships with universities. As is so often the case, our weaknesses are also our strengths. The high stakes nature of the game has led to big pharma actors like Pfizer making their exit and the opening up of the space for a specialty and neurosciences-dedicated outfit like us to consolidate its foothold.

To what extent can Lundbeck become a true partner to the French state in the sense of helping to take costs out of the healthcare system through delivering real value for money and offering efficacious treatment pathways?

With psychiatric and neurological illness, some 80 percent of the overall cost derives not from the pill itself, but from hospitalization and the need to have carers in the home. Naturally if Lundbeck can deliver up an injectable that cuts the hospitalization time and enables the patient to go to work and become a productive member of society, then that is going to generate significant cost savings. Unfortunately, in France, the system is such that those who make the decisions on price of medicines – whether CEPS or public hospitals – must concentrate upon the drug budgets without real consideration of the overall picture and ultimate cost of care. This is where we need the authorities to look at the bigger picture and value our products in the correct manner.

What are your future goals for the French affiliate?

I am very glad that Lundbeck’s French operations have now swung back into growth mode and am quietly optimistic for the future. Lundbeck is staunchly committed to France as demonstrated by our strong manufacturing presence and we are confident in our ability to contribute even more as a partner in mental health and countering neurodegenerative disease. Our ambition is very much to introduce cutting-edge, latest generation therapies in this field to the market and look forward to the efforts of the authorities to facilitate this process as pledged at events like this year’s CSIS.

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