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A relative newcomer to the Nordic countries, Otsuka has successfully built a strong foothold in the region. Pontus Billstam, managing director for the Nordics & Benelux, looks back at the main milestones in the affiliate's development and explains the importance of the Nordic region for Otsuka as a testbed for new product launches. He also talks about the market access challenges inherent in the Swedish healthcare system as well as the opportunities for increasing research collaboration levels in Sweden.

You have been managing Otsuka Pharma's operations in the Nordic region for the past seven years now. Could you introduce our readers to the footprint of Otsuka in the Nordic region and your current strategic priorities as the head of the subsidiary?

The local affiliate oversees operations in seven countries, the four Nordics and, more recently, Benelux. Compared to other Big Pharma companies, Otsuka's presence in Europe is relatively new and the group does not yet have affiliates in all European countries. In Sweden and the Nordic region, the affiliate was only founded in 2001. During the first seven years, we operated as a one-product company, distributing a single medical device, before the pharmaceutical business was launched in Sweden in 2008 and across the Nordic region the next year. We are now strongly established as a Nordic pharmaceutical company and, a few years ago, the Nordic affiliate received

the mandate to develop operations in the Benelux region as well, in preparation for the potential creation of a standalone affiliate there.

CNS is our main therapeutic area. The development of the affiliate was kick-started by Otsuka's international blockbuster compound, an atypical antipsychotic for the treatment of schizophrenia and bipolar disorders. The Nordic launch was done by BMS and Otsuka took over the full local responsibility in 2013-2014. The next-generation of the treatment, a monthly long-acting injection, was approved by the EMA in 2013 and has continued to drive performance until today. In collaboration with Lundbeck, we continue to launch improved treatment options within schizophrenia and our latest product was approved by the EMA in May 2018.

Another important therapeutic area is nephrology/endocrinology where we work with a molecule available for the treatment of two indications, hyponatremia and autosomal dominant polycystic kidney disease (ADPKD), a rare genetic kidney disease.

Going forward, Otsuka has high expectations for future products within nephrology and we will continue pursuing our ambition to become a leader in the CNS area. As a result of that, we are also focusing on the treatment of Alzheimer's Disease and dementia, a growing global health challenge and burden on individuals, caregivers, governments and healthcare systems, especially in rapidly ageing countries such as Japan. Otsuka has high expectations in this area.

Finally, Otsuka is determined to provide new treatments for individuals diagnosed with cancer, focused mostly on blood cancers with high mortality rates such as leukaemia.

In all these areas, our ambition is to be able to launch new products in the coming years.

When interviewed your colleague Steward Pearce, then managing director of Otsuka in the UK and Ireland, he stressed the importance of Europe as a testbed for their global success. To what extent is this true of the Nordic region?

I could not agree more. Europe, in general, is a tough market, and among European countries, the UK and the Nordics are the most challenging in terms of HTA and market access. In many ways, they offer a representation of how the future will look. Moreover, these countries are used as benchmarks by other European nations for pricing and reimbursement decisions. For all these reasons, they are the perfect testing ground to launch new products. Both the UK and Sweden are used by Otsuka as early launch markets, which for me is very exciting.

Regarding market access, what do you see as the most challenging part of the Swedish system?

In Sweden, there are many layers to overcome in order to launch a product on the market. The first is the national layer with the Dental and Pharmaceutical Benefits Agency, or TLV. Depending on the outcome of TLV´s assessment, companies may have to negotiate with county councils and other regional and local payers, which takes a long time and sometimes leads to different outcomes across regions, causing unequal access to healthcare which should not be acceptable in a developed country like Sweden. This delayed and unequal market access does not benefit anyone, neither patients, taxpayers nor companies.

In 2016, the TLV decided not to include one of your products in the pharmaceutical benefits scheme. However, the next year, the NT Council recommended its use to all county councils. How challenging was the market access journey for this drug?

This is a good example of an area with room for improvement for the Swedish system. Even though Otsuka had a first-in-class treatment option that adds value to patients, it took too long to get access in Sweden. But thanks to the recommendation from the NT Council, we managed to receive access in all 21 counties.

As you mentioned, Otsuka now wants to become a leader in Alzheimer's treatment. On May 2018, the Swedish government introduced a new national strategy for dementia care and is one of only 32 countries with such a plan. What do you see as the strengths and weaknesses of the Swedish model of dementia care?

In mental care in general, Sweden is relatively advanced. However, there is still room for improvement. About a decade ago, Sweden introduced a healthcare reform which drastically reduced the number of hospital beds. The idea was to have mental health patients reinsert themselves in the community, instead of being hospitalized. While I agree with the intention, there is now a lack of hospital beds and big regional differences in quality of care.

Regarding Alzheimer's disease and dementia, there is a high awareness among the Swedish public about this growing health challenge. Her Majesty Queen Silvia of Sweden has contributed

enormously to raising awareness about this issue. She founded the Stiftelsen Silviahemmet foundation as well as the Swedish Dementia Center and is now Ambassador for Alzheimer's Disease International.

The regulatory authorities are concerned about the situation. I hope there will be more investment in this area.

Since 2007, Sweden has had a national registry for dementia. Can Otsuka leverage this asset?

I really hope we can. Generally, Sweden is sitting on a wealth of fantastic data thanks to its unique quality registries. While Sweden is good at using them, it could be much better. In this regard, collaboration with pharmaceutical companies could bring a win-win situation for everyone.

One of my main ambitions for the future is to develop our research collaborations in Sweden. Thanks to its quality registries and other assets, Sweden is an excellent place to conduct research, especially in terms of real-world studies.

Among Otsuka's extensive pipeline, what are the products you are more excited to launch?

Personally, I am very excited about the potential of our drug candidate for Alzheimer's disease. We have seen positive results with a drug intended to calm agitation in patients with *Alzheimer's* disease, one of the most challenging symptoms in dementia care.

Moreover, Otsuka is collaborating with Akebia to develop and commercialize a treatment for anaemia associated with chronic kidney disease (CKD)..

What are some of the best practices you have implemented here that the group can learn from?

We collaborate with our customers on a deeper level, going beyond simple product presentations but instead building true partnerships to drive healthcare forward in a positive way.

Moreover, as access to customers is relatively difficult in the region, we are developing peer-to-peer digital platforms to interact with and educate our customers. At the moment, we have a pilot project underway in the Netherlands.

Where do you want to take the affiliate in the next three to five years?

We have proven ourselves able to execute launches successfully and build strong customer collaboration. In the next few years, we must continue on this path and prepare for the big launches ahead of us. I would for the affiliate to become a role model in market access and real-world data generation. Finally, our presence in Benelux should reach the same level as in the Nordics.

On a more personal note, while the turnover of general managers is generally quite high in Sweden, you have now been leading the Nordic affiliate for seven years. What makes you so dedicated to developing Otsuka's operations in the region?

As Sweden is a small but challenging market, it often used by pharmaceutical companies as a learning ground for new managers. However, I have always felt that it is much more preferable to have a local manager dedicated to achieving a long-term vision. This mentality fits well with Otsuka's corporate philosophy. As a Japanese former family-owned business, Otsuka operates with a long-term view, and not on a quarterly basis. As such it is a unique company. So far, I have never got bored as there are always new developments. And since we have shown our ability to deliver results, I have been given the opportunity to stay.

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