

# Interview with Martin Soeters, President, Novo Nordisk Europe

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13.06.2010

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Many companies that are focused in the diabetes segment have recognised the need to strengthen their operations in emerging markets, due to the increased prevalence of the disease in countries such as Mexico and Brazil. Indeed, Novo Nordisk's biggest insulin production facility outside of Denmark is in Brazil. Given these priorities, how has Novo Nordisk approached the European market in recent years, and to what extent is the region a priority for the company today?

The facilities in Brazil are roughly the same size as the facilities that Novo Nordisk have outside Paris, in Chartres. Novo Nordisk acquired a company called Biobras, and turned that company into part of our business and facilities. Novo's third site is in Clayton in the US. Those sites are the company's main producers outside Denmark. The company is establishing a stronger site in China, and have started insulin pen production and expanding its staff. Novo Nordisk today has over 65% insulin market share in China.

Europe comprises one third of the company's global interests. The company has been in Europe since its creation more than 80 years ago, with diabetes as its core business. More than 80% of our activities are in diabetes and based on our pipeline, it will be even at least 80% in the years to come. The company's core competency is its proteins. Novo is extremely good at making large quantities of proteins. Biotech is always exciting and innovative, but as soon as small companies need to move from small quantities to huge quantities, it is always a big issue. Over the years, Novo Nordisk has been able to provide millions of patients globally with proteins: the company started its development with insulin, and has progressed from this onto insulin analogs, which are today first choice across the globe. Now the company's newest product is the first human GLP-1 analogue on the market, Victoza, which is a completely new method for treating diabetes type 2. Outside of the diabetes segment the company produces growth hormones, and recombinant Factor VIIa, which is a product for people with haemophilia, incorporating a specific antibody. The number of patients using this Factor VIIa in Europe is around 1000, with 1000 patients in the US and around another 1000 in the rest of the world. Novo Nordisk decided to develop that compound before there was no treatment. The children who suffer from this, usually boys, cannot go to school, and are effectively confined to their beds for their whole life. Today, with the help of Novo VII, which is a recombinant protein, and thus has no risk of hepatitis or AIDS risk.

In the past, the company employed consultants to evaluate Novo VII, who concluded that we should not develop the drug, as the business it would bring to the company was minimal. Like an orphan drug. However, we concluded that the drug would meet a real medical need, and although it would have a small target audience, that we would develop it. However, today the drug is used in other

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areas, and many patients's lives have been saved by the development of this recombinant factor VIIa.

Novo Nordisk is globally respected as one of the leaders in diabetes care, but as big pharma encroaches increasingly on the company's territory, what can you do to maintain this reputation, and how can you ensure the sustainability of Novo Nordisk's development?

Usually, pharma companies spend around 14-16% of their revenue on R&D, although this is different from company to company. Novo Nordisk is on the higher side of this amount, but since we are mostly focused on diabetes, a much higher percentage than other companies is focused on diabetes research. Novo Nordisk has been developing insulin analogs, which have now been introduced into the global market, and their patents will still run for a few years more. The company has just started phase III studies with the successors of these insulin analogs, SIBA and SIAC, and there are already quite a large number of patients recruited, and due to competitive recruitment we expect the rest of the patients to be added to the study very quickly, reaching our target of 10,000 patients very soon. These products will be approved and on the market well before the patents of their predecessors have expired.

A few months ago, Novo Nordisk launched Victoza (liraglutide) in Germany, which is doing very well. The effects of the drug are already impressive, but doctors prescribing the drug are experiencing even better results than predicted during the clinical phase. The results are focused on four things: the glucose lowering effect is very significant, and better than any other product available. Patients also experience a 2-3 kilo weight loss in the first few weeks, rather than the traditional year-long time frame, and in some cases this weight loss is even more impressive. The drug also causes a significant reduction in blood pressure, and finally, from pre-clinical data, we have seen a significant improvement of the beta cell function. A beta cell is a cell in the pancreas where insulin is produced, and people with diabetes either have reduced (type 2) or completely non-functioning beta cell function (type 1), which is the reason they need insulin. With this product, we see regeneration of the beta cells, although it is very difficult to investigate that in humans for this to be conclusive. This product was launched in Germany first, followed by the UK and then Denmark, and Novo Nordisk is in the process of launching the product in other European countries.

Diabetes care is all about improving quality of life for patients that are currently resigned to a lifetime of treatment. Novo Nordisk has always made a priority out of making sure that those using its products are able to lead as normal a life as possible. This is not just down to drug development, but also the creation of new delivery systems. What examples would you point to specifically that Novo have undertaken in order to improve the quality of life of diabetes sufferers?

Between 40 and 60% of all people with diabetes are not in good control of their disease. As a result of that, you see very dramatic complications: blindness, amputations, kidney disease and heart attacks. Every year, hundreds of thousands of patients across Europe die from diabetes. Those are dramatic figures. Many studies have shown that if patients gain metabolic control, and in particular glucose levels in good control, then there is a very positive impact on late complications. In a sophisticated country like Germany, 23% of all orally treated patients are still not in good control of their disease, and around 50% of all insulin treated diabetics are not in good control. In Germany, at least two million patients are not even diagnosed. This is sophisticated country, and still doctors do not recognise that the symptoms people experience are a diabetic concern. Doctors, and particularly primary care doctors could be better educated; more motivated and feel more comfortable in the communication process with the patient. Diabetologists of course are different and know very much.

The second issue is the compliance of the patient. Patients don't always understand or want to do what the doctor says, and so it comes down to the drug and the drug delivery. If diabetes

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medication is not well used, not in the right dosage or not in the right way or at the right time, it can lead to problems. To increase compliance of the patient, and to increase their accuracy in self-treatment, Novo Nordisk decided in the 80's to develop the pen delivery system. In the past, the patient had to use a syringe and vial, and with elderly patients, this would often lead to problems. We wanted the patient to receive the right dosage every day, in a way that was easy and convenient. That is the reason why we developed the pens and offered since 1985 as the first company a convenient device like that. At the same time, the company worked on improving the delivery needles: we made them thinner, and worked on the angle and siliconization of the needle. With Novo Nordisk's pens, the patient can hardly feel the injections.

Today, the big issue remaining is that patients have to finger prick to test blood-sugar levels, and this can be painful. This is one advantage of Victoza: you don't need to do blood testing any more. That is one reason why Novo Nordisk is seeing a very positive response to this new drug. The only requirement is that the patient still needs to have some beta cell function. If the patient is at the end of their beta cell function, then it will not work, and insulin is needed.

The numbers of people with poor control over their diabetes in Germany are big, and that is the reason that Novo Nordisk has a huge potential business opportunity, because the doctor always has the right intentions: they want to get the patient under good control. The patient also has the right intentions, as they want to be in good control. These patients who are not in good control and not using Novo Nordisk products present excellent business opportunities. The same with the patients not diagnosed.

The dichotomy is clear between Germany's reputation as an innovator, and the country's attitude to generics. Given this, and Novo Nordisk's priorities in terms of R&D, how much of a challenge is it to position the company as the diabetes caregiver of choice in the country, in a sector where there are so many cheap insulin alternatives?

Metformin was a diabetes drug developed in 1950. Since then, nothing has been improved on the product: it is generic and a low cost drug, and very effective. The product is still used quite a lot, and it is good for the diabetic market that there are generic alternatives. However, Novo Nordisk is a true innovator, and considers itself to be a real diabetes care company.

Insulin was discovered in 1922, but it was short acting. Novo Nordisk developed two long-acting systems. One based on protamine (NPH), and the other on zinc. These two concepts were not patented, but left free for anyone to use, and are still used in Germany. Quite a number of patients are still using NPH insulin, which stands for Neutral Protamine Hagedorn, named after Hans Christian Hagedorn, Nordisk's founder. From this animal-derived insulin, the company changed some amino acids, and made a human-structured protein, but eventually moved from biosynthesis to recombinant structures. Now the company has the new generation analogues in phase III development, which will come to the market in a few years. On top of that Novo Nordisk has three different insulins that are short, mixed and long acting. Then there is Victoza, and in the late-stage pipeline is looking at oral versions of our current products.

There are two million undiagnosed diabetics in Germany. In Italy, Mr Mastro Monaco was talking about how the level of education and recognition rates for diabetes in Europe are actually much closer to those of less developed markets than you would expect. Compared to other Europeans, how do you rate the education level of Germans about diabetes, and how has this affected the way that Novo Nordisk operates in the country in terms of making education a priority?

In the US, trainee doctors get 4 x 50 minutes in their five years education before they are fully qualified. Therefore, I think it is important that companies like Novo Nordisk are actively involved in

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education, and the affiliate here in Germany is involved in a whole range of activities with GPs and offers a whole programme called Novo Nordisk Academy. The diabetic specialists in Germany are excellent: very knowledgeable and with a high reputation compared to those other countries. The GPs are in the process of becoming more knowledgeable and confident in treating people with type-2 diabetes. This is necessary: diabetes is a serious disease with grave consequences if it is not recognized.

The costs involved in treating diabetes in Germany are €16 billion annually, whilst the amount spent on diabetes drugs is €1.2 billion, or 7% of the total figure. At the same time, 75% of this figure is spent on the treatment of late complications. If diabetes treatment is optimized, this figure can be dramatically reduced.

Another aspect of this situation is that if patients are not in good control of their diabetes, then patients are tired and often sick, and people stay away from work or school, and stay at home. There is a lot of absenteeism. At the same time, when people do not feel optimal because of their fluctuating blood sugar level, they are not as productive. Many diabetics lose their jobs and have to depend on social security, and so do not pay taxes. From an economic perspective, it is much more effective if people stay in the labour process and continue to pay their taxes.

If we were to come back in five years, what would you like to have achieved in that time?

If we don't have the patients in good control in a significant way in the next five years in Germany, Novo Nordisk will not have done their job well. The company encourages a certain culture towards diabetes in its employees. We call this the "Novo Nordisk way of management", and it encapsulates the company's values and fundamentals that we encourage. Novo Nordisk believes that all its employees should be concerned and have a social attitude towards getting patients in good control of their diabetes. During their free time, our employees attend patient meetings, not because we ask them to but because they want to do it.

In five years from now, I hope I will be able to tell my future grandchildren that I did not just sell three million insulin vials to patients, but that I have done something significant for the wellbeing of patients. Since Novo Nordisk is so focused on this, I hope that we should be able to do something about it in the coming years. The company has just opened a European Changing Diabetes Advocacy office in Brussels, next to the European parliament. We took people from different companies, and from government. Its only objective is to get diabetes on the political agenda, something that we work on in Berlin as well.

On a personal note, you have been in the company for a very long time. What attracted you to Novo Nordisk, and how has that attraction developed over the years? What is it that motivates you today?

I have been at Novo Nordisk for thirty years, and I have always wanted to stay at the company. The reason I joined the company was that it was very different from other companies, in that it is owned by a non-profit foundation. The company has A shares and B shares. All the A shares are in the hands of the foundation, and the A shares have voting rights, which means that the foundation has 70% of the votes. The B shares are listed on the Stock Exchange, and have done very well. Compared to its peers over the last few years, Novo Nordisk has outperformed. We are doing very well from a commercial perspective, from a cash perspective, and from a share price perspective. The reason that people like to work for Novo Nordisk, and why we have repeatedly been selected as the best employer in different places all over the world is that this foundation is very appealing. The company is able to take risks and really make advances in medicine without to worry about the share price dropping. Our social attitude is seen in our commitment to projects such as the World Diabetes Foundation, where the company has invested over €70 million, to give the poor access to diabetes

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treatments. In countries in Latin America and Africa Novo Nordisk is involved in many different projects to increase access and education, but as a company Novo Nordisk is conducting its business in such a way that people feel proud to work here.

Of course, as well as our social commitments, we have also to deliver our commercial objectives. This awareness is referred to in the company as its triple bottom line: the financial aspect, social responsibility and environmental responsibility. Novo Nordisk uses windmills to run its factories, encourages the use of hybrid cars, reports its animal testing numbers and tries to reduce them, and recycles water. The company's pen delivery system uses polypropylene, which is much more environmentally friendly than PVC, but more difficult to produce. Overall, Novo Nordisk is very consistent in the way it does business.

What is your final message to the readers of Pharmaceutical Executive about Novo Nordisk in Europe and in Germany?

Novo Nordisk considers Europe to be its home ground. In Europe, the company wants to be recognised as a good company with continuously innovative products in the area of diabetes. Apart from promoting and marketing those products, we want to be recognised for our contributions in changing the infrastructure, education and reimbursement of diabetes. We also hope we will be recognised as one of the best employers, and that employees join and stay with us until their retirement. I came to the company in my early 20s, and I will stay here until I retire.

Germany is one quarter of Novo Nordisk's European business, and Novo Nordisk is working on improving its organisational structure here. Next week the affiliate will get a new country manager to run the German operation, and it recently got a new head of HR. We want to increase our expertise of being an excellent employer. The company has around 565 employees, two-thirds of which are in the field. We want those employees to be happy and proud to work for Novo Nordisk. Our biggest challenge is the recognition of the contribution of our diabetes drugs in the context of total diabetes care. There are some challenges, and work to do with the regulatory authorities. It is not that they are unwilling; it is simply that it has not been communicated to them yet what the overall picture looks like.

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