Interview: Sanne Groenemeijer â?? General Manager, Novo Nordisk, the Netherlands

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30.09.2015

Tags:

Holland, the Netherlands, pharma, pharmaceuticals, regulations, healthcare, government relations, diabetes, Tresiba, Europe, Novo Nordisk,

In a market under strong pressures to contain costs, launching innovative products in a crowded market can be a challenge. Novo Nordisk GM Sanne Groenemeijer believes his organizationâ??s willingness to try various solutions has helped them to maintain their dominant position as the market leader in diabetes.

Since you took the reigns in 2012, what were the market dynamics then, and how have they changed since?

Starting in 2008 and 2009, it was clear that there would be significant changes in the marketplace and that some challenging years would lie ahead. The financial structure of our healthcare system was simply no longer sustainable. There were many different ideas and plans at the government and payer level regarding how things should be reformed; from our perspective, we were unsure what to expect. We did our best to prepare for anything and everything. As Novo Nordisk Netherlands, we were very much aware of our responsibility to contribute and support the necessary changes.

Starting in 2012 some significant structural changes were indeed introduced in the Dutch healthcare space, which had become effective by the beginning of 2013. Perhaps the most significant change was the transfer of the budget for in-patient medicines to the hospital budget. Individual hospitals were now responsible for high-cost, in-patient treatments. Novo Nordisk has portfolios of products in hemophilia and human growth hormone, so these budgetary changes impacted our business too. Sales of our hemophilia medicines fell by around 50 percent in two years, which was mainly driven by price cuts arising from this transfer of in-patient medicine budget to the hospitals.

We knew maintaining previous sales levels would be difficult, but were confident that we would be able to defend our position with our innovations such as new injection pen systems for patients. Unfortunately, given the environment, these â??value-addedâ?? treatment options had zero impact on payers and doctors alike, the latter being a surprise. However, with reimbursement for these innovative in-patient medicines now coming out of hospital budgets, prescribers were suddenly faced with impossible decisions such as having to choose between either retaining a nurse, purchasing new equipment, or prescribing an innovative therapy. Unless the clinical added value of the more innovative therapy is very substantial, very few doctors would choose it.

At the same time, dynamics in the diabetes market completely changed in 2012, when some of our competitors launched their DPP-IV inhibitors. Novo Nordisk operates differently than most pharmaceutical companies. We have had good working relationships with stakeholders in the diabetes community â?? even at the GP level â?? for more than 30 years. We recognized that, given the recently introduced cost containment measures, the diabetes market was not prepared for a strong product launch, with a more typical approach in which products are pushed at full force. The Netherlands has highly effective treatment regimens based on the Dutch diabetes treatment guidelines. Because of this, most patients can be effectively treated with generic versions of metformin and sulphonylureas at a cost of about two euros per month. When other players started pushing products in the same class at 40 times the price for a patient group of approximately 800 000 patients, this caused a tremendous pushback against innovation in diabetes.

I understand and even agree with these priorities. But we must always consider the patient, and thatâ??s where we have some concerns regarding the way innovations are currently weighed in the Dutch healthcare system. If the decision to use an innovative therapy is purely based on budgetary considerations, I vehemently argue that we would be heading in the wrong direction.

What have you done to adapt the organization to the new market?

The first step was strengthening the dialogue with payers. We did so immediately in 2012. This was the first step to diffusing the hostile atmosphere that had arisen, where the general attitude was that pharmaceutical companies were greedy and aggressive, motivated by nothing but profits. We can understand this emotion in a few instances, but in general it just isnâ??t the way things were. With between 60 to 70 percent market share for our insulins and GLP1s, Novo Nordisk Netherlands represents two thirds of pharmaceutical costs for diabetes. Thus, payers recognized, as did we, that more dialogue is paramount.

We aimed to position Novo Nordisk as the company to turn to for specialized cases in diabetes, and to be a collaborative, constructive partner for the diabetes community at large. The majority of the roughly 940 000 people living with diabetes in the Netherlands can be effectively treated with either dietary and physical exercise regime changes or with generic therapies. Thus Novo Nordisk Netherlands does not have the aim to target the whole of the patient population with our innovative medicines. However, there is a subset of patients who do not do as well under the standard treatment regimen. It is these patients who can benefit most from our new, innovative medicines.

One of our biggest challenges at the moment is that we donâ??t have a national diabetes registry in the Netherlands. As a consequence, we donâ??t have a clear picture of how the general population of diabetes patients is actually doing. This makes it difficult to determine where we should draw the lines in terms of clinical parameters for access to the more innovative solutions. It is also a challenge because there is no system in place to define a specific subgroup for reimbursement. Thus far clinical trials have not been designed to demonstrate the effectiveness of our products within certain specific subgroups. In a market where cost is a major concern for payers, it is clear that this is the way forward. That way, those who can benefit significantly from innovative medicines can have

access, while improving the sustainability of our healthcare budget.

At the same time, the governmentâ??s experience of working with the industry is â??all or nothing market accessâ?•. After all, historically speaking, pharma companies usually call for unlimited access. When we start discussing â??segmented or partial market accessâ?• for only a subset of patients, and thus acknowledge that our products are not needed for every patient, itâ??s a discussion that they are not used to having. This was the start of our dialogue, to seek constructive collaboration to find the right group of patients who can benefit significantly from our innovation. As such our approach in our discussions with other stakeholders is very different from the overall discussion in diabetes treatment today.

What are some of the other items on your agenda in the Netherlands?

We have to understand that, even if the vast majority of diabetes patients are well treated with older generations of treatment options, if only a few percent of the nearly one million diagnosed diabetics are not treated well, the cost of future complications could go through the roof. Unfortunately, the Dutch healthcare financing system is quite rigid and compartmentalized. Therefore, despite support from various stakeholders who see the long-term benefits of investing in innovative insulins, the insurance companies had no choice but to respond saying that they are legally obligated to contain costs while delivering a certain standard of healthcare. Advancing this standard and considering external costs is quite simply not their responsibility. Another example is the reimbursement policy for insulin pumps â?? which cost approximately EUR 10 000 per year to the payer. While the cost of our most innovative basal insulin, which in theory could replace a pump in some situations, only costs about EUR 800 per year, the reimbursement authorities only agreed to reimburse this innovative basal insulin partially. As the budget for the insulin pump comes out of a different budget, this is a separate consideration from the reimbursement decision for our innovative basal therapy. The system has not yet caught up with the current treatment landscape. But this is where we are working with policy makers and government to change the way we look at access for innovative drugs.

What steps have you taken to encourage change in this regard?

We see that all stakeholders are aware of the need for change and we as Novo Nordisk Netherlands aid where we can to encourage policy alignments. We feel we have a strong obligation as a partner in gathering and processing the right information. As a country that has no diabetes registry, information is absolutely key to opening up these conversations on changing the way we look at innovation.

So the first thing we did in this respect was huge data analysis. Based on the guidelines, we identified certain parameters to measure who can be considered well treated, and found that only two thirds of patients are. Weâ??re currently at the stage of having this study peer reviewed and published. These findings are very significant for our discussion with policy makers, as it is very clear evidence that there is tangible room for improvement.

Given that this model is still under development, how did the launch of your most innovative insulin, Tresiba, proceed in 2013?

The payer saw benefits for this innovative therapy, but did not feel that the price was acceptable at the time we launched it. They were willing to reimburse the portion of the price equal to the cost of the previous generation of insulins. Given the pressures of the reference pricing system, trying to set up a new rebate scheme at the start did not make the most sense. So we decided to try launching Tresiba with a co-payment.

We really didnâ??t know what to expect. Looking across Europe there are many examples where patients are perfectly willing to pay sometimes even a significant co-payment. This goes for countries like Switzerland, but also in for example Slovenia, where the income per capita is lower than in the Netherlands. With roughly 60 percent reimbursement, the co-payment for average usage of Tresiba was between EUR 20 and EUR 30 per month. So we decided to try this out. As the first new basal insulin in 10 years, which was developed with a particular patient focus to tackle unmet medical needs, everyone was extremely excited.

After a year, we saw that patients were not willing to pay for it; 400 patients in a market of 250 000 insulin users. Doctors embraced the product, but despite developing co-payment materials and calculators, patients remained unconvinced about paying the out of pocket costs. The cost itself was not the issue. What is important to realize is that Dutch culture means that people are not used to paying for therapies that are prescribed to them. We have the lowest out of pocket spend for healthcare in the whole of Europe and tend to be unaware of the costs for individual therapies. Although the co-payment might be said to be low in relation to the benefits, it simply did not fit in Dutch culture.

As Novo Nordisk Netherlands, we understand and respect these cultural considerations. So, after a year of trying to sell Tresiba with a co-payment without seeing the uptake the innovative therapy deserves, we established a compensation scheme to reimburse the out of pocket costs for patients.

Yet, innovation must be rewarded and incentivized somewhere; if all healthcare systems took the current Dutch approach, companies would lack the incentives to take risks in developing new drugs.

It depends on the level of reimbursement. In Germany, where Novo Nordisk recently withdrew Tresiba from the market, the level of reimbursement offered was too low. It was set at the level of human insulin, a therapy now over 30 years old. Here in the Netherlands, the government is willing to pay something within the range of what we feel our innovative therapies are worth. So while we might not get what we feel is right, I truly believe that if you want to move forward, you must move forward together. This way, we are giving patients access to the best new drugs that we have developed. This lives up to our promise and the Novo Nordisk culture. The other part of our culture that is key to our success is that we tried the other options first. We took a few different angles and approaches in terms of marketing strategy and patient engagement, which played a key role in convincing our headquarters to support us in the decision to negotiate a new rebate scheme which would be acceptable to payers and lift the co-payment decision from patients.

Looking at a new iteration of this market access process, Novoeight was approved for Hemaphilia A earlier this year. How has the process advanced since Tresibaâ??s launch in 2013?

This was a fantastic challenge, because factor VIII products belong to the â??high priced drugsâ?? group and were moved to the hospital budget. The market for hospital drugs is effectively done by tender. We first had to effectively communicate the advantages of the new, innovative therapy. Then it was all about price and as a newcomer it was easy to come in at a competitive level. Because of this, since the product launch, we have been able to gain a market share of about EUR 2.5 million in a market of roughly EUR 100 million.

Netherlands is a highly developed market, but there are some gaps in terms of patient registries for diabetes and hemophilia for example; given the fact that the Netherlands encounters some issues first, what role can the Netherlands and Novo Nordisk Netherlands play within the European and global organization?

I think we are more or less a testing ground. We were the first to try the co-payment model for Tresiba, for example. Our sales and marketing organization is very good, so you can rule out the possibility of a certain commercialization model not working due to poor implementation. So you can really see how it performs. In terms of entrepreneurship, Dutch culture fits with Novo Nordiskâ??s culture very well. We are all willing to try out new ideas, be it as a testing ground within our global corporate organization, or as a Dutch company that looks at new ways of constructive collaboration with the government. We are not always fully aligned with our partners, but weâ??re willing to try out whatever points we can agree on.

This is your first position as general manager, what is the main thing you learned while shepherding your team through this tough period?

I think it was for my benefit that I didnâ??t have a lot of experience, because I wasnâ??t set in my ways. I was able to look at the situation with relatively fresh eyes and try to come up with creative solutions. If youâ??re on the same path for ten years, itâ??s difficult to change the way you operate. Iâ??ve learned that the world is three dimensional and you have to do your best to understand the perspectives of those parties that you have to work with. When you understand their perspectives, you can focus on how you can help them achieve their goals while achieving enough of your own.

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