

Interview: Bert de Jong – General Manager Benelux, Sanofi Genzyme, The Netherlands



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Bert de Jong, General Manager Benelux at Genzyme, discusses th

e solutions Genzyme is offering to patients suffering from rare diseases and MS in the Benelux and how these treatments add value overall to society, as well as the company's changing role in the Sanofi organization with the addition of the oncology and immunology portfolio to the Sanofi Genzyme business unit as of January 2016.

In Sanofi's announcement of 2015's third quarter sales, Genzyme recorded double-digit sales growth in all territories. What has been the key to this impressive growth?

The third quarter Sanofi results were good, and Genzyme offered a substantial contribution, coming particularly from the strong performance of our MS products Aubagio and Lemtrada. Genzyme's successful growth trajectory is seen as one of the reasons it has been decided adding the oncology and immunology franchise to the new Global Business Unit (GBU) as of January 2016. This GBU will be named Sanofi Genzyme. With the addition, Genzyme will become a bigger player within Sanofi. The Sanofi Genzyme business unit is expected to be an important growth driver in the company in the coming years. The other GBU's will be Sanofi Diabetes & Cardiovascular, Sanofi General Medicines (including Consumer Healthcare), Meril and Sanofi Pasteur.

How has this strong growth been reflected in the Benelux region?

Both Belgium and the Netherlands are contributing significantly. With two new MS therapies (Aubagio and Lemtrada) launched over the past two years in both countries, we had the opportunity to grow significantly. Belgium is doing particularly well, as one of the best performing launch countries worldwide for these therapies. Although uptake is slightly slower here in the Netherlands, these MS products have done very well. Generally speaking, there is a nice balance in the Benelux organization; the uptake from MS products has been better in Belgium, while the identification of patients penetration in Rare diseases is higher in the Netherlands compared to Belgium. Rare disease treatments represent a significant part of our activities in the Netherlands. In the Netherlands there are dedicated Centers of Excellence, with a strong international reputation, and also well-organised patient organizations. Next to that, the European headquarters for Genzyme is based in the Netherlands with roughly 250 employees. In Belgium we have over 600 employees working in a production facility, which is completely dedicated to the production of Myozyme for Pompe disease. So the Genzyme's footprint in the Benelux is important from several perspectives.

It is fair to say that the Netherlands is seen by its peers as one of the most challenging EU markets in terms of accessing the patient and pricing. What is your assessment of the Dutch market?

The Dutch market is indeed challenging, and the public opinion and that of the authorities is often pretty harsh regarding pharmaceutical companies. There is a perception that prices of drugs are too high and that pharmaceutical companies are making profits unfairly. Within HollandBIO but also together with Nefarma, we are addressing these misperceptions and encourage discussion about the added value of the pharmaceutical business. The total cost of pharmaceuticals within the healthcare budget, representing only seven to eight percent of expenditures, is quite low in Europe. Moreover, within health care costs over the past few years, the pharmaceutical segment stayed flat or even declined.

Today, one of the major challenges remains the imbalance between the intra-hospital system and reimbursement system outside the hospitals. Since the most expensive and innovative treatments fall under the quite restrained hospital budget, it is much more difficult for patients to access therapies when they are under hospital care. On the other hand, the products outside the hospital budget receive little scrutiny, apart from the preference policy, which has particularly impacted generic prices. The savings generated from the lower cost in one area (outside the hospital) should be used to fund necessary innovative treatment in the intra-hospital system.

The Netherlands will hold the Presidency of the European Union in 2016. What would be your key message to the Minister of Health at this important moment?

There is a growing collaboration between the Minister of Health and pharmaceutical companies, and I hope we're able to continue moving forward. Today, companies and trade organizations are invited more early in the process to inform the Ministry on our pipeline, while, in the past, we were only invited to submit dossiers rather than to face-to-face meetings. This is an improvement. At the same time the Ministry is asking pharmaceutical companies for more transparency on how prices are determined. Authorities claim the system is not sustainable and too many drugs have huge prices. I believe that pharmaceutical companies should take responsibility when it comes to explaining prices when they are above a certain level. I also strongly believe that we can still be much more efficient in quite some disease areas with regard to pharmaceutical treatments. The additional savings here could increase the access of innovative specialized treatments even if would be more expensive. The Minister of Health should foster the importance of innovative initiatives and consequent treatments in the Netherlands to ensure Pharmaceutical companies will continue to invest in the Netherlands or the Benelux.

What is your perspective on the initiative by the Dutch and Belgium Ministries of Health to negotiate jointly for lower prices of orphan drugs?

If you look at the part of the orphan or expensive drugs in the overall pharmaceutical budget, it is only a small proportion of the total healthcare costs. By focusing on this small market, few advantages are gained. Let me be clear, companies should be able to explain why there are sometimes significant differences in prices for orphan drugs, but again, in my view, it would be wiser to focus on the block-buster markets and to look into the efficient use of these drugs. A focus on more efficiencies within the hospital and general practice prescribing habits would be much more impactful than initiatives on orphan drugs. In the orphan drug market or expensive drug market it's key to assess the benefit-cost ratio. This has been guaranteed now through implementing strict start and stop criteria. Furthermore, the savings you can make in this wider segment can be used in the innovative segment, where more often, patients are suffering from an unmet medical need.

In 2013, after discussions took place between the Ministry of Health and parties concerned, reimbursement for the treatments for Pompe and Fabry disease continued. How will the government's agenda to further drive down the cost of medicines shape the Dutch affiliate's strategy vis-à-vis the availability of its products?

Although I do not know what will happen in the near future in the Netherlands, it is clear that the Minister of Health is focused on products in the hospital budget, as she believes that an enormous number of expensive drugs will soon arrive in the Netherlands. This is not a given, especially if you look back at the last ten years for guidance, and the current pipeline of pharmaceutical companies does not differ substantially. There is a trend in the larger pharmaceutical companies to look more into biologicals and the rare disease market, and, in my view, this is the only reason you could possibly expect more expensive products in the near future. However, it remains difficult to get registered at all and to get local access for new products in the Netherlands if the reimbursement authorities remain as critical as at present, no tsunami of expensive treatments should be expected. Overall, the authorities' main objective is cost cutting rather than transparency or aiming at realistic costs, creating a one-dimensional viewpoint and discussion. There seems to be a belief that the profitability of pharmaceutical products is huge and that profits arise already after only one or two years a product is on the market, which is very often not the situation.

Cerdelga was approved for marketing in Europe for the long-term treatment of Gaucher disease type 1 in 2015. How much progress have you made in bringing it to patients here in the Netherlands?

Cerdelga will hopefully be launched in 2016, and the conversations we had with the reimbursement authorities were very positive. It is a very straightforward reimbursement process for Cerdelga, as it will not cause an additional budget impact. The overall yearly costs for Gaucher patients will be roughly comparable with the current costs. Firstly, we will not find more Gaucher patients because of Cerdelga since patient diagnose levels are already very high. Rather, we anticipate that a limited number of Gaucher patients will make the switch to Cerdelga. Secondly, the reimbursement system in the Netherlands also states that a different route of administration is not seen as an added value for a new product. Therefore, the system does not accept a premium price for Cerdelga compared to the current treatments, despite being the only first-line oral therapy for Gaucher disease.

Regardless of the pricing situation, Genzyme has a sustained long-life commitment to helping patients with Gaucher disease. We launched our first and the world's first Gaucher product, Ceredase, in the late 1980s. As the product was extracted from placentas, it required well over 20,000 placentas per patient per year, an unsustainable figure given the number of Gaucher patients

globally. Genzyme thus identified a new platform – the recombinant DNA platform – as the basis for a second generation treatment, Cerezyme. And even with Cerezyme we realized, based on some patient stories, that the impact of an infusion every two weeks could be quite debilitating for some patients and started the development of an oral compound for Gaucher patients, Cerdelga. The same logic also reigns in our research efforts for Fabry and Pompe disease, where we are also working on more effective or easier to administer products.

Since the company started to focus on MS a few years ago, the data published on Genzyme’s treatments has been very positive. Considering that a number of major players are also present in this segment, what is the added value of Genzyme?

Our science driven approach, which has proven to be very successful for rare diseases, and in the past also for oncology and nephrology, we believe is the right approach within the MS world. MS is not a rare condition, but less than 10,000 of the approximately 17,000 diagnosed patients with MS in the Netherlands are receiving immunomodulation treatment. Our goal is to bring our products to as many patients who need our therapies and make physicians aware that treating MS early should be beneficial for patients. At Genzyme, we really believe in partnering with care providers. We are convinced that just aiming for as many patients as possible may help boost short term sales but will not help all these patients nor the company in the long term. Our MS team strives to make sure that the right patients are getting the right treatments at the right time. Aubagio and Lemtrada could be breakthrough solutions for the right patients.

Whenever we go to a Genzyme office anywhere in the world, there is always a strong sense of corporate culture. What makes Genzyme special and has allowed the company to keep its unique flavor within the Sanofi organization?

Before Genzyme started in 1981, there were hardly any pharmaceutical companies interested in rare diseases. Patients suffering from rare diseases were left aside, as the market was small and it was not seen as profitable. There are 6000-7000 orphan diseases, and the solutions in this segment are still very disappointing, just over a hundred. There is thus a lot to gain, and Genzyme is focused on further contributing to the quality of life for such patients. We feel that the story should be more often about the value that we as part of Sanofi bring to the healthcare system, even for a small population, rather than the cost of treatments. Within the Sanofi group Genzyme will remain responsible for the specialty care products and therefore the science and patient driven approach continues to be a key driver for success. We have always maintained our very strong patient-centric focus. The mentality of our people is driven by a true belief that the right patients should get the right treatment.

Where would you like to take the Dutch affiliate in the next five years?

The main objective is to maintain our current strategy and to successfully integrate the oncology and immunology platform into the Sanofi Genzyme business unit. Within five years, hopefully we launched some additional very interesting products. For example, two promising monoclonal antibodies for patients with immunology disorders will become part of our business unit. One in the field of rheumatoid arthritis is planned to be launched in 2017, which will be a very different ballgame given strong market competition. The other product, expected for 2018, is in the field of atopic dermatitis or severe eczema, a highly debilitating disease for which there are currently mainly topical applications. As such it is right on target with Genzyme’s overarching goal to address unmet medical needs.

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