Interview: Bart Vanhauwere – General Manager, Roche Netherlands

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Roche Netherlands General Manager Bart Vanhauwere explains how the company has managed to foster growth at the Dutch affiliate thanks to its long-term strategic vision and the collaborative approach it has taken with stakeholders, as well as the affiliate's role as a pioneer in introducing innovative pricing models like pay for performance, contributing to registries, and introducing personalized treatments.

You first took on the role of General Manager for Roche Netherlands in 2010. Which trends have had the most impact for the pharmaceutical industry in this period?

The trend I see most clearly is that the Dutch market is becoming more and more unpredictable, as you can unexpectedly be presented with new government measures that add additional obstacles to delivering new medicines to patients in the Netherlands. I personally support the intention of Minister of Health, Welfare and Sport (VWS) Schippers in calling for faster access to innovative drugs and in monitoring in daily practice (e.g. through registries) the value of medicines. However, the execution of this policy is not working as completely as it should. Last year, the Dutch Cancer Society (KWF) released a report highlighting several issues with the current organization of the system. Namely, the costs of medicines are rising, and, as a result, some patients may not get access to their optimal treatment. In response, the Minister has introduced a lock, which in my view

seems rather in contradiction with fast access to innovation.

In its first half of 2015 results, Roche announced 5% growth in the pharmaceutical division globally. To what extent is this growth reflected in the Dutch affiliate?

This year we are growing at approximately 9%, which is remarkable in a European context. Despite difficult circumstances, we are doing very well, having introduced several new medicines in the Netherlands in the last two to three years for melanoma, gynecological cancer, hematology, and breast cancer, as well as pirfenidone (Esbriet) for idiopathic pulmonary fibrosis (IPF). Overall, the main growth drivers are pirfenidone, and pertuzumab (Perjeta) in HER2-positive metastatic breast cancer medicines. Thanks to this rich portfolio, we have above average growth compared to Roche worldwide and the local pharma-market in the Netherlands.

What is the significance of the Dutch affiliate within the Roche European ecosystem?

In terms of revenues Roche is number six in Europe. However, the relevance of the affiliate goes far beyond the revenue figures, as the Netherlands is a market where Roche takes a long-term holistic view. We experiment with new innovative pricing models and assemble real world evidence through registries, among other innovations, and, in this way, stand among the frontrunners in Europe.

Everywhere in the world, we are confronted with the same issue. New medicines are being developed to bring value to patients and society, but these treatments represent an increased cost. As long as you take a long-term view and cooperate with all stakeholders, progress is possible, and this is the strategy we are advocating here in the Netherlands.

Given that oncology is one of Roche’s key focus areas, how would you say is the attitude towards oncology treatments here in the Netherlands?

In past years, patients and oncologists were perhaps taking progress for granted. There are several trends. With products like pertuzumab, as well as new developments in immune therapy, people start to realize that the industry is delivering on its promise to bring new valuable treatment to patients. At the same time, oncologists have been showing an increased interested in costs and health economics, out of necessity due to budgetary cancers. It is tempting to say that lowering prices will solve these budgetary issues, but, if you take the time to dive into the topic, people quickly realize this is not the solution. Pricing should be responsible and sustainable in the long term, but calling for drastic price cuts is unrealistic and polarizing.

Most local affiliate directors have indicated that placing many pharmaceuticals in the hospital budget, rather than in the reimbursement system (GVS), has created challenges for patient access. What is your perspective?

That statement is clearly true. The key issue is that the hospital budgets are not allowed to grow by more than one percent annually. However, expenditures on intramural medicines are growing overall at a rate of eight to nine percent annually, with oncology medicine spending increasing by 14 to 15 percent. If you are a hospital administrator, this creates a problem, and many oncologists are told to put on the brakes in prescribing given the budget constraints. Given these circumstances, we advocate that the system of separate reimbursement for intra and extramural medicines is not in the best interest of society. All patients need to have access, whereas with the current system there is much variation based on where you live and where you go to the hospital.

Of course, you cannot change this policy overnight. The KWF report recommended increasing the hospital budget, which is a possibility that has not yet been excluded. Some stakeholders advocate pharma companies lowering prices to fall under one percent, but this is a very short-term, biased view and is not in the interest of all parties. For the short term, we have an agreement with all hospitals in Netherlands and are offering a price that is absolutely defendable even if it differs from the list price. At the same time, we need long-term structural measures to achieve our goal of introducing new innovative medicines at a fair price and make sure that the total healthcare system remains affordable and sustainable.

When we spoke with Gerard Schouw at Nefarma, he mentioned new innovative pricing models such as pay for performance. How involved is the Dutch Roche affiliate in these schemes?

We are very involved and even pioneers, although we have not looked for publicity on this matter; we prefer to work in relative silence to make sure these schemes are put in place. Our breast cancer treatment trastuzumab-emtansine (Kadcyla) is being offered on a pay for performance scheme, while we have also introduced combination pricing for pertuzumab and trastuzumab (Herceptin), also breast cancer treatments. This is more and more the future for oncology, as it is a short-term view to have prices of different medicines and simply add them up.

Could you please elaborate on Roche’s contribution to developing personalized therapies and the impact that these will have on Dutch patients?

While we are not the only company developing personalized therapies, we are a pioneer in this field. In about 60-70 percent of the products Roche is currently developing, we have a companion

diagnostic. We are also significantly investing in developing diagnostic tests for the remaining 30-40 percent of treatments in order to select the most appropriate therapy for patients.

The best-known example is trastuzumab, where we introduced a diagnostic test to select patients with over-expression of the HER-2 receptor to identify the patients that will benefit from the treatment. At the same time, trastuzumab only binds to the HER-2 receptor, only harming the cancer cells and leaving the healthy cells. This may have benefits in terms of efficacy and side effects for patients, and is cost-effective since the therapy is administered only to patients that may benefit.

What is Roche's contribution to the Dutch Melanoma Registry?

This a good example of our philosophy – we strongly believe that you need to show the facts. When we were about to introduce vemurafenib (Zelboraf), a targeted treatment against metastatic melanoma, we proactively went to speak with the Ministry of Health, Welfare and Sport and health insurers, as we expected, based on the findings from our clinical research program, that the demand could be high. We wanted, together with other stakeholders, to ensure patient access. Two measures were taken as a response – limiting melanoma care to 14 hospitals in the Netherlands in order to build-up expertise and establishing a Registry to monitor these patients and to verify that the effects seen in clinical trials were reproduced in real life.

Alongside with two other pharma companies, Roche was the front-runner in championing for one registry for the disease, not simply individual medicines. Even if some healthcare stakeholders doubted in the registry at first, Roche's successful initiative can now be seen as a blueprint on how to set-up a registry. Major efforts are ongoing to launch new Registries, and it is on Nefarma's agenda. Having proven it can be done in melanoma, we are expanding to lung-, breast-, colon-, and prostate-cancer registries, and there are also ongoing discussions for multiple sclerosis and rheumatoid arthritis. Registries are tools where you need to cooperate with a common goal, and we need a more leading and coordinating role from the government on tactical implementation to progress more rapidly.

Roche undertakes clinical trials in oncology, infectious diseases, cardiology, virology and disorders of the central nervous system in the Netherlands. Why is the Netherlands an attractive destination for clinical trials for Roche?

Possessing a good infrastructure and many well-known therapeutic area experts makes the Netherlands an attractive country to execute clinical trials. We, for example, have a partnership with the Dutch Imaging Hub. These centers have world-class imaging technology and expertise. It

is more effective and constructive to make use of this expertise rather than try and build it ourselves, and the partnership has contributed to our decisions in go-no-go decisions for early programs.

On a global level, Roche places great emphasis on its Corporate and Social Responsibility. What initiatives is the Dutch affiliate engaging in?

We focus on the portfolios where we are most active and have the most expertise and knowledge, and I would thus like to highlight two examples. The care for elderly with cancer can be further improved, as there is both over and under treatment, and the population for clinical trials usually does not include a lot of elderly. In cooperation with the Haga Hospital in The Hague, we are cooperating on setting up a national standard to deal with the elderly in cancer in a holistic manner. On the other spectrum of the scale, we support a program for adolescents and young adults with cancer, who currently fall in between in the current system. These patients are indeed sometimes too young for classical oncology treatments, as it is rare before 35/40 year-old to be confronted with cancer, and too old for pediatric treatment. The Adults and Young Adolescents (AYA) program aims to set up optimal overall care for this group.

As the Netherlands will hold the Presidency of the EU in 2016, what idea would you like to express to the Minister of Health?

I would like to encourage the Minister to continue advocating the concept of collaboration in Europe to guarantee faster access to innovation, be it through HTA models, new regulatory frameworks, or other methods. Furthermore, we should increase transparency to monitor in the real world the value of medicines via registries at national and European levels. Finally, I would like to invite her to ensure that the translation from the European framework to our national level always preserves the initial objectives. There is clearly room for improvement, and the only way to make progress is when patients, physicians, hospitals, health insurers, government, and pharmaceutical manufacturers cooperate.

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