Interview: Marynika Woroszylska-Sapieha, General Manager, Sanofi, Poland

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Sanofi's General Manager in Poland, Marynika Woroszylska-Sapieha, shares two very important concepts that showcase the situation in Poland, stating that: "The biggest obstacle to innovation in Poland is the threshold on reimbursement costs" and that "Poland's patent system has flaws, and consequently our products faced competition from generics much earlier than in the rest of Europe."

According to IMS Poland, Sanofi is ranked third in Poland and fourth in global rankings. How would you explain this performance and what does Sanofi Poland represent for the group?

In comparison to European Sanofi affiliates, Sanofi Poland is ranked sixth, which is the same as Poland's pharmaceutical market in Europe. Last year, our affiliate was amongst the best performing in Europe and this year again we will demonstrate that we can guarantee a sustainable performance for the long run.

In recent years, Sanofi Poland has changed its strategy, reinforcing its presence in Poland by using a different portfolio. This was implemented because Poland's patent system has flaws, and consequently our products faced competition from generics much earlier than in the rest of Europe. It was therefore necessary to adapt and find new ways to blossom in this competitive generics environment.

In the past, we built a very strong presence even though we did not have access for our new compounds. Today, our strategy is in line with Sanofi's global strategy where we rely on our platforms of growth, investing our efforts and resources to maximize our chances of success.

Despite the fact that the Polish environment has changed significantly, access to innovation is still challenging. This is not because Poland cannot afford innovation but rather because there is no recognition of the value of innovation. It is not only the role of Sanofi to change this perspective, but the industry as a whole. INFARMA, the association representing innovative companies in Poland, has been acting since the beginning to change the perception of innovation. I hope that this will change in the near future and make way for Polish patients to have access to more innovative products.

What are your views on the 2012 Reimbursement Act, and where do you feel there is room for improvement?

There is greater transparency today, and the authorities have respected most rules. However, there are still challenges to resolve. Changes must be made so that the original intentions of law and policy makers will be reached. One of the most important original goals was to give open access to innovative medications to Polish patients, and the savings incurred by this act were to be reinvested into innovation. So far, this has not happened.

We are waiting for this situation to change, considering that savings amounted to USD 659 million in 2012, and around USD 329 million in 2013. Today, these savings are mostly on the side of the payer and although patients are now paying less, there is still a whole fully paid patient segment that is not reimbursed. This segment and the products concerned are increasing in value and in the share of the pharmaceutical market. These points need to be corrected in the near future and along with INFARMA we will keep providing positive and constructive dialogue with the authorities to resolve these issues.

As an industry, we have clear goals and common issues and our aim is to convince the authorities that this Reimbursement Act needs to be amended.

In the end, the reimbursement law regulates not only the way innovative products are reimbursed, but provides the framework for all pharmaceutical companies to operate in the market as well. This means that this law can be beneficial for everyone.

Sanofi Poland took a step towards diversification in 2010 by acquiring Nepentes, a Polish manufacturer of pharmaceuticals and dermocosmetics. How much has this acquisition contributed to Sanofi's performance in Poland?

Diversifying our business has been essential to our success in Poland. Before 2010, OTC represented 12 percent of our turnover, whereas today consumer healthcare (CHC), which includes OTC, accounts to 20-21 percent. Given these results, last year we were the fastest growing CHC company in the Polish market with 16 percent growth. If we continue with our strategy in the CHC business we will become one of the leaders in the market. Today, we are ranked seventh in CHC, but we have the ambition to become one of the top three in the coming years.

Besides CHC, Sanofi has reinforced its presence in generics with the acquisition of Zentiva. We currently have a very strong position in this segment and are proud to supply patients with affordable high quality generics.

We are developing our growth platforms, which include diabetes solutions, human vaccines, innovative drugs, CHC, emerging markets, animal health and Genzyme. Diabetes is a very important area of focus for Sanofi, especially in Poland. Our presence in diabetes shows how difficult it is to have access to the reimbursement budget: we have been fighting for the past 11 years to get Lantus on the list, one of our major products. However, with last year's access to type two diabetes, we see potential to grow in this segment.

How is Sanofi approaching market access challenges in Poland?

All companies are struggling at the moment with market access. Today, it is not enough to have very good products to succeed; we also need to have the ability to convince the payer that we are bringing benefits to the patient and the whole healthcare system as well. This is probably our biggest challenge, but also an opportunity to bring accurate data and solid arguments to convince the payer to reimburse our products.

As a company, how do you adapt cost utilization studies and health technology assessments (HTA) to show the benefits of your pharmaceutical products?

At the moment, it is set at USD 32,000 which is too low for any oncology treatment, rare disease or specialty care product. The way this must be tackled is again at an industry level, and we must collaborate to ensure this threshold level increases dramatically. Only then will we have products available for patients in areas like oncology.

We must also be innovative in risk sharing agreements and find the best solution for both sides. Of course we understand that payers must make sure that they do not exceed the budget; however, there is room with these agreements to make more products accessible to patients and at the same time affordable for the payer.

Another very important challenge is that at the moment, we do not have early entry schemes for new products. This implies that the time between a new product being ready to enter the market and its actual availability for the patient is too long. We would like to convince the payer that early entry schemes are crucial for patients, especially the ones affected by very serious diseases. For this to happen we must be seen as a partner of the health authorities and work towards the same goal: bringing faster, better and more affordable products to patients.

Nearly three decades ago, Sanofi established a production plant in Rzeszow. Over the years this plant has supplied both local and international markets, and there is room for expansion. Would it be possible for Poland to become Sanofi's main European manufacturing center?

This is probably impossible as we have larger manufacturing sites in Europe. Poland is a low cost manufacturing site and highly flexible. These two criteria make our production plant in Rzeszow really important for the industrial community at Sanofi.

Today, we export 55 percent of our Polish production to international markets. In the coming years, given that most of our local products manufactured are mature and shrinking, there will be room to increase our exports. Of course, there are limitations to expand our capabilities in Poland while remaining a low cost and flexible manufacturer.

How will clinical trials help Sanofi Poland in the long run?

We have a very strong clinical research organization in Poland and we will continue to develop these trials. Even more so, since Poland boasts a very good education level, bringing highly qualified doctors to the market.

Today we can prove that we are one of the best centers, with one of the highest recruitment speeds of medical staff. We have also had very good experience of recruiting patients for our

clinical studies in Poland. This research is fundamental for the development of our products and to ensure that quality is always our priority.

With a positive economic outlook for Poland (two percent GDP growth expected in 2014), what do you foresee for Sanofi Poland over the next five years?

We will continue investing in our growth development platforms. This includes our ongoing work in diabetes, oncology, and pushing our most important product in low molecular weight heparin (Clexane). This product, as of today, is the most important product in Poland for this niche. Moreover, we intend to keep growing in CHC and this means building our competitive edge in OTC where we are already strong and where we can keep bringing valuable products to patients. With Nepentes, we have a broad portfolio to capitalize on and finally on the generics, with Zentiva, we still have room for development and we expect to have timely launches.

Overall, this gives us good prospects for our ongoing and future operations in Poland. Of course, it is difficult to say that the Polish pharmaceutical market will develop at a high pace, but we expect the market to grow at a rate of three to four percent. The Polish market is and will keep being interesting for the industry, not only because there is room for development (as Poland is the sixth largest pharmaceutical market in Europe), but also because the gap with the fifth market (Spain) and Poland is still huge (Spain is 2.5 times larger than Poland according to IMS). Once innovation starts to be recognized and more products join the reimbursement list, innovative drugs will boom in Poland. This is also fundamental to resolve inequalities in treatment, which must be addressed by the authorities. The introduction of additional health insurance by the National Health Insurance (NFZ) may well give room for quicker market development.

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