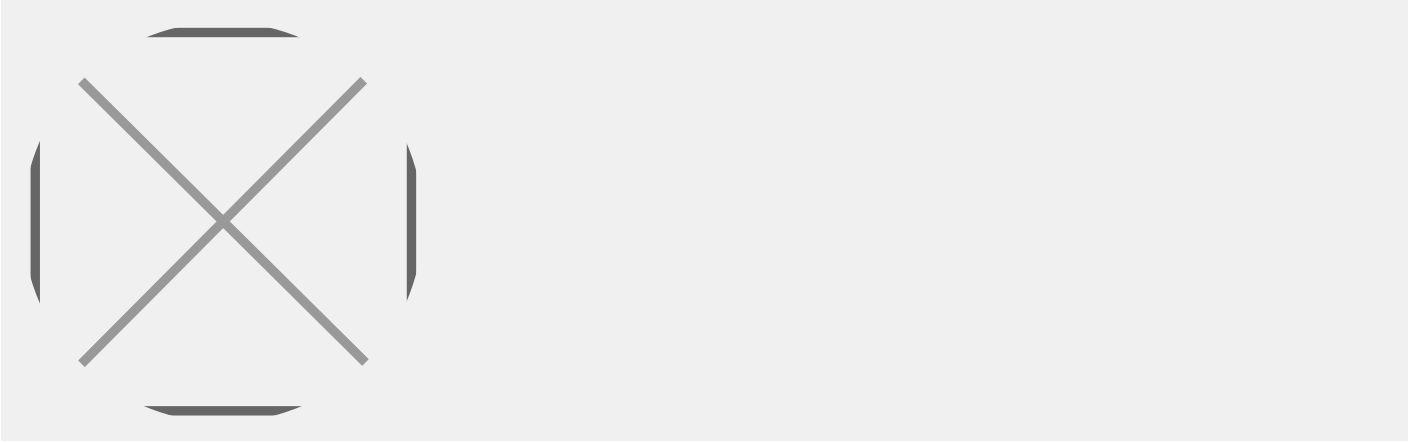
Interview with Pawel Miskiewicz, General Manager of Genzyme NCE (North Central Europe), Genzyme Poland



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With the current acquisition of Genzyme by Sanofi-Aventis, the French giant is planning to have Genzyme as a centre of excellence for rare diseases. Genzyme operates in the genetic market, in bio-surgery, in oncology, and also in transplant. What area has been driving the growth in 2010?

In value terms, rare diseases have driven Genzyme's growth last year in Poland. The company has three products on the market that are already reimbursed: Cerezyme for Gaucher disease, Aldurazyme for Mucopolisacharidosis I (MPS1), and Myozyme for Pompe disease. Moreover, the product Fabrazyme for Fabry disease is currently under discussion regarding its reimbursement situation.

Although the company specializes in rare diseases, any business has to be diversified in order to spread the risk. Therefore Genzyme took the strategic decision to build another franchise. These are nephrology, bio-surgery and, recently Genzyme has entered oncology and haematology segments. These are are very promising markets, with many unmet medical needs, the business paradigm fitting well into Genzyme's idea of conducting commercial operations.

In the past years Genzyme has shown its ability to grow diversified business operations relying on either acquisitions or rich internal pipe-line. Today rare diseases and Genzyme Transplant and Oncology business (GTO) remain the two main areas of focus for Genzyme in the NCE countries as well as for global operations.

Genzyme was the first company to demonstrate that money could be made by making drugs for diseases with small patient populations. If rare diseases areas show strong growth opportunities given the many unmet medical needs, what are the major challenges that come with them?

In this part of the world reimbursement is the main challenge faced by companies involved in rare diseases. Therapies in these areas are extremely expensive; therefore existence of any sort of the reimbursement system is key. It still remains one of the major barriers in Poland as well as other countries I am responsible for. Formation and further implementation of the reimbursement systems require deep understanding of the rare diseases therapies by the healthcare leaders who manage public expenditures in the country.. Although very well rationalized, the pricing of the rare disease therapies, in light of the significant shortages in the HC expenditures in this part fo the world, is initially difficult for them to accept by the stakeholders of the HC systems.

In order to deliver therapies to patients in need, in the situation when no reimbursement system is available, Genzyme has always been offering charity programs to patients qualified by the medical condition. I think this is quite unique for Genzyme as there is rather few companies that has developed this strong and honest desire to deliver therapies to the patients, even considering rather unclear horizon regarding commercialization of particular treatment. It is surely unique to Genzyme that once the patient is enrolled to charity program, the treatment is delivered as long as it is needed and is not at all related to possible further commercialization.

In Fabry disease for instance, fourteen patients have been treated in Poland for free for six years already, although the reimbursement horizon is really far away.

In Poland we are currently talking about the positive results of Alemtuzumab for the treatment of multiple sclerosis. Taking into consideration the difficulties in finding reimbursement for innovative drugs in Poland, where Mr Zimmerman of UCB said that Poland was one step behind the schedule of the world in that respect, what are your expectations for this product in Poland?

Poland is indeed far behind Western Europe in this regard. Although it may seem that there are some procedures to follow (i.e. reimbursement applications need to be submitted to Ministry of Health, assessed by Agency of Medical Technology Assessment etc.) the whole decision making process remains rather unclear as well as deadlines, ways to appeal etc. I am for example still trying to get through with reimbursement application delivered already in 2006!

But I think there is a light in the tunnel. The government has sent to the Parliament a whole set of healthcare legislations, planed for implementation early 2012. Within this set of regulations there is one regulating the reimbursement process. If passed this should finally include description of key points as formats of files, the timelines, risk sharing schemes etc.

Once the country has that in place, Poland will make a huge step towards EU standards.. Nonetheless, everything always relate to funding: you may have a beautiful system; it will not work without reasonable financial resources.

As far as Alemtuzumab is concerned, we are all extremely excited in Genzyme. Multiple sclerosis is a very serious disease that affects many patients in Poland but only around five percent of the patients are getting reimbursed treatment now. This creates enormous opportunities for company bringing a break through therapy. I strongly believe that Alemtuzumab is just this what MS patients need and Genzyme is the company which can deliver this to them.

Having led the affiliate for many years and with your strong knowledge of the market, how challenging is it for Genzyme to plan strategies ahead in Poland?

It is today still very difficult, but I do have hopes that we will soon have a reasonable legal framework helping us to manage long term planning. I would rather look at the glass half full than half empty. Implementation of this framework may be delayed, but at least the MoH along with Poland's Prime Minister Mr. Tusk have a strong desire to deliver changes regulating the HC sector in a firm, efficient and transparent way.

We mustn't forget that Poland is currently spending over 40 billion Polish zlotys for healthcare, out of which a good part seems to be hard to control.

This turbulent environment is especially hard for Genzyme considering that almost 100% of the products are we are delivering to patients depend on this or the other way of reimbursement. Nonetheless, the authorities seem to increasingly understand that i.e. the rare disease products have to be delivered to suffering patients as they have the same right to receive treatment as any other patient with "common" disease. Moreover polish patients deserve to be treated the same way as other patients within the EU community. Following the EU standards in Poland, as one of the EU member state should, and indeed have, increasing importance for the decision makers. These standards serve as a guidance for legislation and decision making processes.

Rare diseases are key part of Genzyme's growth strategy. However, other businesses like oncology and hematology are also very important,. Within this highly diversified portfolio Genzyme even markets products which targets open market and are fully paid by patients in pharmacies. This is our Biosurgery franchise where we deliver hyialuronic acid injections (Synvisc classic, Synvisc One, Jonexa) Although placing these products with a premium price on extremely competitive marketplace, we manage to achieve very good Market Shares and segment penetration. This again proves the quality of Genzyme products with excellent value-for-money ratio.

In the fight against serious disease, biologics are playing an increasingly prominent role. Jarek Oleszczuk, Chief Executive Officer (CEO) of Abbott Poland, said that it is also time for Poland to be the next Biotech hub in the world. How do you evaluate Poland's potential to develop Biotech?

The Biotech market in Poland is developing however remains still a bit behind Western Europe. Still, the understanding of issues is here, it is just a lack of funding. Once the country finally has a HC system set in order, then investments will come. I truly believe that Poland will be a very attractive market to work on then.

Several data sources clearly indicate that, Polish pharmaceutical market is very price driven and thus sensitive to generic entries. But my experience also shows that the medical society in Poland is very keen on looking into novel therapies and supports innovative projects as frequently as possible.

Will there always be a space for innovative products in Poland?

I believe so, especially considering the size of the market, education level, and connections with the EU. For example the year 2010 was announced by EU a Rare Disease Year, where all EU governments were obliged to present National Plans for Rare Diseases describing country approach towards this problem. If not for anything else, only by this obligation Poland has to be open to innovative therapies.

Globally the pharma industry outlooks look uncertain: the models are changing, there are weekly announcements of layoffs, numerous mergers and acquisitions. Do you still recommend young professionals to embrace this career, and what advice would you give to those who choose to do so?

Absolutely, I would encourage them to join the industry. Layoffs are a reality of many segments of the market and do not concern only pharma. The world has been experiencing a major financial crisis, no wonder that situation in many sectors worsened. Within this environment Poland actually had managed very well, withstanding the biggest waves of the crisis with still positive GDP figures. I think the situation is getting better now, so I have no doubts that our sector will also get better. And working for pharma is not only interesting but also creates enormous learning opportunities linked with the possibility of helping people sometimes in really critical needs. I think it is appealing. To me for sure.

The issue is we all have to adapt to constantly changing environment. We have to acknowledge the budgetary constraints forcing price reductions and thus lowering profits. But tying to maintain profitability by reducing costs through lay-offs is too easy. One has to look at longer perspective. Reducing the work force is meanwhile a very short term solution. You will save the profit but in a long run you will be wiped out of the market. Therefore, any organization with a strong long term

strategy will use lay-offs as the latest saving resort. Genzyme is definitely one of them

Surely, as a Stock Market company we need to deliver results and profits to maintain and grow our financial standing in line with the expectations of our shareholders. This is an obligation of every Stock Market company. Nevertheless, they should avoid choosing the easiest way in difficult times – “We are out of this product, the profit is gone, so we need to lay off a hundred of people”. Instead what they should look for is alternative businesses, redesigning of organizational structures in a way to increase effectiveness in areas still available..

As a biotech based company, human resources are crucial. Why do you think Genzyme is a good place to work in, and what attracted you to this company?

I have a PhD in molecular biology, so I was personally attracted by Genzyme’s product portfolio and areas of focus. When I came to Genzyme in 2004, there were five people, and today we are 55. The company is fairly young – Genzyme has been created in 1982 in Massachusetts-, entrepreneurial company, whose roots are in science.

In rare diseases, patient’s focus is highly important: this is why Genzyme recruits only people with a specific profile, who prove to be able to work in such environment. In a normal pharma company, the market is seen through the amount of products or the number of pills that can be sold. At Genzyme, we first find patients and evaluate their needs, and then we think of the products to be developed to match these needs. Working with rare diseases, where I have a very countable number of patients served, in many cases I happen to know them personally. That is making the whole perspective immensely different.

Genyzme is an organization which gives the employees the feeling of doing something really good and vital. Take Cerezyme as an example – you either deliver the product or the patient will pass away as there is no alternative. When you have a human life in hands it makes your work different.

What are your objectives for the affiliate in 2011?

I would like Genzyme to be recognized as Centre of Excellence for the treatment of rare diseases but also in oncology and haematology segments. We have very specific products bringing the brake through effects for patients – this product however has to be very well understood by clinicians – we have to constantly work to improve awareness of our therapies. I also would like Genzyme Poland to serve as an example for other countries of my region, especially fairly newly incorporated Belarus and Ukraine where HC systems are unfortunately far behind our standards. It is my role to implement Genzyme presence there and assure our patients are served.

What is your final message to the readers of Pharmaceutical Executive?

Treat the market with respect and it will pay off.

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