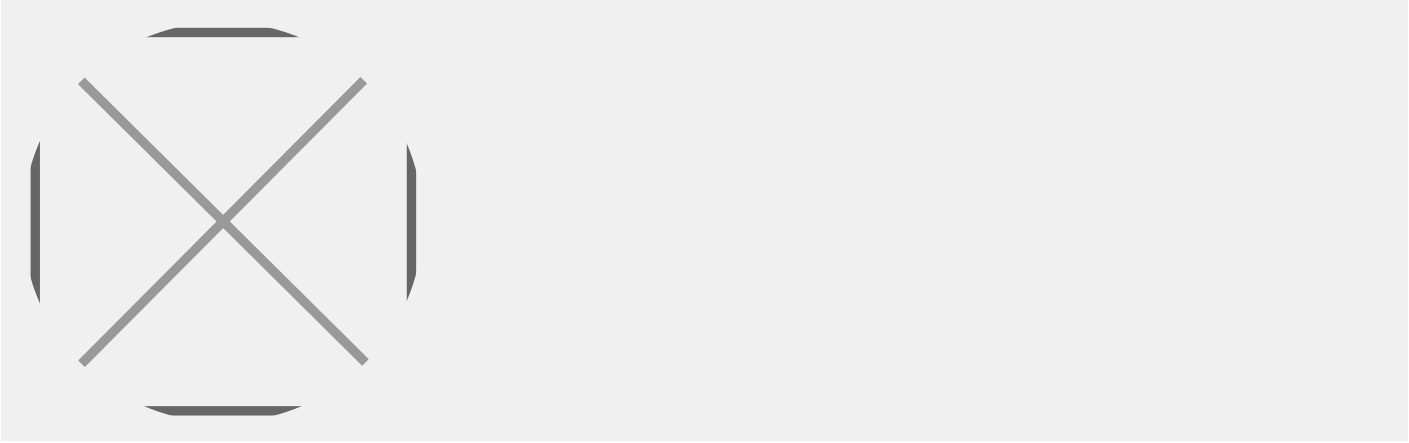
Interview with Marthin Kwakkelstein, Country Manager, Hungary, Estonia, Latvia, Lithuania, Celgene Hungary



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The Hungarian pharmaceutical environment has been undergoing a turbulent time recently, with many new measures being implement by the Government. What are your observations, and how do you expect companies to be adjusting their strategies in this market?

The government has a large majority in the parliament since 2 years, and has announced many changes in several directions. A first is controlling the budget, which has resulted in firm statements that politicians here want to stay in control, rather than head in similar directions as certain other European countries.

Many of the players in the field, ranging from healthcare to pharma professionals, are still waiting for the results of what has been said. There were announcements of cost-cutting earlier this year, which have been further clarified in June. However, there are still many tactical details missing to act upon. These are expected to come later this year, even though I would not be surprised to see new rules and regulations coming in in early 2012.

You are still in the process of establishing Celgene's operations in the country and developing the strategy for this market. How do you cope with this changing environment?

You have to be extremely flexible and adaptive on the one hand. On the other hand, you need to put people in place that have the experience of working in countries like Hungary. For example, I have a personal background in dozens of countries in various regions, including Eastern Europe, Asia, Africa and South America. We have seen examples of what can happen in any country, and

we are familiar with market access schemes from here to Taiwan and the Philippines.

For us, it is important that the other players in the field are open for communication. Turmoil like this is going on everywhere. Countries like the US and Switzerland are also constantly reforming their systems. There is quite a focus on budget at the moment, while the environment is changing too. In oncology for example, you can specifically see in Hungary that the old chemotherapy is very commonly used and known. This means that you give a rather toxic drug for a short time, killing both the normal and healthy cells.

Celgene brings to the market drugs that have a completely different approach, which rather focus on controlling the disease over a longer period of time. They thus do not have this very severe side effect profile. This requires a completely different approach from both the oncologists and the authorities. They have to realize that through these modern drugs, diseases can be kept under control for many years.

Globally, Revlimid and Vidaza have been Celgene's key products. To what extent have you been able to translate this success in Hungary and the Baltics, a region you are also responsible for?

The products are so successful that whichever doctor you speak to –even if you have not yet met him or her- already knows the ins and outs of the drug. They perceive our drugs as great products that should come to the market as quickly as possible. Wherever we come, the doors are already open. There is an extremely high interest from the medical community even in countries we have never been to before.

The payers, or the government, is a stakeholder that is less familiar with this information. They have other priorities, larger volumes, and overall other aspects in the total healthcare budget. They are thus less acquainted with the details of some of the orphan drugs which we operate on. These drugs have relatively small patient numbers.

Talking about orphan drugs with someone in the reimbursement authority will probably first generate the reaction that these drugs are so expensive for such a small number of patients. However, once they know the details, they will realize it is only 4% of the total budget, and barely increasing over time. We thus require an approach based on education and dialogue with the payers, as they are sometimes prone to make decisions based on the wrong facts.

You also need to juggle in managing your priorities as you are currently setting up Celgene in 4 countries at the same time. How do you set your priorities in nurturing these stakeholder relations?

Our priorities are building up the network with the payers and the other partners, which I find essential. In any discussion on healthcare, classically only 2 or 3 stakeholders are being involved in

discussions, which is a standard mistake that should be avoided. The first reaction is always the doctors, followed by the payers and the pharma companies. For me, there are two other key players, which are the patients (and their associations) as well as the media. I believe all these stakeholders play a role.

The first thing for us to do when we enter a country, is to start speaking to all these parties. We try to find patient groups, journalists, the payers, and so on. We try to show them the facts and the data, by portraying how we manage to change fatal diseases into chronic diseases where patients live 10 years longer.

In Hungary however, patient associations are still less developed than, for example, in the US. How can you still maintain a patient-centric attitude then?

Patient associations are not necessarily linked to a certain volume. In Germany, for example, there are maybe 150 breast cancer patient groups, which have even started fighting each other in getting funding. On the other hand, I have seen extremely powerful patient groups in Bulgaria consisting of only 10 to 15 members. You only need a passionate person to lead a patient group, who is willing to speak up and fight for her colleagues and fellow patients. This person needs to be able to confront the minister and sit down with him or her to find new solutions. Rather than volume, this requires a certain quality of discussion.

Celgene has a strong focus on oncology and inflammation. Can you tell our readers more on how this fits the unmet medical needs of the Hungarian patients?

I would like to keep focusing on oncology and hematology, particularly because the inflammation area is a little bit further down the line. Cell therapeutics is a rather large focus in our clinical pipeline which also remains a little bit further down the line.

Today, we have breakthrough therapies in oncology and hematology that can change the patients' disease from one day to the other. In Hungary, like in any other country in Europe, patients should have the same right to live as long as other Europeans. There is no difference on whether we are here or in Romania for example, as everyone in Celgene is working to get the best for the patients.

Celgene is now a 25 year old company that has managed to build a lot of expertise in the areas you just mentioned. To what extent are you able to translate this experience to a country's medical community, and help train the local doctors and healthcare professionals?

We can do so in several ways. One way is through our clinical trials, which we already started performing in Hungary before having a legal presence in the country. In 2007, we started our first trials here, and they keep growing and growing. Every major center is participating in our trials and provides good quality and high numbers of data.

The physicians are therefore already familiar with our drugs. As we work in an area of breakthrough therapies, it has also been nice to see that there now is a lot of competition. Quite some other companies are now having their drugs tested, and are using Celgene's drugs as standard comparators. Thus, even if our competitors are doing clinical trials, they are still involving our drugs too.

We further also invite doctors to medical congresses to support their medical education. At this moment, I am not involved in any marketing activities, as I would first like to ensure that we manage to obtain reimbursement. At this moment, we thus purely engage in scientific education and clinical trials.

What made Hungary attractive to start conducting these clinical trials in 2007?

Hungary is a country of 10 million inhabitants, which from a clinical trial perspective is always quite interesting. Also, Hungary has a very concentrated number of expert centers. There are 6 or 7 university centers that see almost every patient in the second line. Some patients may still be seen in the first line outside of these centers, when they first are diagnosed, but the moment they relapse or go through referred therapy, they need to revert to these university centers. These are exactly the type of patients that you want to involve in clinical trials.

If you compare this to other countries such as Switzerland, roughly 70% of the patients may be going to private oncologists and cannot be involved in clinical trials. It is the same story in Germany for example. In Hungary, patients are in a well controlled environment as soon as they are in second line.

In addition to that, the quality of the physicians is excellent. They also have strong language skills, which helps significantly.

You mentioned competition before, but we also see Celgene partnering up with companies such as Novartis and Acceleron. To what extent have you been able to leverage these partnerships?

Every time one of our competitors plans a study, they have a dialogue with us on the most appropriate design, the best treatment, and how to further improve the current results.

The second area of collaboration is at the level of patient groups and activities. In that sense, we can engage in multi-company funding which guarantees objectivity.

Diagnosis also remains an important area, especially in the area of orphan drugs. It is a pity that diagnosis is not yet optimal for many of these patients, because for many of these diseases life-extending treatments are available.

In your view, what can be improved to have better diagnosis in the country?

It is a matter of training of the different centers I mentioned, while it is also an attitude element of the first line in healthcare, meaning the general practitioners (GPs). A certain attitude, what you also see in Western countries, is for doctors to ask themselves why they would still invest significantly in older patients. However, this attitude is now changing, with older patients being given the same rights as the younger ones.

You have now set up the operations here 9 months ago. Where would you now like to take the operations in Hungary in the coming 5 years?

In the short term, we definitely need to achieve reimbursement for both our drugs in Hungary. The bottom line is that patients in Hungary should have the same rights and opportunities as any other patients in Europe. Getting this access as quickly as possible is the key priority. We are perfectly aware of the economic situation, but we are ready to find a solution that will have a very interesting outcome. I hope to achieve this before the end of 2011.

For Revlimid, alternative treatments are already available on the market, but Vidaza is currently the only treatment available that can extend life. From a medical point of view, the need is thus even higher. The moment this reimbursement comes through, we will need to expand our operations and hire additional people in Hungary. The growth is going to be extremely rapidly. Achieving reimbursement will also pay back to the government as patients will live longer, physicians will be able to treat with the most appropriate therapy, more clinical trials will be possible, more people will be employed and so on. It is a win-win situation.

What would be your final message on the commitment of Celgene to the readers?

Celgene is committed to do whatever it can to get its therapies to the patients in Hungary, just like in any other country in Europe. We are open to dialogue with all the stakeholders in this field, to come to this position as soon as possible.

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