

Interview with Bernie Tobin, General Manager, Amgen B.V.

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You are still relatively new to the Netherlands having been here for one year. This must be a very insightful experience abroad. What were your initial expectations and first impressions when first starting here and how have they evolved over the course of your year as head of Amgen in the Netherlands?

It is difficult to answer that without splitting the cultural part from the business side. So allow me, please, to cover both elements. From a business standpoint you always hear that the Dutch are very efficient and effective business people. That is a reputation which, in my experience, is well-earned. A word that I use to describe my colleagues quite often is "pragmatic." It is not fancy, it is not fluffy, it is just all about getting it done. So I have not been disappointed.

From a personal standpoint, the Dutch are travelers. As such, they have adopted a lot of cultures. Something that I have been very surprised by are the many cultures within the Netherlands. It is not a large country by geography but there are so many different types of people in the Netherlands. There is much more variety and flavor in the country than I first expected when I originally arrived here.

Having previously worked for Amgen headquarters in the United States you probably have a good sense of the company's international standing and global framework. Now moving into this new market how would you assess the strategic importance of the Netherlands for Amgen globally?

It is very important for us. This is the European headquarters for several parts of our business. Amgen has been here since 1989 in some way shape or form. Amgen is only 30 years old so it is quite a significant amount of time that we have been in the Netherlands with some part of our business.

We have 36 different clinical trials going on at the moment around the world, 2% of the patients are enrolled in the Netherlands. I often heard before coming here, and have found to be true, that we "punch above our weight" in relation to the number of people, the size of the country, and the number of key opinion leaders in this market. There really is a lot of respect worldwide for Dutch physicians. Amgen has found all of those things to be true, helpful and important to us.

Very few of the non-European innovative, multinational companies that we have been meeting with choose the Netherlands for their European headquarters, often preferring France, Germany, or the UK. Why do you think Amgen is unique in this regard?

I think there are some practical reasons behind our decision. Geographically speaking the Netherlands is in a great location and we have found that useful for our logistics. From a cultural reason, the Dutch are wonderful linguists when looking for a workforce that can speak multiple languages. We have also found it a relatively easy place to get expats to come in and out of. If you are an American based company that is going to have large operations in Europe, you would like it to be in a country where you can have people come and go in a somewhat seamless fashion. So geography factors into it as well as the cultural piece and, of course, financial reasons.

The biotech industry in the Netherlands started to gain traction around the mid-1980s — only a few years before Amgen established a presence here. As such, the history of both the industry and Amgen in this country almost run parallel with each other. What is the symbiotic relationship between the two? How has Amgen contributed to and benefited from the development of the Dutch biotech sector?

Biofarmind, the local biologics association, is an important organization that Amgen is proud to be a member of. That organization has a variety of members ranging from start-ups to mature companies like Amgen. You can imagine that when we participate we are able to share our thoughts and best practices with people who are more early-on in the start up phase given our stage of company development. We are pleased to do that. At the same time we are running across innovators who come up with ideas that we would like to take advantage of; so it is good to interact in that arena and benefit from it as our organization grows and develops.

Taking a snapshot of Amgen in the Netherlands today, what are the most important product lines that are driving growth in this market?

The face of Amgen in the NL is largely around the specialist market. Within that, we have a very extensive supportive care franchise of medicines, in oncology, being the largest. In oncology we are led by Neulasta® , a very important medicine for patients undergoing chemotherapy treatment. It is an effort to really try to stave-off low white blood cell counts so patients can get the chemotherapy for their cancer. Not far behind that is Aranesp® which is important for oncology and nephrology — it straddles the two franchises. They are our two leading therapeutics in the Netherlands. Amgen's history is based on nephrology, with EPOGEN® being the first medicine developed by Amgen which started the company. As we fast-forward to today, the relationship we have with the nephrology community is at the foundation of who Amgen is.

What does the future mix between these established franchises and upcoming blockbusters look like?

As you know, with patents companies have to reinvent themselves every 10-12 years. The current therapeutics that we have within that patent lifeline will be surpassed by others. But oncology is right at the heart of Amgen's focus. With four therapeutics in that franchise today and a fifth on the way, we are looking at a pipeline which has a heavy emphasis on oncology going forward. I expect that to continue. We do have a medicine in front of the reimbursement authorities in the Netherlands called Prolia® for osteoporosis which is a new therapeutic area that we expect to be very important for us in the coming years. We are anxious to get this therapeutic on the market for patients.

The 2006 healthcare reforms, a cost-containment mentality, and the reimbursement system in the Netherlands have been very discouraging components of the Dutch pharmaceutical system for innovative companies. It has redefined companies' sales and marketing strategy and reshaped the ways in which they promote the health economics of their products. How has Amgen adapted to these trends?

Nefarma, the Dutch branch organization of the innovative industry, speaks on behalf of its members and contributes to the discussions about sustainable health care reform and secure innovation. Amgen is an active member of Nefarma.

Getting reimbursement approved is a challenge for regulators to make sure that they allow medicines which are truly innovative, safe, and effective for patients. The frustration that it creates is the longer timelines that are necessitated by that. We have to make sure that we do studies that meet all of the needs and adjust what we do with health economics. Having said that, there is a European standard of 90 days to get that reimbursement decision made; right now in the Netherlands the average is 180 days. When you think about the strategy that you use and the investment that you make, it is very difficult to predict when a new medicine becomes available for patients. The Netherlands has typically been an early launch country, but that reputation is not backed up by fact.

Who do you identify as your main competitors in this market?

Amgen has had a bit of a fortunate situation because we focus on previously untreated illnesses or those with significant unmet need. However we do have competition today. With Prolia® we will enter the osteoporosis therapeutic area which has been very well established since 1995. It will be a challenge given that there are 5-6 competitors who are well ahead of us. Of course, Amgen is bringing biotechnology into this area, using different mechanisms, actions, and approaches, but the competition is already established. There are very few competitors to Neulasta® and Mimpara® but with Aranesp® we face strong competition from Janssen and Roche. With our other products there is some competition for Vectibix® from Merck-Serono. When you look at Nplate® there is new competition just launched within the past 30 days from GlaxoSmithKline.

When entering new markets, Amgen traditionally looks for a strong and established R&D presence. This was a comment offered by your colleague Richard Davies when interviewed in Australia and supported by the fact that Amgen historically invests more in R&D than commercialization. The Netherlands certainly has that lasting R&D presence. What type of boost to the business has this alignment provided?

I sense that there is more of a medical decision that is made and more guidelines that are followed in the Netherlands than perhaps other countries. As a result of that, it is important to establish a collaborative relationships with the local physicians and that they can use the knowledge that you gain through studies for them to develop guidelines that are beneficiary for patients. As we look at what we do and how we commercialize, what happens on the medical side is frankly more important for us than what happens on the sales and marketing side. As we are a science driven organization, our first inclination is to add someone on the medical side ahead of someone in a sales or marketing job. It is a very important marker for us, and it is certainly true here in the Netherlands.

The new government has targeted life sciences and through that biotechnology as a key economic area that they would like to further develop. What opportunities do you see for the industry-at large and for Amgen?

I believe that the government is very sincere in what they want to do. Frankly, the Dutch healthcare system can be called the "envy of the world" in many respects given its low spending as a percentage of GDP yet the high value and quality offered. There is a lot to be admired in what the Netherlands does.

I think the challenge that the government faces, like all governments, is to make sure that they can pay for it in the future. It becomes a vicious cycle where you say you want to pay for innovation and allow it to happen but are reducing reimbursement at the same time and cutting what companies rely

on to pay the bills for the next generation of innovation. It limits our ability to be able to do that. The opportunity I see is to closely collaborate with the government and help them make the tradeoffs between what we as an industry want to give and get in order for innovation to continue. While those words are said in every country, this is a fairly tight community and a small country. So it is very possible for it to happen in a productive way. I have reason for optimism despite some of the rhetoric that you read in the newspaper about slashing costs.

The Dutch healthcare system has been studied in the US as a benchmark to potentially model the American system after. Do you see complementarities between the two?

I think it is fascinating that the Dutch in many ways are intrigued by America. I hear for instance that the Kaiser healthcare system is quite interesting for the Dutch and groups from the Netherlands have gone to the US to study it. At the same time, President Obama and others talk about the strength of the Dutch healthcare system. There is a bit of mutual admiration and probably aspects of both that you would like to copy. But while I do think that the Dutch government privatizing the healthcare system and letting the market guide decisions is admirable, you need to be cautious in how you do that. Done without any specific thought, costs can rule the day and quality that has been worked so hard to achieve can be easily lost. I think that is the part to be cautious about when copying too much of what has happened in the US.

Companies in the pharmaceutical and biotech industries are always looking for ways to more strongly establish themselves as partners to and stakeholders in the industry. How has Amgen achieved this through its 2care Service?

What surprised me most and delighted me about the business when I came here one year ago was the 2care home distribution system. The heart of why it was done was to provide Neulasta® injections to patients within 24 hours of receiving chemotherapy treatment. If a patient suffers that kind of setback by missing an injection they may have to delay the next round of chemotherapy because of a compromised system. It is very crucial that they receive the immediate care. But for anyone who has just undergone chemo, the last thing that you want to do is leave the house to go somewhere and get a shot - it is physically difficult. We sat down and assessed how to make sure that this happens on behalf of patients and that they get the injections like they should. The solution was to have nurses pay home visits. I think it is a brilliant solution when you think about patient care.

The Dutch healthcare system requires an approval for a Neulasta® prescription, which can take up to three weeks. When a patient needs an injection within 24 hours of chemo, the two requirements cannot co-exist. You simply cannot wait for that approval. Amgen went ahead with its deliveries, and assumed the risk that it will get approved - believing that it will - because the patient needs to get that treatment. We had to marry the Dutch healthcare system, the insurers, the patients, and the company all together. The program is successfully running for six years, and the compliance rates are outstanding. When a medicine is prescribed and administered in the way it should you have the outcomes that clinical trials suggest.

As an American coming here having never seen this before, I was stunned as to how this was done. This is in fact something that we share with other countries. Sweden and Spain, for example, have been asking us how to do this in their countries since it is a program that benefits patients.

Is a system like this capable of expanding to other therapeutic lines that Amgen is involved in? How can this system evolve?

There are signals that medicines in the retail setting will shift to the hospital budgets, currently believed to happen in January 2012 for at least some therapeutic areas. If this becomes effective, the component of the pharmaceutical companies paying for services, like 2care, will become the

responsibility of the hospital. It will certainly evolve in some way and my sincere hope is that what the Dutch citizens have gotten used to in healthcare will not be taken away. As it evolves, the hospitals will take it on or the 2care organizations themselves will be able to continue it with a broader focus than just the individual company. It is difficult to imagine losing something, that beneficial, once you have had it.

Amgen is a unique hybrid between the pipeline and R&D focus of a biotech company and the global reach and financial wherewithal of a Big Pharma company. Overall, how would you classify Amgen?

I think that type of identity is something that Amgen is still transitioning towards. In many respects we still have the intimacy of a smaller company and the many positives and negatives that come with it. As someone told me when I came here, you will often find as many dirt roads as paved roads when it comes to processes and systems. But the beauty of that is, you can change things. This is not a 130 year old company whose traditions you have to overcome. We really are going through a transformation. It is an exciting transformation because we have the financial wherewithal to do things that the innovative nature of a small biotech wishes that they did. That is the piece that causes us to have such a productive pipeline. Last week Prolia® was given the Scrip Best New Drug award for innovation. Additionally Nplate is basically treating an orphan disease, which big pharma does not really do very often; it is more in the biotech realm. You can see even with our most current pipeline molecules that we are still straddling those two arenas. I can argue that our pipeline going forward has big potential, but is also treating more orphan drugs since that is the right thing to do as the science leads us.

As you better familiarize yourself with the country, the culture, and this managerial role, what would your advice be to a new manager coming into the Netherlands?

I am fortunate to have a lot of really good people around me who are willing to tell me when I make mistakes, because I sure make a lot of them. I would advise them to ask a lot of questions and be direct like the Dutch are. It is something that they appreciate and will respond well to. Also, do not be afraid to bring along some of what you have learned from your years of working somewhere; the Dutch are anxious to learn from elsewhere and are not parochial about if it was not invented here then it does not matter. They are very pragmatic, willing to listen and learn, and are good at receiving feedback.

What is one of the best lessons that you have learned along the way that you are now applying here?

I have been able to add value through my previous experience working with health insurers, wholesalers, and pharmacy benefit managers. As the Dutch try to evolve and look for ideas from elsewhere I have been able to add insights into what that really is like. From a distance it is hard to understand but I have had the fortune of working closely with those parts of US business for quite a few years. It is nice to add some value to that evolving debate.

What would be your final message to the readers of Pharmaceutical Executive about Amgen in the Netherlands?

Come to the Netherlands, it is a great place!

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