Interview with Michel Dutrée, General Manager, Nefarma

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When it comes to the pharmaceutical and healthcare industries in the Netherlands, the country has one of the highest generic penetration rates in Europe, it does not have a strong manufacturing presence, and the market has been described as very regulated. Given all of this, what do you believe is the Netherlands-specific appeal for multinational innovative companies and what underpins their growth potential in this country?

We are very good at the way of doing research, clinical research predominantly, as well as some aspects of pre-clinical research. The Netherlands has invested heavily in clinical research infrastructure that is based in universities and the country’s top hospitals. We have almost 28 top clinical hospitals, which also serve as teaching hospitals, whose excellent medical specialists provide valuable research for industry. The industry very much appreciates the research done in those institutions.

Similarly, the Netherlands has an extremely solid and active group of professionals who like to be involved in research projects. A lot of patients and volunteers are proud to be members of a research study. Our researchers are reliable and trustworthy and perform at a very high professional standard. . As Nefarma we emphasize these qualities, within our country and abroad. Holland has a lot to offer, yet our government has to underline these qualities actively instead of neglecting them. Pharma is an international business with international rules.

The industry is currently facing a lot of trouble with research carried out in Eastern Europe or especially China.

The other attractive offering of the Netherlands is our strength in pre-competitive research which we do through public-private partnerships in the Top Institute Pharma (TI Pharma). We are very proud of our system of research because it is a combination of public and private funding.

The vast majority of your association's members are international companies. With such as a strong knowledge infrastructure in medical research why is it that the Dutch pharmaceutical industry has not gone one step further and grown its own multinational pharmaceutical giant?

One reason is because we are such a small country. In fact, we did have a local multinational player in Organon which is based in Oss and very famous for its research on women's health. Organon was first sold to Schering-Plough and then afterwards to MSD. MSD is now downsizing Organon through a worldwide plan to consolidate their R&D to 28 centers. As a result, MSD had to close 6-8 of their R&D premises, one of them being Organon. This will lead to the lay off of almost 2,200 people, most of whom are working in research with a smaller amount working in production.

We try to invest in a certain climate that will attract foreign investors, such as the pharmaceutical industry, to establish their production facilities here. Perhaps more important is for them to base their distribution centers here much like MSD (Merck in the US) did. MSD houses one of its biggest European distribution centers – servicing the Middle East, parts of Africa, and Eastern Europe – in the Netherlands. In addition to production and distribution facilities, we also have quite a flourishing vaccine industry.

What are the main issues and most important priorities facing your association today?

The most challenging issue is to keep our bioscience parks filled with small and medium enterprises (SMEs). What we have seen over the past 5-6 years is that SMEs grow to a certain size but are eventually bought out or transferred outside of the Netherlands. Our aim is to keep them here and bind them to bigger pharma companies. For that reason, TI Pharma is very important because they have the ability to combine "big pharma" with "small biotech;" sometimes "small biotech" is grouped in that precompetitive field. For example, through the "cookie jar" model of GSK – that all patents hiding in big closets are now open to researchers – SMEs can buy and lease certain patents to follow up on. We have very good and rich soil in the Netherlands for the kinds of activities focused on combining the work of SMEs and big pharma. We work in close collaboration with the government through various stimulus regimes – such as the Stimulus Law for Knowledge Workers – that funds any research that generates local jobs. Our research strength and our good

relationship with biotech firms and universities is very important and a major reason why big and intermediate pharmaceutical companies are interested in the Netherlands.

In contrast to other European countries, we have a network of universities here. Rather than competing with each other, Dutch universities work together since, ultimately, they are all government financed. Private financing streams do exist for Dutch universities, but base funding all comes from the government. It is very easy for government and industry to work together in the Netherlands since we are such a small country. The collaboration between the two entities is very pleasing for government.

However, government and industry working together were not able to prevent the closing of Organon's R&D center, as you previously alluded to. In response to Organon's closure you once commented that it was "a totally missed chance" and that "now you see what happens if the government does not have a proper strategy for innovation." Is the Organon experience a matter of not having a proper strategy for innovation or not being able to stop the forces of globalization?

If you dive into the former Organon case you see a few things. You see a big multinational that has the world as its playground. They are redefining their R&D strategies and are now on the path to organize the business more efficiently. MSD has put so much money into R&D and they are now trying to make it more efficient by diminishing their number of sites. Additionally, they are also trying to automate more of their systems by investing heavily in IT. They are able to run a single molecule through computer modeling and combine it with the power of fiber fixed computers to do things more efficiently. All of that results in less people, less sites, and less lab benches.

The Netherlands does not have the proper answer to that changing world. We, as the Netherlands, need to market our country better. We are not good at that. I believe that we could have worked better to keep former Organon in the Netherlands. But marketing and promoting ourselves it is not necessarily a Dutch trait. We are a very Calvinistic country, meaning, we do not show off. For that reason we sometimes miss the opportunities presented to us by multinationals because we are not openly proud of our industry. We do not have a friendly climate towards industry and towards R&D.

With the change of government and the new ministers being sworn in this week, this seems like a very opportune time to promote the interests of the industry anew. What are Nefarma's plans to do so?

One very big advantage in the new agreement with the new government is that life sciences will become a focal point of their attention. Just a few weeks ago there was a big debate in parliament about the industry. Many people were arguing to keep former Organon and Abbott and blame was

being placed on why government did not do anything. There was a round table focused on industrial policy and it was then that life sciences were designated a key area for government.

We tell government that life sciences are a good field to invest in, but that it also includes pharmaceuticals. We have to redefine the life sciences field. We want to see more investment in TI Pharma to build up a good, strong, and solid structure of innovation so that we can keep pharmaceutical innovation in the Netherlands. We especially want to focus on biotech because that is our new line of business; chemical entities are old hat, more or less. Almost everything in the pipeline now are biotech drugs combined with diagnostics and biomarkups. We are trying to put that forward and that is our main agenda on this particular field. We want to combine the innovation agenda with the reimbursement agenda. We tell government that if they want big companies to invest in this country there needs to be a system through which they can earn back their money, rather than block the return on investment.

The Netherlands, like much of Western Europe, finds itself in an environment of fiscal austerity with deep budget cuts expected for the next few years. What do you believe will be the long run implications of fiscal austerity for the innovation agenda?

Our fiscal climate is very healthy here in the Netherlands. People are perfectly aware of the fact that if you enter the Netherlands with your innovation, you have a quiet environment because we do not have very angry unions. We have a nice fiscal climate and some very good investment schemes, both private and public. I do not think that the crisis will have a big influence on the investment climate. Yes, we have to cut budgets very heavily in the Netherlands. But we are always interested in attracting new money. We as Nefarma try to convince the government to promote a healthy return on any money attracted here. One of the toughest points in our debate is government’s concern that if industry receives a better reimbursement scheme like conditional reimbursement, pay for performance or price volume deals, then pharmaceutical companies will earn more money and consequently the use of medicines will increase. That is not necessarily a good thing in the government’s opinions since they are very proud of the fact that the Netherlands uses only a small amount of drugs. Our country, alongside Denmark, has one of the smallest populations of pharmaceutical prescribers in Europe.

For that reason there is an imbalance between the eagerness of the Netherlands to get money in and the reluctant reactions on reimbursement schemes. The government has squeezed out an enormous amount of money from the system due to the preference policy that was implemented several years ago. Most of the money, however, came at the expense of the generics producers more so than the innovators.

What, then, were the flow-on effects for the innovators of the preference policy?

Prices have certainly gone down. The prices of medicines have declined in a period of 20 years by approximately 30% whereas the prices of other consumer products have risen by approximately 25%, creating a price gap of approximately 50%.

IMS projects the global pharmaceutical industry to grow by 5-7% in 2011, despite inhibiting trends of imminent patent expirations and payer mechanisms that limit drug spending. The five largest pharmaceutical markets in Europe are expected to grow by 1-3%, according to the same study. What are your projections for the Dutch pharmaceutical industry's growth over the next year?

We are predicting 1-3% growth at most. There is a policy in the Netherlands to further diminish the use of branded drugs because our physicians are asked to first prescribe generics. If one of those generics does not work properly then they prescribe another generic and after a few steps the physician may consider the administration of a branded drug. For that reason we are trying to squeeze the innovative market very heavily.

The percentage of generic use in Holland is the highest in Europe, with a penetration rate of about 70%. That is very high. We, as innovative firms, tell the government to feel free to start with generics. But when the patient needs a branded one, you have to give it. That is still the regulation in the Netherlands. You can start with a generic. But if there is a medical need, then the insurance companies are obliged to pay for the branded drug.

What we are trying to prevent is a substitution between therapeutic areas; for instance, interchanging one kind of growth hormone with a biosimilar. The government, meanwhile, is trying to shop around various medicine clusters to get a better deal and see if they are able to get more generics on the market or more generics in the minds of the physicians. That is being done very wisely by influencing the contracts between health care insurers and physicians. A certain stigma is affixed to a doctor if he or she prescribes more than a certain percentage of branded drugs; similarly a physician is looked favorably upon by the government when prescribing a high amount of generic drugs. There is some countervailing power from the Royal Dutch Physicians Association discouraging this tendency since the doctors are professionally autonomous and they decide what is best for the patient.

We are now facing two major topics. First are the guidelines. If we are outside the guidelines, then we are out of business, to keep it simple. Second are the clauses that the health care insurers are trying to get into the contract. The insurance companies have significantly increased their role in the healthcare system since 2006. Before 2004-2005 the Netherlands had a sick fund system

together with a private insurance vehicle for the more affluent. Since 2006, however, we have had a public system carried out by private insurance companies that are allowed to compete with each other. What happened was they merged and we now have five big players who divide up the Netherlands.

Insurance companies say that they compete on quality, but they are in fact competing on price. The lowest price for the insurer is the most important. However, the system wants to increase quality, which is the reason why it changed in the first place in 2006. There is a bit of an imbalance between quality and price and the amount of money used for our system is under a lot of pressure. Although the system is privately owned, there is a pressure on the amount of premiums for the insurance companies.

In brief, the government essentially runs the system as an NHS. In Dutch society, it is common knowledge that you cannot profit from the diseases of others. That makes life even more difficult for the innovators because you have an emotional factor to the debate. The debate will only get more emotional because we, as the pharmaceutical industry are often seen as the enemy. We have a group of very strong anti-pharma activists in Dutch society. While we are admittedly not saints, we are improving ourselves. We have imposed many codes and a lot of self regulations on our industry.

It seems that there are many difficulties facing innovation in this country. What is the bright future outlook that will attract investment and innovation?

If we are able to continue with our good research infrastructure and if we can fuel our bioscience parks with new initiatives, then we can attract foreign money very easily. International companies are very willing to do business in the Netherlands because of the attractive investment climate. If the new government is willing to go along this road, then it will be of interest to foreigners to invest heavily in the Netherlands, enlarge their distribution capacity in the Netherlands, or even put their European headquarters here. Amsterdam is very active in trying to attract European headquarters to the Netherlands.

The Netherlands is active in both the generic and innovative fields. When we are able to combine the food and agro part of biotech – the green biotech – with the white and the red biotech, we can be even more successful. If we can go further into researching this path then it will be very fruitful.

What would be your final message to our readers about Nefarma and the innovation community here in the Netherlands?

It is imperative for Holland and the Dutch government to realize the importance of innovation for the wellbeing of the healthcare system and its people. We feel that the focus is predominantly on cost, which of course is important given the state of government finances. But innovation is crucial as well. A recent study showed that every €1 invested in the healthcare system generated €1.30 in economic growth. That is an important message for us. Many people in politics only see the cost factor of healthcare. But innovation and investment in our system brings a lot of benefits to our overall economy and has a lot of added value to society as a whole.

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