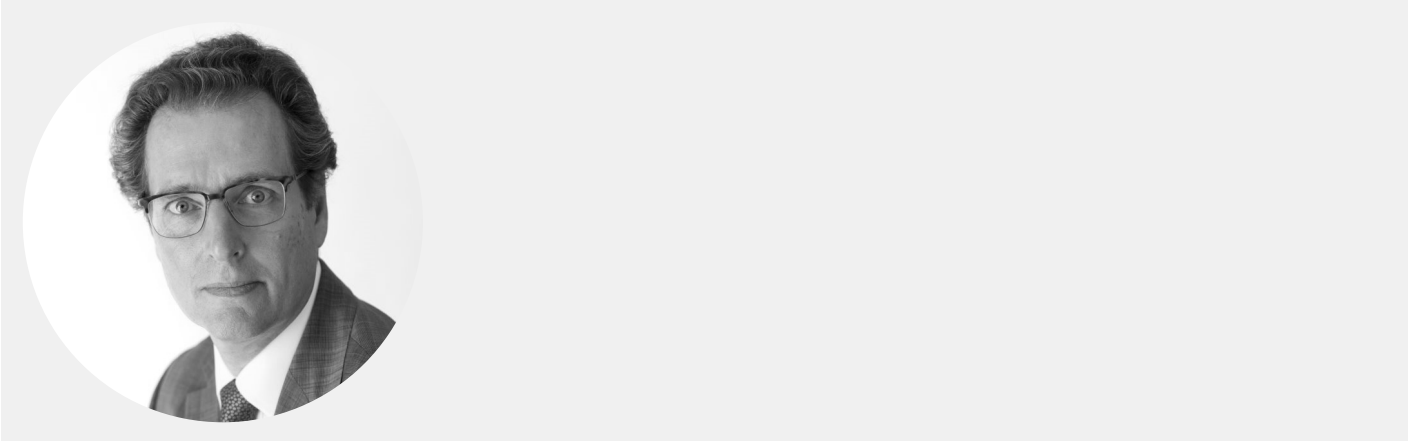
Interview: Michel Dutrée – Former Director General of Nefarma, The Netherlands



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Michel Dutree, former director general of the Dutch association for pharmaceutical innovators, gives a detailed overview of the changes happening in the Dutch pharmaceutical industry, and the Netherlands' role at the European level as the "laboratory of Europe."

It's been four years since your last interview with PBR; what do you see as the most impactful changes that have occurred in that time?

To begin with the obvious, prices have decreased considerably over the last four years as the pharmaceutical industry has made a significant contribution to lowering the cost of healthcare in the Netherlands. However, a significant portion of these savings were achieved on the side of pharmacists and generics players rather than pharmaceutical innovators; the prices of drugs in extra-mural pharmacies, i.e. those on the street, are decreasing, while prices in intramural pharmacies are skyrocketing. The main reason for this is that many new, very expensive oncolytic drugs for small groups of patients have been introduced, and are being used in advanced treatments which require the use genetic profiling and advanced patient monitoring devices/sensors that can precisely monitor the level of drugs and natural chemicals in the body.

In terms of organizational power, we have seen the role and responsibilities of local affiliates change in the wake of the 2008 financial crisis. More companies now have Benelux and EU level

organizations, which have absorbed the authority of Dutch affiliates to some extent, and overall headquarters are taking a more direct role in their affiliates activity than in the past. As a result, strategies have become less tailored to Dutch culture and the Dutch system, and local managers now spend a significant amount of time reporting on local developments to their superiors.

The Transparency Register was introduced four years ago, the first of its kind in the world, to provide insight into the financial ties between healthcare providers and pharmaceutical companies. This initiative has been a topic of discussion at the European level, as marketing and advertising regulators in other countries are also working to introduce similar registries under an EFPIA transparency initiative, with varying levels of success. I actually did a tour to present our approach and explain the major factors for its success, the critical factor being our involvement of healthcare professionals from the very beginning, alongside industry associations, pharmacists, and eventually even nurses and Physicians' Assistants. Without the support of the healthcare providers themselves, who ultimately must submit data on the payments they receive to the registry, such an initiative is impossible; the challenge at the European level is that in some European markets the income of healthcare professionals is relatively low, and payments from the pharmaceutical industry to physicians still make up a significant portion of their normal income. Thus, before a transparency registry itself can be introduced, the government must work with the healthcare professionals, and make the structural changes necessary to ensure their support for such an initiative. The alternative strategy of introducing legal arrangements for transparency may make some progress in the beginning, but it only creates a struggle between the regulators and healthcare professionals in the end, and at the rate things are moving at present the EFPIA will not meet its own targets for 2017; this is largely due to the fact that the EFPIA didn't incorporate the healthcare professionals attitudes and behaviors into their business case in the beginning.

In the European context, what is the position of the Dutch healthcare system?

The Netherlands is the laboratory for Europe, because our government has always been very willing to support experiments. Our minister is now reaching out to Luxembourg and Belgium to see if we can learn from each other, the most public example being the declaration that orphan drugs will be jointly purchased. This particular initiative is likely impossible, as the Dutch and Belgian healthcare systems are very different and the pharmaceutical industry will probably force one party to do the negotiating, effectively buying for the other, but there are many other ideas for potentially effective collaborations with our neighboring countries.

Is the political environment conducive to these types of collaborations at present?

Our government is clearly the leader of the pack in these discussions, and the Netherlands will be assuming the presidency of the council of the EU in January 2016, and Minister Schippers will simultaneously serve as chairperson of the healthcare committee at that point in time. Thus, the Netherlands has a big healthcare agenda to push forward at the EU level next year, the key items being lowering pharmaceutical prices through European cooperation, combating antibiotic resistance, and stimulating clinical research in Europe.

Since lowering drug prices is a politically attractive topic, I see a real possibility for Minster Schippers to gather significant support for this initiative. Furthermore, at least for orphan drugs such an initiative makes a lot of sense because the patient populations are so small in individual countries, and doing research on each individual country only pushes up the price further. There is one large hurdle to overcome however, which is actually the medical specialists; they tend to compete with each other in terms of research and EU level funding, and thus don't collaborate as much as they could.

Has the pharmaceutical industry prepared for such developments, and adapted to the current demands of the market?

European societies have changed their attitude towards the pharmaceutical industry dramatically over recent years, fueled by very high and still rising drug prices and a series of international scandals and allegations of misconduct within the pharmaceutical industry, and as such the public is demanding more transparency around drug pricing. Small and midsized firms seem to understand this shift much better, as they are newer, more flexible, and have done their research and are trying to adapt to societies demands to some extent; they would rather be the companies working with the system to solve the challenges, instead of being seen as a cause of the problems. Big pharma on the other hand has been more resistant to this shift, and their adaptation and collaboration tends to be limited to discussion and developing position papers detailing their CSR activities in developing countries and highlighting the clinical value of their product; co-operation on the key issues, being pricing transparency and levels, has been relatively low.

This delaying tactic worked for many years, but perhaps no longer; payers and politicians have followed the facts, and have seen examples like Solvaldi where the Gilead's investment in the product was fully repaid in the first year alone, and they were looking at an eventual return of over 1000 percent on their investment. Furthermore, there were a few price negotiators who left the industry and took up consulting positions with governments and commercial firms, so the pricing system used by the industry is now somewhat understood by the payers and governments, which is essentially just the price the market can bear, I've been told.

Even when looking at personalized medicine and oncolytics, it is becoming impossible for the industry to justify the rapid price increases any further, as they have reached a point where they've forced healthcare providers and patients to have a discussion regarding how much a few extra months of life are worth, and how much they should invest in a given patients life. Medical specialists, traditionally the allies of the pharmaceutical industry, are now drawing thresholds for how much a treatment must extent a patients life before they will prescribe it; two months for EUR 100 000 isn't enough at this point. They are even having direct discussions with patients regarding what lengths they should go to to keep them alive, and if there is a point where 'enough is enough'. Furthermore, with patient organizations have been discussed the topic of quality of life related to the amount of severe side-effects and the extra time gained. These are important discussions going on in the Netherlands, and they have far reaching implications for drug pricing overall.

As such, we are beginning to see more creativity in financial negotiations, yet there still needs to be more. There have been a few price volume deals, but there is no reason such arrangements should not be relatively common, given that patient populations always tend to grow more than forecasted. At the same time, the system needs to improve its ability to ensure rational access, such that only patients who can benefit the most from a treatment have access to it; this will also require a large public education component to explain that not all patients with a similar types of cancer can benefit equally from the same treatment.

A few other stakeholders have indicated that there is currently a shortage of trust in the Dutch healthcare system; what needs to be done to restore trust?

This loss of trust has happened at the international level as I said before, caused by the industry's attitude towards pricing transparency and profit, and fueled by international scandals. To restore trust to the levels that were seen in the past, the industry will have to adapt itself to the current demands of payers and society to an extent, which will begin with approaching governments and payers with an open agenda, and a sincere desire to collaborate and work together. We have of course seen plenty of examples of this in terms of discussion; the change will come once we begin to see real actions and implementation.

Other's have said things along the lines of 'Big pharma is no longer in the Netherlands"; what is your opinion?

This statement is a bit too bold, because big pharma is still using the Netherlands' R&D infrastructure, so on the science side, big pharma is still very interested in the Netherlands, and

still has a significant presence. Of course we have seen their presence on the sales and marketing side diminish, which has been fuelled by the trend towards the Benelux organization which we have seen in other sectors as well.

The Netherlands' has very robust R&D infrastructure, and one of the key concerns in the industry is that the usage of this infrastructure could be improved significantly. It can be difficult to attract cutting edge projects to the Netherlands, largely because we don't do enough to promote ourselves and show off our capabilities and strengths. Dutch culture is very modest, very Calvinistic, and in the global arena this can hurt us when we are effectively competing with countries that are happy to aggressively promote themselves; Belgium for example has the "pact of the future" initiative, while we rarely see the Dutch Ministry of Health publically take any pride in the healthcare system or in Dutch medical research capabilities. This aspect of Dutch culture is standing in the way of progress, and we really should be doing everything we can to leverage our biggest assets.

One of the challenges you mentioned in 2011 was keeping SMEs here in the Netherlands, as several had been acquired. Do you still see this as a major threat?

In recent years we have seen relatively few acquisitions and integrations of small companies, and many more creative agreements with mechanisms such as milestone payments. As such, many of the SMEs here in the Netherlands are remaining largely independent and continuing their operations here to a much later stage than we saw previously. A key factor behind this trend has been the involvement of the Ministry of Economic Affairs and the Ministry of Education, who have helped to create an environment where these companies can flourish; as such it makes far less sense for MNCs to pull the companies out of the Netherlands.

Where do you see the healthcare and life science industry in the Netherlands in 2020?

I think we will see strong growth among our SMEs, as we have an excellent group of startups and young companies with very promising technologies that are reaching a critical stage in their growth just now, and will likely be able to launch their products by 2020. Big pharma will probably continue to move their activities to the Benelux level, so overall the local activity will shift further towards the local SMEs in the coming years.

If we are able to reach out to the government to organize an effective multi-stakeholder dialogue, and the industry is able to make some concessions on the pricing side, then I think we will have a stable situation. The 'if' largely depends on the political agenda; if the Netherlands is able to maintain its position as the laboratory of Europe, and if Minister Schippers is able to gain

momentum from the EU presidency, then I think we will see changes made and a new model emerge here in the Netherlands before anywhere else. However, there is a very short window where the government has the opportunity to gain the support of other European governments and if they make a mistake they could easily lose the momentum, and things would likely take a very different trajectory.

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