

Interview with Bernard J. Mauritz, Executive Director, NEPROFARM

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In order to understand the culture behind the business that this association represents, what would you say is the perception of OTC and non-prescriptive drugs in the Netherlands?

OTC medicines are the medication of choice in the Netherlands. Most people will have some OTC medicines in his cabinet and indeed, statistics show that most people will have used some kind of OTC medication in the past couple of weeks. However, that said, the Dutch are quite reluctant to use medication at all; it is not in our culture. This is evident from the number of prescriptions written by physicians: only 55-60% of doctors' consultations end in a prescription. This is quite low if you compare it with other countries; for example in Belgium or France around 95% of patients leave the doctor's with at least three prescriptions. In the Netherlands we have a culture of "if it's not absolutely necessary to take medication, then don't take it." I think this is beginning to change today; young people are not as reluctant as the generations before them were.

Statistically and clinically, the Netherlands is a "healthy" country that enjoys a high quality of life. Is this mindset and medicinal-reluctance necessarily a bad thing?

No. But at the same time people suffer unnecessary for it. For example, if you have a headache, we know it is self limiting - within a couple of hours or a couple of days you will not suffer from it anymore - , but if you take a pill it will disappear a good deal sooner. Therefore you suffer unnecessarily when you do not use OTC medication; indeed life is more convenient when you use

it. However there is another element in Dutch culture which is different from other European countries, in a way we blame ourselves for our illnesses: if you have a headache, it is essentially your fault, you shouldn't have been working so hard, or should not have drank so much!

What role does Nprofarm as an association play in the promotion of OTC medicines?

We have different activities to promote responsible self medication. For example, we have a website - called SelfCare (www.zelfzorg.nl) - where consumers can find all kinds of information about the OTCs available from our member companies. We have also taken other initiatives; we launched another website about Patient Information Leaflets, where customers can look for explanations of words they find difficult to understand which are used in information leaflets that come with their medication. It is interactive to the point that if they can't find an explanation, they let us know and we will find it for them. Earlier this year we also launched an iPhone application enabling people to access all the information from the website on the phone. The iPhone App has an additional feature: you can simply scan the barcode on the package. So if you are in a shop, you scan the barcode with the iPhone and it immediately displays all the information on the product including the package information leaflet.

Combining the cultural component of OTC medicines that you spoke of earlier with the marketing approach of Nprofarm, what is the net effect and financial contribution of OTCs in the larger pharmaceutical market?

The market share of OTCs within the overall pharmaceutical market is comparable to other European countries, even a little lower: 11% in the Netherlands versus 15% in Belgium and 16% in Switzerland. However, in terms of the overall market, the use per capita is a lot lower than in other markets. The use of self medication in Holland is € 39 per consumer per annum, whereas in other countries that is a lot higher.

Cost-containment measures, mainly in the form of preference policy extensions, have characterized the Dutch pharmaceutical market. The strongest and most detrimental effects have been noticed amongst prescription generics. What have been the effects, if any, for the OTC industry? What are the direct and indirect and implicit effects for the OTC market of what is going on now in the industry?

There has been no direct effect yet, but there are very positive prospects for OTCs in the near future. This is because health expenditure has to be cut and general practitioners will therefore have to do more work, much of which is now done in hospitals; thus the only way this will be possible is if we stimulate self-medication instead of going to a doctor.

We learned when speaking with Bogin that the Netherlands has a very low pharmacy-to-population ratio of only 1/8700 people. What accounts for this?

There are different reasons. The most important one is the existence of druggists. These are drug stores which exclusively sell OTC medicines, as opposed to a pharmacy which sell both OTC drugs and prescription medicines. Since there are so many druggists, there are enough outlets for the distribution of OTCs, therefore there is no reason to establish additional pharmacies. Indeed in the countryside general physicians used to dispense prescription medication themselves, so again there was little need for more pharmacies, which is one of the reasons for their low total. However, if you add the number of druggists to that of pharmacies, we actually have one medication outlet per 3250 inhabitants, which is quite comparable with the rest of Europe.

You have been with the association since its early days, having branched out from Nefarma, pre-reforms. What are some of the biggest changes and trends in the OTC market since the early 1990s?

For the OTC market, the introduction of a general sales category was the most important change. Whereas the introduction of a price maintenance system – the preferential system allowing health insurance companies to decide which products would be reimbursed and which wouldn't – was the most important for the prescription industry. Prior to this system in the early 1990s, the GVS reimbursement system had a huge effect on prices of reimbursed products.

Are there any OTCs that are reimbursed?

Yes. OTC medications are reimbursed if they are used for chronic conditions – if taken for more than 90 days per year. There are only five categories of OTCs that are reimbursed, one example being laxatives. It used to be that many OTCs were reimbursed if prescribed and if there was a medical social need for it. Paracetamol used to be the most prescribed medicine in the Netherlands. However this came to an end in 1999. By 2005 all OTCs were excluded from reimbursement. Doctors then began prescribing alternatives that were even more expensive, so reimbursement was reintroduced at least for the categories of OTCs for chronic conditions.

What accounted for the changes in the legislation with regards to the general sales categories in 2007?

The changes came about primarily due to supermarkets' increased interest in selling OTCs, given that they are high margin products, when they began to employ druggists in their stores. Soon however there was a shortage in qualified druggists prepared to work for them, given that once a

person has the qualification they were more inclined to work in a real drug store. This led the supermarket owners to question the need for a qualified druggist simply to be able to sell OTC medicines. They sought a middle ground to delimit the distribution of OTCs. The Medicines Evaluation Board (MEB) also agreed in principle, given that the product information leaflet should be sufficient for safe use of the medicines, and that the added value of pharmacies and drug stores was in fact very limited. This is why this was introduced into the drug law in 2007.

There was another important change in the law in 2002. When self-selection was allowed in pharmacies and drug stores, this was the first big step in the liberalization of the sale of OTCs, since it meant that they no longer had to be sold from behind counter.

This was a very important piece of legislation for us, since it enabled people to buy products advertised by our companies, instead of asking for a branding product and receiving a private label from the drug store chain. This was often the case because the personnel in drug stores were told by headquarters to advise their customers to buy the own-label alternative.

What are your expectations or hopes for the industry with the recent changes in Ministers?

The declaration of the new government states that General Practitioners should pay more attention to the work that is done now in hospitals. I am sure this has to result in the promotion of self-care medication. I do not think that the current minister will change the legislation on the distribution of OTCs, since she was involved in the 2007 changes in the legislation and as a member of parliament always took a stance in favor of a liberal distribution for OTCs medicines.

Looking further down the pipeline and forecasting industry trends, what do you see as some of the main OTC therapeutic product lines that will have a big impact in the market over the next couple of years?

It will have to be real innovative products that bring new therapeutic opportunities to the OTC market. For instance, the H₂-antagonists or the Proton-Pump Inhibitors (PPIs) have not led to a notable growth in the market because there are already existing solutions for the consumer. It is more likely to be new drugs such as Alli that give a real boost to the market. I expect that Viagra will be available OTC soon, although there are certain procedures in Europe that have to be followed first.

I know that Pfizer halted the procedure several years ago because some southern European countries were against it, but as it happens the Dutch Medicines Evaluation Board was the driving force behind the switch of Viagra. I am sure that they will try again once the climate has changed a

little.

Where does the Netherlands rank in terms of OTC availability compared to other countries, across the board, are there generally fewer OTC equivalent products in the Netherlands?

Not anymore. It used to be the case 15 years ago, when we were quite behind the UK for instance. However nowadays we are in line with other European countries. This was driven by the fact that in the 1990s a number of products such as H2-antagonists and hay fever products became OTC. Today there are once again a lot of blockbusters running out of patent soon, which should give another good stimulus to the OTC market.

To sum up, what do you consider the main growth drivers or the future outlook for the OTC market?

There will be new categories of products. There will be new solutions for ailments for which consumers used to have to go to the doctor to get medication. If these are introduced as OTCs they will have a much greater chance of being sold. Take the example of Zovirax cold sore cream in the mid 1990s which switched from prescription to OTC: when it was on prescription only, around 10% of people with cold sores actually went to the doctor to get a prescription. When it became available as OTC, 80% of sufferers could get treatment. Some ailments, like cold sores, are not problematic enough to go see the doctor, but if you have easy access to a solution, you will buy it. These are the sort of treatments that will be interesting for companies to switch from prescriptions to OTC, since their use will increase if they become more widely available. However, there are some cases where this doesn't apply; for example there has been a lot of discussion over the years regarding oral contraceptives. I don't think that there would necessarily be an increase in sales if oral contraceptives would be switched from prescription to OTC, since 50% of females of the reproductive age already use oral contraceptives and this is unlikely to increase just because it becomes more widely available. But it would be the case for ailments people don't bother to go to the doctor for.

On another note, we can forecast medicinal products and also medical devices coming into our OTC market. There are quite a lot of products introduced nowadays, which legally are medical devices because the therapeutic effect is not realized by pharmacological means but by physical or another kind of means. These products are therefore regulated by the Medical Devices Law, which is not as strict as the registration requirements for medicinal products. If you consider that eczema hydrocortisone for instance, which is OTC in many European countries such as the UK, was never introduced as an OTC medicine in the NL since there is some reluctance towards cortical steroids, but now you see that medical devices are beginning to take the share of the eczema itching

markets. I am sure that if medicinal products were introduced for these minor ailments, they would have greater opportunities.

What would be your final message to the readers of Pharmaceutical Executive about the role that OTCs can play in the Netherlands?

OTCs are very important for the overall image of the pharmaceutical industry. The pharmaceutical industry is very aware of the fact that they receive a great deal of negative press for bribing doctors and so on. However consumers are actually quite satisfied with the medication that is available to them; what pharmaceutical companies too often forget is that 3 or perhaps even 5 out of 10 of these medications are OTC. The market share of OTCs may only be 11%, but this is mainly because OTCs are cheaper, since their share in volume is a lot more than that of prescription medicines. The average consumer is more familiar with Aspirin, Paracetamol and OTC medicines than they are with prescription medicines. Thus OTC can play a much more important role in the overall image of the pharmaceutical industry than pharmaceutical companies may be aware of.

Secondly, pharmaceutical companies should pay more attention to the value of their brands. I have witnessed that the OTC alternative to a drug, only comes to a consumer's mind when all other alternatives stop working. Of course, when a product is on a patent, why should a company pay attention to the OTC market, since the margins on prescription products are much better? When a product loses patent then companies start to produce their own generics to keep as much of their sales as possible. It is only when all the Indian companies for example have entered the market, that a company considers marketing their product as an OTC. By which point it is too late as everybody has already forgotten the brand name.

If however a company switches a product from prescription to OTC while it is still on patent, when people still know the brand name of the product, then there are considerably better prospects in the OTC market when the patent expires. Otherwise you will be competing with generic companies. This was the case with Pantozol (PPI) in Germany. When Pantozol was marketed OTC in Germany there were at least 30 generic versions available at the same time, so there was no time to establish a brand preference, and the advantage is lost. I advise pharmaceutical companies that if they do decide to switch a product - bearing in mind that not all products are suitable for OTCs - to ensure they carry out all life-cycle management and switch it before patent has expired, while the brand name still has added value.

I know in some countries you cannot keep your brand name when you switch from prescription to OTC but in the Netherlands you can and you can even advertise your brand as an OTC. As long as you do not mention the fact that the same product is reimbursed or on prescription, you can

advertise your OTC version to the general public, and consumer business is very different from the B2B and prescription market.

However I am very aware that Holland is only a small country, and that it is very unlikely that a company will introduce an OTC on the Dutch market alone; nowadays these decisions are taken at European level.

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