Interview: Dr. Martin Favie – Chairman, Bogin, The Netherlands

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Dr Martin Favle, Chairman of Bogin - the Dutch Generic Medicine Industry Association, representing the interests of the generic medicines industry in the Netherlands - shares his fears about slow growth in the

Dutch generics market and the state of the biosimilars market.

You were quoted in the media last year saying '2014 was a lost year for generics'. Could you expand on this statement, and share with us your views for 2015?

Not much has changed since last year; 2015 is much the same as 2014. What I meant before relates to the fact that the healthcare insurance system has a preference model that selects the label with the lowest price for reimbursement, regardless of other factors. The risk is that with this approach the market can be disturbed significantly when a new label is selected as the "preferred" one; the risk of losing reimbursement leads to companies maintaining very low stocks, and for those that don't have reimbursement they have little reason to participate in the market at all, and may leave the market. With only a few companies in the market for each molecule, and each maintaining low stocks, the risk of supply shortages and supply interruptions is quite real.

We have tried to persuade healthcare insurers to modify this system, so that more than one company is selected as the preferred supplier, and also to look at other arguments in addition to price like a company's reputation and continuity of business, to ensure a more stable market. With

one insurer, Menzis, we have agreed upon a new model whereby they will set the price for a given molecule, and every generics industry that offers their product at or below that price will be included in the reimbursement system. There are three other big healthcare insurance companies in the Netherlands, and discussions are still in progress with the others,.

In the same interview you said that patients have no choices when it comes to generics in the Netherlands; why is this the case?

The healthcare insurers decide which products will be reimbursed, and if the patient does not want to pay for a product out of pocket, they must accept their insurer's choice. For a given medication, there may be as many as six or seven generic labels on the market to choose between, and each year as generics prices evolve, insurers select different generic products to reimburse. When they select a new label, the one that they covered previously stops being reimbursed, and this mean that patients are often forced to switch medications that they have become familiar with.

For patients who take several different medications daily, many of whom are elderly, changing labels, meaning the box and pill color, can be confusing. Pharmacists have been complaining that changes in reimbursement guidelines create a risk that patients will not comply with their therapy properly when they are forced to start using a new product. Furthermore, switching products carries its own medical risks, as while two products may contain the same API, their formulations can differ significantly and have different side effects for a given patient. This is an unnecessary risk for patients to take, and if prices are low, patients should be allowed some choice amongst and continuity of access to generic labels.

How great is the risk of supply interruptions in the Netherlands due to these pricing pressures, and since you became Bogin president in 2013, what changes have you suggested to fix this situation?

There are two types of shortages, relative and absolute. Absolute shortages, where a molecule is completely unavailable, are a very serious risk as a patient's health and survival can depend on continuous access to a given drug; this has happened very seldom in the Netherlands, only once in the last three years. Relative shortages happen relatively frequently, when a given company can sell out of their stock, forcing patients to switch labels. Furthermore, there is a risk that the patients who must switch to another label will cause stocks of that label to run out as well, and so on, causing an absolute shortage by a domino effect; there are usually between three and eight suppliers for each product, so this chain reaction can be quite short. Even if a relative shortage does not escalate into an absolute one, they will force patients to switch products introducing the

risk that patients will not properly comply with their prescribed therapy.

This risk is particularly significant in the Netherlands, as all companies maintain low stocks due to the uncertainty regarding whose label will be preferred for reimbursement in the coming year; if a company is unable to sell all of their stock, and products expire, they must dispose of them losing their entire value.

The type of solution that we earlier discussed, where more generic producers would be eligible for reimbursement by insurers, would reduce the risk of shortages as well, because companies would have more certainty that they can sell their products and will be more willing to maintain larger stocks in the Netherlands.

How significant is the use of generics in the Netherlands at present?

Generics currently make up 72 percent of retail market volume in the Netherlands, and yet this makes up only 16 percent of the market value. Generics prices in the Netherlands are very low, comparable to the levels in Germany and Denmark. Our member volume, market share, and total revenues are increasing at present, but prices per unit are still very low and will almost certainly stay that way. Overall, I would expect that generics growth will reach a limit at about 75 percent in volume, and will stay at 15 to 16 percent of the market by value; generics penetration is about 92 percent in the Netherlands, and perhaps we could increase this to 96 or 97 percent if we achieve the proposed reforms and patients are able to choose amongst a variety of generics.

As for how this situation came to be, the current situation began to develop in 2005, when healthcare insurance companies were given the legal right to only reimburse one product in each product category. Prior to this point, generics companies primarily marketed their products to pharmacists as they were the ones to select a generic brand for patients, and were finically motivated to do so via a system of discounts and bonuses that incentivized them to promote generics over originals. By 2008, insurance companies had started adapting to the new law and were only reimbursing one product, so pharmacists could no longer choose on behalf of their patients; the discounts disappeared, and companies competed for reimbursement by dropping their prices drastically. This race to the bottom continued until the status quo was reached.

Does the situation differ significantly in the hospital market versus the retail market?

However, the more expensive drugs are all paid for under the hospital budget, and hospitals are an entirely different market. The price of the drugs is included in the total price of the treatment, and this effectively creates competition between the healthcare services and the drugs. The choice

becomes hiring more nurses versus more expensive medicines, given that the budget for a given treatment is fixed, they cannot afford to use new drugs under this model. As such, there are now discussions happening in parliament, the Ministry of Health, and physician associations, regarding how to fix the model to adapt to this situation, yet all of these parties believe that new drugs are too expensive. We can treat people who are dying of cancer, helping them to survive years longer or even curing them sometimes, but it is very expensive and has put a lot of pressure on budgets; but using generics has saved us EUR 1.3 billion each year.

Looking at discussions with the government and insurance companies, how has the government responded to the overtures you've made to insurers?

They are afraid of potential shortages, because relative shortages can lead to absolute shortages, and they clearly understand that our members are not opposed to low prices, but want a predictable market. As such, the government is supporting us to some extent in our goal to ensure that more than one generic supplier is eligible for reimbursement, but they are also very keen to ensure that insurers are maintaining the same level of savings.

To what extent is the generics market consolidated amongst your members?

Bogin has eight members, and six of them both produce and sell on the retail market. At this moment we have about 92 percent of the generics market in terms of both volume and value. Members of Nefarma, the association for innovators, hold about four percent of the market, while an assortment of small, new trading companies cover the other four percent.

These smaller companies often come onto the market with only one or two products getting which preference, and often leave the market when they lose it again. They are having a hard time entering the market because our members are very well established, having worked in the Netherlands for 20 to 25 years, and have large portfolios with between 800 and 1500 products. Due to economies of scale, it is difficult for these smaller traders to build much of a toehold in this market. This has also limited the ability of international generics players from countries like India to establish a presence in our market, however Aurobindo now has a strong presence as they purchased Actavis's business across seven European countries.

In 2011 your predecessor told us that biosimilars offered strong savings, but that the uptake in the Dutch slow because prescribers believe that biosimilars are not truly equivalent to the reference product. Has this situation evolved?

Nothing has changed really. The government and insurers believe in biosimilars, but there is still resistance from prescribers and even patient associations. They remain unconvinced that the quality is the same, and it is difficult to prove to them that there is no difference. For products that patients use for only a short period of time, like epoetins, it is easy to build market share as they are less concerned about the risk profile, but for patients who will need to take a biological product for many years, like TNF alpha inhibitors or Human Growth Hormone, then it is more difficult to convince prescribers.

Starting in February of this year with infliximab's patent expiry, a new generation of biosimilars is reaching the market. The TNF alpha inhibitors market is worth EUR 400 million in the Netherlands, and switching to biosimilars could bring savings of up to EUR 200 million, but convincing doctors and patients to make the change is very difficult.

Do you have any specific initiatives in this sense?

Yes, we have tried repeatedly, but to be honest biosimilars are at this moment not our members' core market. Many biosimilars will be coming from members of the innovative industry, as the investments required to develop biosimilars are so high. Looking at the world market, two of the top biosimilar producers are from South Korea, and there are a lot of innovative players who have been entering the generic and biosomilar industry more though acquisitions and partnerships

How does the Netherlands generic market differ from its peers in Europe?

There is a difference between the northern and southern countries in Europe. In the north we have a lot of competition, preference systems in Germany, Demark, and the Netherlands, and the Class M system in the UK. In southern Europe, they are looking to the northern markets and are beginning to transition models more like ours, because prices are lower here. However, generic penetration in these markets is lower because prescribers and patients believe more in original products. The insurers here in the Netherlands [have] a lot of bargaining power.

How do you forsee the future roll of Bogin, given the increasing fusion of the global innovative and generics industries?

We have a very good relationship with Nefarma, and carry out many initiatives together. Innovative players understand and accept that when a patent expires that it is time for the market to be genericized. We also have had discussions about working even more closely, because we have many of the same discussions with the government, insurers, and patient organizations. Personally, I believe that within five years we will have one organization for the pharma industry, with different

chambers for innovative products, generics, biosimilars, orphan drugs, etc. The innovative and generic pharma industries are increasingly hybridized with Pfizer's acquisition of Hospira for example, and a hybridized industry will require a hybrid industry association.

What sort of changes or evolutions do you expect to see in the generics market in the coming five years?

The generics market is declining in terms of new products, because there are very few blockbuster-type small molecules still under patent. Growth will come instead from value added products, either in combinations or with new formulations that support better treatment compliance, or from drug repositioning.

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