Interview with P.F. Bongers, Chairman, Bogin

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Tags: Bogin

Having one of the highest penetration rates in Europe, generic medicines play a very important role in the Dutch pharmaceutical market. As this is the principal association for the generics industry, I would like to begin please with a brief history of Bogin. What was the market landscape in the late 1980s that called for the founding of this association?

In those days products were starting to get off patent and the market slowly developed itself to a new type of market. Bogin, of course, was still very small. One of the first companies to be active in the generics market were Multipharma, a daughter of Novartis, which is today known as Sandoz and Pharmachemie, now known as Pharmachemie Teva. The generics industry gained ground based on the fact that more and more products went off patent and that the lower cost of the products were attractive to control costs of healthcare. That was generics' main role and they started off very slowly and the generic industry gained more importance as turnover increased and they played an increasing important role in medicines therapy. In my "earlier life" I was the vice-president of SmithKline Beecham in the Netherlands and a member of the executive European management committee. I was also the vice-chairman of Nefarma for about seven years from 1990 till 1996 and again member of the board of Nefarma in 2000. I joined Bogin in 2002.

Generic players in the Netherlands are few in number, but large in size. For example, Bogin's eight member companies account for approximately 90% of generic market volume. Additionally, there are a number of smaller players in the Dutch market. What accounts for this structure?

The Dutch market is not specifically known for having a very large Dutch based pharmaceutical industry nor for the innovative or the generics industry. We do not have a rich tradition in development and production, apart from Organon, which is now MSD, and Solvay (formerly Philips Duphar), which is now part of Abbott; but neither of them were part of the world top players. The Dutch market is mostly dominated by subsidiaries of (big) international companies and also most Bogin members are daughters or subsidiaries of the international firms. In a number of other countries you will see the same players and in certain EU markets also a number of national players.

Taking a snapshot of the industry now, who has established themselves as big players with a manufacturing presence in the Netherlands?

On the generics side, Teva, Centrafarm, and Apotex are producing. Ratiopharm closed their production facility end 2009. On the innovative side we have a number of companies doing production or packaging or both, like for instance Amgen, Astellas and MSD. We also do have a number of biotech companies.

The Netherlands does not have a history of being a country with a lot of pharmaceutical producing companies, perhaps due to the small size of the country. Comparatively, Belgium with an even smaller population size has been more active and houses more producing pharmaceutical companies in its market.

What is the role and importance that generics play in the present day Dutch market?

Generics offer high quality products at lower prices. That is their mainstay and the reason why they exist. Like in every country, the focus is to save money wherever possible without sacrificing quality, certainly in times of ever-growing healthcare budgets. Therefore the role of generics is to develop and introduce good products, available all the time, and at a lower price level. That is the driving force in all markets, whether you produce or not. Generics offer good quality products at lower costs. They also invest in product improvements like new dosage forms.

The environment of fiscal austerity, deficit trimming, and healthcare budget cuts sweeping the Netherlands must certainly favor generics. A new government will soon begin. What do you see the new government’s impact being on the pharmaceutical industry?

That is difficult to say because the pharmaceutical industry has always been under a sort of pressure-pressure on pricing and positioning of (new) products and pressure on the price of generics. The new government will have to reduce cost and therefore to focus on cost

effectiveness in healthcare. With respect to the medicines industry my expectation is that they will focus on medicines pricing in relation to European averages; we already have a system like that in place (WGP pricing).

Secondly they might consider recalculating the GVS system – the reimbursement system based on clusters of comparable products or develop a new pricing and reimbursement approach. But we have to await what the real plans will look like. The only thing that is for sure is that there will still be a focus on the measures to maximize quality without increasing costs and that the Healthcare Insurance companies will play an increasing important role .

How exactly does the pricing system work in the Netherlands?

The government introduced the GVS system in 1991. The GVS system is a reimbursement system that clusters all products having the same mode of action and comparable side effects. They are clustered into one group and the average price of each cluster is calculated based on comparable doses. The first price below the average is the reimbursement price.

In 2005 the government introduced another law – the WGP – which is the maximum price that can be set on drugs; it is based on the average prices, based on comparable price lists, from the 4 reference countries Belgium, France, Germany, and the UK. The WGP (the maximum price) is calculated twice a year. The maximum price is the price that you are not allowed to exceed and it is essentially an overall economic measure.

The WGP works as a ceiling price while the GVS price is the maximum price that will be reimbursed by the insurance company to the pharmacist. The GVS and the WGP do not work necessarily work together. But they do, of course, influence each other. Any drug that exceeds the reimbursement price requires a copayment from the patient, which rarely happens. Copayments are very limited in this country.
The introduction of generics in the reference countries also had its influence in the Netherlands through the WGP. Our GVS system has been recalculated once since the introduction.

Given this system, and against the backdrop of cost-containment policies to curb rising healthcare expenditures, does the time now seem more appropriate than ever to recalculate the GVS?

There has been a discussion for many years about this. It is not an easy discussion. Of course the innovative industry is strongly against. But you will also talk to the innovative industry and it is better that you discuss this with them. The Bogin is of the opinion that cost effective prescribing is a better way to go forward. Generic medicines are in many diseases the gold standard in treatment

and cost effective prescribing will result in more prescriptions of generic medicines and at the same time stimulate an appropriate use of still patented, more expensive medicines.

The Government has the intention that the Healthcare Insurance companies will have to play an important role in the cost effective prescription and dispensing of medicines.. But to understand the developments in the Netherlands I will have to take you back a few steps. In 1991, pharmacists were being reimbursed on the level of the pharmacy buying price of a drug – the pharmacy price list published every month – while being paid a dispensing fee. The income of pharmacists was coming from the dispensing fee and not from the margin on the product, which is unlike many markets.

The government could not increase the dispensing fee in 1991 because of budget shortages. Instead, they allowed pharmacists to keep 1/3 of the difference between the price of the original drug and the generic. That was a very clever thought because it stimulated a maximum substitution by pharmacists. It worked for only a short period because afterwards pharmacists could basically declare the official reimbursement price and keep the bonuses all to themselves. The consequence was that the 1/3-2/3 regulation did not work anymore and prices went up so that the pharmacists could earn the maximum bonus. That all developed in the late 1990s and early 2000s. A lot of products went off patent and bonuses were increasing. It was not a situation the government wanted and consequently in 2003 the government took action to slash prices across the board for multisourced products by 40%.

At the end of 2003 the pharmacists filed – and won – a court case against the government. The generics industry, together with the pharmacists, took immediate action to reach an agreement about how to go forward, knowing that the bonus level was too high. The innovative industry was not part of that discussion. Together with the pharmacists association, we engaged in discussions right away with the government and insurance companies to find a solution to the problem. Within six weeks we agreed on a covenant to not slash prices across the board by 40%, but to instead have an average price reduction of 40% across generic (multi source) products.

Taking part in that first covenant were the government, the pharmacists, the insurance companies, and Bogin. It worked quite well. Because of the fact that a part of the income of a pharmacist was coming from discounts – the dispensing fee was still not adjusted- not all of the bonuses were slashed. An important part of the first agreement therefore was examining the pharmacy operating and other costs and determining on the basis of that information the appropriate dispensing fee. That discussion started in 2004, but that discussion takes a long time. We are now in 2010 and the discussion is still ongoing. The direction is now that the pharmacist should be paid for the

pharmaceutical care for patients and not on the basis of a dispensing fee.. But that is complex and at the end of 2010 we still do not have the answer or agreement.

Can you elaborate, please, on how the Preference System, works?

In 2005 the first preference system was introduced for only 3 products. It had a very limited effect because it was introduced at the time of a running covenant and also because, everybody knew that discounts were still in the system in order to make up for the shortfall in pharmacists' dispensing fee.

In 2008 it was extended, which will be discussed after I explained the new healthcare insurance policy.

What was the effect of the new healthcare system?

In 2006 the new health care insurance policy was introduced. We previously had a private and public component but on January 1, 2006 the legislation was introduced which essentially privatized the insurance market. Everyone had to be insured and the government was still setting the basic package, covering essential healthcare, to be insured. The premium was set by the insurance companies but there were compensations for lower incomes and additional taxations for higher incomes.

The solidarity principle is still an important factor today even though the system is being executed by private companies. The system is based on solidarity, accessibility, and quality. The government also still sets the healthcare budget for the year.

That legislation was introduced in 2006 and the government thought it would produce more patient mobility from one health care insurer to another. Because there is basic competition and the premiums are pretty close together, there is minimal shifting going on, apart from the very first year that the new policy was introduced. As of last year, only 3% of the total market shifts from one healthcare insurer to another.
The government has also set up the healthcare competition authority, the NZa. The NZa's role is being the "market master", setting the guiding rules for the healthcare market and controlling them. The intention of the new healthcare insurance system was that healthcare insurance companies should, on behalf of their patients, be the "directors" of the healthcare system, of course within the limits and guidelines of the government and the NZa. Because the Government is still strongly involved through setting budgets and guidelines and the NZa more regulating the market than setting the framework and controlling that, the shift to a truly free market is not

happening yet.

At the end of 2007, after another two covenants, industry, Government, pharmacist associations and the healthcare insurance industry signed the transition agreement 2008/2009 – called so because the government wanted to transition to a more market-driven healthcare system from 2010 and give healthcare insurers more room to maneuver and negotiate with healthcare suppliers. By 2010 the government wanted to get rid of the centrally calculated dispensing fee and leave it up to the insurance companies and the pharmacists. It did not happen of course. In the mean time the healthcare insurance companies thought that in 2008 they should go an extra step, beyond what was laid down in the Transition Agreement, in curbing discounts by extending the preference system.

Within the scope of the transition agreement it was tried to solve the problem, but that failed. The first big extension of the preference policy came on July 1, 2008 which brought about “savings” of just over €300 million. However, that had to be compensated by an increase in the dispensing fee. The NZa calculated and decided that the dispensing fee had to be raised. About €220 million was given back to the pharmacists through an increased dispensing fee. It showed not only that discounts were an essential part of the pharmacists income, but also that the market was still heavily regulated.

Who do you assess as the main beneficiaries – the “winners” – from the preference policy?

I would not like to speak about winners or even losers. Ultimately patients should benefit from savings in the system, but as mentioned, we are still in the transition phase where regulation plays a big role.

The lesson to be learned is that for change time is needed. The government decided to not introduce the free negotiation system between pharmacists and healthcare insurance companies in 2010 or 2011, and it will be difficult to be introduced by 2012.

Conversely, it seems that majority of the generics industry has been negatively impacted by the preference policy. What are the main problems that you have faced as a result of the policy’s extension?

There are several serious problems facing the generics industry since the extension of the preference system. Currently a major part of multisource medicines is in the preference system. The preference period is too long, in most cases one or even two years, and after the preferent products are “chosen” there is only one or sometimes two month running in time. Logistically this

causes problems in the supply chain. This results in discontinuity of supply. But the effect is also that companies are withdrawing products from the market. In one month you might lose substantial sales, and face excess stocks in your warehouse or you do not have enough stock in your warehouse when you “in” the system. Logistically, it is not a good system if you have to stock up in about a month to meet increased demand. By extending the system to almost all products it gets even more problematic.

Another negative aspect is that if a company lost out once, the limited shelf live of medicines will force to make the choice to sell the stock at a low price or destroy the products. With continuous extension it is very difficult to meet logistical demands. We see nowadays that preferred products are regularly out of stock and unavailable to the patients. You cannot just simply say that you need a double quantity next month. It certainly doesn’t work in the generics industry which produces worldwide and a full range of products, many more products than the innovators who typically live off of only 10-20 products.

Our biggest problem is the exclusion of products for a long period of time. If you have a new product that comes to market that you have stocked up on, you can easily be out of business in another 2-3 months. You are developing a product, introducing it to market, but are out of business. The system is very negative on the continuation of the broad range of products. So getting a fair return on the investment is at high risk. We currently see a number of products being withdrawn by our members from the marketplace. They cannot make money from them since prices are too low, so why should they sell them?

But also at patient level discontinuity creates problems, for instance in patient loyalty to treatment of mistakes in medicines usage. At the level of the pharmacist it results in more administration and time for explanation spend with patients.

Another challenge is the current introduction of bio-similars. The investment in bio-similars is far bigger than in so called “small molecule” generics. Bio-similars offer substantial savings, but the uptake in the Dutch market is too slow. Prescribing doctors sometimes think that bio-similars are not as good as or different compared with the reference product. We sometimes hear the same arguments used in the early days of the introduction of generic medicines. But sciencific documentation proves differently. The European registration Agency (EMA) clearly states, based on an extensive dossier including clinical trials, that bio-similars do have a comparable effectiveness and safety as the reference products

For the generics industry, if only the lowest price possible is the guiding principle next to long periods of preference, then you are endangering the continuity and quality of supply. Our aim is to fair market competition, but the preference system is not stimulating normal market competition within generics.

To put it into context, the following market data are of interest. The market for medicines in the Netherlands is about €5 billion. After all the rounds of the preference system, generics account for just over 400 million €. Bogin members supply more than 60% of volume for just over €400 million. We are very worried that if the pressure continues like this, it will endanger the continuous flow of (new) generics to the marketplace. We are very worried about current developments. This philosophy also opens up the market to non-regular partners – companies finding extra supply in the world and transferring it back to the Netherlands to sell it here. Some markets might export against marginal costing, which is very tough to compete against.

The biggest danger might be that the Dutch market might turn into a spot market – wherever the product is cheapest we will buy it and transport it to the Netherlands. In addition to endangering continuity of supply, a cost of other issues such as vigilance, packaging, and associated costs are difficult to manage if lowest price is the only determining factor.

With so many inhibiting trends facing generics in the country, what are the positive growth avenues – the “green-shoots” – of the industry?

Growth will come from a number of big products coming off patent. There is growth potential, but at the same time there is saving potential for government for healthcare costs – money they can reinvest in healthcare. If current developments do not allow for those products to be competitively brought to the market, then it is not only having a negative effect on potential growth, but also on potential savings that government could realize. Savings are essential because of ageing populations and rising healthcare costs. Costs should be curbed where possible without losing quality. The market should take advantage of the saving offered by generics. There is a future for us, but only when there is a future when you can do your generics business with a potential reasonable return on your investment. Our industry is being put under severe pressure. If you only want to go for the lowest price possible, you are not helping to create a sustainable market for the generic industry. A recent report from IMS underlines this point. Next to that, as said before, the introduction of bio-similars offer new opportunities – opportunities for the introducing companies but also opportunities for additional savings. But the right market environment should be there to realize those opportunities!

Having previously worked for SmithKline Beecham and served as vice-president of Nefarma, what drove you to the generics industry?

When I was at SmithKline Beecham focus on innovation was essential. However, we at SmithKline Beecham in the Netherlands, we believed that we have also had to manage the product life cycle better. We did this by exploring all options, like giving a license to a generic company. We always were of the opinion that generics were part of the marketplace. Innovative products are needed, because they bring about new treatment opportunities for patients. But when products lose their patent, they certainly do not lose their proven clinical value.

When I left SmithKline Beecham I was asked to be chairman of Bogin. Having also worked in the field of off-patented products, it was not a huge step for me. Generics are a normal part of the market. The controversy between generics and innovative producers will be getting smaller and smaller because we all benefit from a good functioning market where new products are being taken up to the market and generics are being introduced as good quality, trusted products at a lower price. As my former boss at SmithKline Beecham once said, “generics create headroom for innovation.”

Looking around nowadays, Pfizer and Sanofi-Aventis are stepping up their activity in generics. GSK has bought a stake in Aspen and is active in branded generics in the developing world. AstraZeneca is working with Torrent and MSD is thinking about going into biosimilars. You are seeing a thinning line between innovators and generics. It is important that both innovative and generics industries perform their role in a good functioning, dynamic marketplace This is a growing awareness between the two industries. We have different philosophies on some issues, but we are coming closer and closer together than we were 10 years ago. Innovative companies realize that they cannot live off patents forever so they must constantly innovate and bring products with noticeable clinical advantages. Similarly generic companies have their place, because they bring a good quality, with proven clinical value, and trusted products for a lower price to the market, contributing to control healthcare costs.

I have always kept a good relationship with the innovative industry. We are in the same market, we are serving the same patient, and the patient should benefit from the activities of both the generics and innovative industries to get the best and most cost effective treatment available at the moment. In many cases it is the generic. In a number of other cases it is a new patented product that has come to the market that shows a definite clinical advantage for patients. The complementarities between the two in a competitive, efficient market are how we bring a sustainable, cost effective healthcare forward.

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