Interview with Joris Van Assche , Managing Director, FeBelGen

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Looking into your background, we see that you've spent 8 years at pharma.be, where you were advocating the traditional drug producers. What encouraged you to head FeBelGen since 2006, representing the generic and biosimilar drugs industry in Belgium?

When I started to head FeBelGen in 2006, my goal/objective was – and still is – to create a better understanding of the benefits that generic and biosimilar medicines create for the patient, the economy and the health insurance. It is not widely known that generic & biosimilar companies are also making huge investments to bring their (often ameliorated) products to market. They furthermore bring competition (and massive savings) to the market, which encourages all actors – including brand products companies – to further investigate and propose new products to meet medical needs. Eight out of the top ten generic companies worldwide are also investing directly in R&D of new innovative medicines. Indeed, a number of large and leading generic companies – or so called hybrid companies – in Belgium are investing in research and development of new molecules. Some companies derive up to approximately 30% of their revenues from innovative molecules. In addition to this, other companies are focusing on the development of biosimilars, which requires significant investments and R&D activity as well.

The generic industry plays a key role in securing the sustainability of the Belgian healthcare system since 2001 – the start of the reference reimbursement system in Belgium – generic medicines have already realised saving of over €3.2 billion for the Belgian health insurance. We are

very proud of these achievements, even if a lot of work still has to be done in Belgium to extend the use of the generic and biosimilar cheap alternatives available to patients.

Hence, one of the main roles of generics is to bring competition to the market when patents expire. Pharmaceutical brand companies (originators) are certainly familiar with this economic model – where they maintain a monopolistic position for a number of years. Subsequently however, competition is introduced and generics are allowing for price decreases and savings for both health insurance and patients.

Generic medicines companies introduce high quality and safe products to the market, which in many treatments are considered to be the gold standard. These products are highly efficient and cost effective. As mentioned before, generic medicines manufacturers often invest heavily in their products and technologies to market ameliorated products. Therefore, an important characteristic of generics is that they guarantee the continuity of treatments as the market moves from a monopolistic basis to a multi-source market. This multi-source market also creates important savings for the government as noted earlier. Moreover, along with the gigantic savings triggered by generic medicines, generic companies make further valuable contributions to the economy, since about 50% of generics sold in Belgium are produced locally.

Mr van Assche, can you please introducing our readers to FeBelGen and highlight its most notable achievements and milestones since it was founded in 2001?

Although the generics industry in Belgium is relatively small, I would first point to the fact that FeBelGen brings together nearly 100% of the generics companies in the country. Along with this, I would once again highlight the industry’s ability to have generated €3.2 billion in savings for the health insurance since 2001.

As FeBelGen represents nearly 100% of the generics sector in Belgium, it is surely intimately aware of the latest developments. What are the most pressing issues and market peculiarities facing your members today?

This can still be summed up in one word: volume. That is, we have recently made significant efforts in terms of price cuts to create extra savings for the authorities in a difficult macroeconomic context. As I mentioned earlier, we are providing the government with budget savings as a result of the price decreases stemming from competition in the market. However, given the current small size of the generic market in terms of volume, I firmly believe that requests for further price decreases are excessive, since the output volumes considerably determine the price.

In this regard, our main message to the competent authorities is to acknowledge the contributions the generic industry has made so far and to allow us the opportunity to grow. Needless to say, only this can allow generic companies to be able to reach the critical volume levels required to realize economies of scale and hence increase savings.

I believe that the underlying issue here is that the concept of ‘cheap medicines target’ applicable to our doctors is not ambitious enough. This quota on inexpensive drug prescriptions is in fact at the same level of the already occurring prescription levels in the market. At the same time, such quotas are not applied in hospitals, which further weaken the incentives to utilize inexpensive medicines. On the contrary, there are disincentives in ambulatory hospitals to use generics, since all of the more expensive medicines it prescribes are still fully reimbursed by INAMI, the Belgium Health Insurance Agency.

I believe that it is high time that an environment that promotes the use of cheap medicines, especially generics & biosimilars, is created. We must certainly further stimulate the use of cheap medicines and generics by both practitioners and hospitals. This is an absolute necessity.

On the other hand, biosimilars in Belgium experience a very low level of penetration, with only three drugs on the market representing a market share of less than 1%. However, in several other countries these same products make up as much as 30% – 70% of the market. I believe that this represents a problematic situation, since 50% of the value in patent expiry over the coming 5 – 10 years will come from biotech products.

Traditionally, the market share of generics in Belgium has been much lower than that of originals. What in your view is the fundamental reason for this?

On the one hand, this relates to the “cheap prescription” concept that allows original post patent products to hold the market. More specifically, doctors lack the incentive to change their prescriptions, since they consider these products as being cheap medicine. As a result, 50% of the market eludes from the generics. On the other hand, the matter is further aggravated by the lack of incentives to stimulate prescription of cheap medicines.

A closer look into the post patent market will reveal that 66% of the genericized market (where a generic alternative is available) are brand products (this figure is split evenly into cheap and expensive post patents with supplement paid by the patients), while the remaining third are generics. Therefore, it becomes clear that the potential to shift patients from using expensive post patent products to cheap post patents or generics is huge.

It seems rather contradictory that given today's cost containment measures and the authority's efforts to bolster their budget, the generic & biosimilar market is struggling rather than thriving. What do you think can be done to correct this?

As I mentioned, one thing we can do is to adopt quicker the cheap prescription targets for practitioners, incentivizing the doctors, while also modernizing the concept of cheap medicines to make it more cost efficient and measurable.

On this topic however, I must praise the minister of health, Mrs Onkelinx, for her recent achievements which led to the introduction of a number of new mechanisms designed to promote the use of biosimilars. But a lot of work remains to be done before these alternatives for branded biotech products are effectively used by the doctors in Belgium.

With worldwide growth rates for biologicals in 2011 of 8.5%, compared to 4.5% for the total pharma market, companies are making biosimilars a priority. In this respect, how do you see the role of biosimilars in Belgium and what can be done to enable a better environment for these drugs?

The potential market for biosimilars is undoubtedly growing at a faster rate than traditional markets. In Belgium in particular, the product's growth rate in ambulatory hospitals (mainly expensive biotech products) is at around 9% per annum, which is contrasted by flat growth in traditional ambulatory and hospital (intra muros) markets. Today, the three biosimilars already available on the market represent €51 million in healthcare expenditure per year.

As mentioned, the challenge here relates to our future ability to capture the potential savings derived from the patent expiries of biologics over the next 5-10 years. More specifically, we expect to have as many as 10 new biosimilars introduced in the market by 2015 – 2016. These cheap alternatives are expected to replace drugs that are currently costing the government as much as €350 million per year. Therefore, we must implement incentive schemes and mechanisms to promote the use of these cheaper alternatives in the future to help ease the budgetary pressures.

Despite these benefits, we continue to face reluctance to head in this direction due to an issue of regular misinformation about generics and biosimilars. To put this into perspective, a recent damaging report from the French academy of medicines suggested that generic drugs were unsafe and ineffective. This prompted Minister Onkelinx to refute this claim and convince stakeholders of the contrary. Despite the falsehood of these claims, this kind of messages is reaching physicians & patients, which hampers the use of these medicines. This is a rather frustrating situation, since in many other countries there are as many as 30% – 70% of patients using these biosimilars without

negative repercussions! Why should Belgium be one of the few EU countries not benefiting from such immense savings from top quality but cheaper products?

Overall, we have had a number of positive achievements. Nonetheless, we must continue to advance towards developing a better and more precise understanding of what biosimilars are and what they can bring to us all, while also stimulating their use by practitioners. Moreover, given the significant investments and long development periods involved with biosimilars, there is also a need to develop specific mechanisms. Biosimilars development will be economically unfeasible, if for instance the reference reimbursement system applied to generics would be applied to biosimilars.

A recent article in L'Echo newspaper pointed out that there was no evidence of generic counterfeit product slowdown in the EU. What is your position on this and how has this affected your members?

Generally speaking, counterfeit drugs represent one of the central topics in the field of medicines and I think we have to adopt the necessary measures that are required to resolve this phenomenon. However, it is most interesting to point out that within official distribution channels there are absolutely no reported counterfeit cases with regards to any generic products. This is a result of the multi-source nature of generics supply and the overall lack of appeal in falsifying these products due to their inexpensive nature. Hence, our message to the authorities on this topic is not to further make the generics sector even less sustainable by imposing unnecessary expensive measures to counteract a problem that does not apply to the sector. Instead, it would be far more effective and efficient to focus their efforts on combating innovative counterfeits that patients are potentially consuming. To this end, we are actively in discussions with the competent authorities since it is expected that the Delegated Act (transposing the EU Directive), will hopefully take the specificities of generics into account and exempt them from any expensive, unnecessary measures that would jeopardize the sustainability of the sector.

What is on the agenda of FeBelGen for the coming 1-2 years? What challenges do you wish to overcome for your members, and what reforms would you like to be carried out in the market in the short term?

Our challenge, in the broadest sense of the word, is to develop a sustainable market for generic and biosimilar medicines. We are constantly advocating for increased growth in volume of generics in general, since there is much potential to be had. In the same way that the originators industry is enjoying a sustainable environment, we would like to obtain this status as well.

We would like to highlight the further savings and benefits that the generics sector can provide as a consequence of higher use of these qualitative, effective and totally safe, though cheaper, products. At the same time, we would like to point out that, despite our positive efforts and contributions, we are not being rewarded with any gains in market shares due to the lack of incentives to increase the consumption of generic drugs. To put things into perspective, in 2011 we launched 20 new generic molecules on the Belgian market, representing savings €66 million per year for the Belgian State, but only obtained an average of 5% market share for these generic molecules in 2012 (estimate FeBelGen, June 2012). Cheap prescriptions have stagnated 50% in Belgium since 2010. Whereas in the meantime not less than 40 new generic molecules have been launched!

In conclusion, I reassert that we must create the sustainable conditions required to develop and grow our sector for the benefit of the government and society, as to guarantee that a strong generic sector can continue to bring competition and generate further savings in the future. This should be done by promoting the use of cheap prescriptions, both of generics and biosimilars.

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