Vincent Verschraegen – Country Manager, Mylan Belgium & Luxembourg

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Vincent Verschraegen, country manager of Mylan Belgium and Luxembourg, speaks about his onboarding in the company and what attracted him to join the organization. Verschraegen also discusses Mylan's evolution from a pure generics player to a full solution healthcare provider and offers insights into Belgium's complex biosimilar landscape as well as the changes which must be realized in order to fully unlock the opportunities of this growing segment.

After a 14-year career with Sandoz you shifted teams and joined Mylan in October 2018. What was it that attracted you to the organization?

When I joined Mylan coming from the competitor Sandoz, I discovered that the portfolio of Mylan is unique compared to other pharma companies. Mylan may historically be known to some as a pure generic player but we are much more than that. Our portfolio of course leverages generics, but we also have well-known, established brands in key areas like hospital injectables, biosimilars, and drugs for treatment and prevention of HIV. Not to mention an important pillar in OTC or vaccines.

My trigger to lead Mylan in Belgium was the opportunity to offer to healthcare professionals and patients a full solution in the face of growing challenges. I believe this is a model that allows Mylan to be ready for the future, knowing that the needs of healthcare professionals, patients, and other

stakeholders will evolve and be so diverse as we enter a new era of health.

Do you experience any culture shocking coming to Mylan after a decade with its competitor?

Every company has its own culture of course. A strong element within Mylan is that our focus is on finding solutions for all stakeholders including patients, professionals, and authorities. This is clearly reflected in our portfolio with important pillars like biosimilars for severe chronic diseases and HIV drugs, which will become more and more important for patients and prescribers in protecting their access to medicines. Helping find answers to the hurdles we will all face in healthcare is what drives Mylan to differentiate and to be ready for the future.

Looking back on your first full year in Mylan, how did the affiliate perform and what are your priorities for 2020?

One of our top achievements in 2019 was growing to become a top three player in the Belgian generic market.

Furthermore, with our HIV portfolio, Mylan has been able to grow from very low market share to very important player, with 7 in 10 HIV patients in Belgium now using a Mylan medicine. From that perspective, we have successfully been able to provide solutions with a quality and accessible generic alternative.

Moreover, we launched our first biosimilar in January 2019 for Humira (***adalimumab molecule, Hulio brand)***. Mylan now holds the top position in this biosimilar market amongst three other competitors.

These three examples reflect the excellent performance of Mylan last year as we were able to further strengthen our position and successfully bring new solutions. This focus on success will continue forward to 2020 as we continue to put more emphasis on bolstering our biosimilar offering.

Meanwhile, Mylan’s generic portfolio will continue to grow through established brands as well. For example, last year Mylan also surpassed competition as market leader by volume for providing Belgium with the seasonal flu vaccine – Influvac. This truly shows where we have come from as a company and where we are headed for 2020.

What were the factors that helped you achieve this success?

As in every diverse portfolio, there is a richness but also complexity. Therefore, we decided to focus on specific areas where we could drive market share and at the same time have a very solid targeting and segmentation approach. It is important to position Mylan not just a generic player but as the leading solution provider.

Belgium is a very competitive environment but the medical community has really found a partner in Mylan. For example, the generic world is very competitive and can be complex to make choices in, but we see that doctors and pharmacists recognize our quality, portfolio, and determination to bring new products on the market. These are the drivers of Mylan's success.

What is your assessment of the biosimilar landscape in Belgium?

There is a lot of visibility around biosimilars and Mylan will continue investing in these areas. Stepping into the biosimilar environment is related to five to nine years of R&D investment – about EUR 150 to 300 million is needed to develop one product, based on industry data. If Mylan has decided to follow this direction it is because we want to bring alternatives to biological medicines that are more and more welcomed in the market.

Looking at the European context, we see that in many markets biosimilars have adequate uptake, making Belgium an island in Western Europe. Honestly speaking, the Belgian uptake today is too low. With Medaxes, where Mylan is actively represented through the Board, we continuously debate with the authorities how we can find solutions to finally generate improved uptake of biosimilars. This is a major change that needs to happen as we see that some biosimilars that have been launched in other European countries are no longer launched in Belgium. For Belgium to remain an interesting market, a predictable and sustainable environment is absolutely essential.

From a regulatory point of view, we should be able to launch faster. The timelines that are applicable to get biosimilars into the market are lengthy and must be shortened. There is no need to repeat the HTA assessment as this has already been done for the reference medicine. More importantly, as biosimilars increase accessibility, they should be allowed to start the (shortened) pricing and reimbursement applications as soon as CHMP positive advice has been granted. This can speed up savings for the healthcare budget.

There is a double assessment meaning even if EMA has approved a biosimilar we must resubmit the data for HTA assessment /reimbursement dossier locally. This is a very concrete example of how we can improve a launch of a biosimilar.

Would you say that the perception of the medical community of biosimilars is adequate or is there still a knowledge gap between the healthcare professionals?

Of course, we should continuously work on awareness. However, looking at the data available in Europe from millions of patients being treated with biosimilars this should not be the debate anymore. It is difficult to identify the reason for this uptake hurdle – there are many factors at play, but we will continue to inform prescribers and build trust. Nevertheless, the discussion should not be whether biosimilars are good solution – we already know the answer. The question should be how can we ensure patient access to biosimilars. From the examples we see in other countries, uptake measures must be taken by authorities.

What is the value that biosimilars can bring to the healthcare system?

In terms of pricing, the average biosimilar coming to market is 30 to 38 percent lower in price than the originator, based on publicly available data. Biosimilars that are currently available in Belgium are already generating more than EUR 270 million savings annually. With the pipeline of biosimilars that could come on the market in the coming years we can increase these savings. To give an example, the 20 most important biological medicines generate a revenue of around EUR 480 million every year. Introducing biosimilars will generate a more competitive environment and bolster the savings that we already have today. Biosimilars are a win-win-win; patients have faster and easier access to affordable medicines, healthcare professionals have more choices in treatment options, and authorities create solutions for budget challenges. This is a call to action for the Belgian market. Biosimilars are an opportunity we cannot afford to miss.

In 2015 Maggie De Block Minister of Health signed the crucial Pact for the Future with the industry. What are your expectations for the future of industry authority relations?

The purpose of the pact was to offer predictability and transparency in the market which are priorities that should remain on the table. As Belgium’s new government eventually forms, it would

be interesting to evaluate what has been accomplished and further build on the concept. There will be a need for a new agreement to remain in this predictability of the market. All players asking for as much transparency and predictability as possible. From that perspective, we should also discuss as an industry what could be the future of biosimilars in Belgium.

What makes Mylan a true partner to the Belgian health authorities?

We always strive to partner with health authorities.

When, in the beginning of 2019, the Belgium authorities approached Mylan to discuss alternative ways of managing the healthcare budget for HIV, we immediately took up the challenge of increasing our production capacity to deliver quality treatments at affordable prices for Belgium patients. By doing this, Mylan confirmed its commitment to serve every physician and HIV patient in Belgium.

Being a partner in health, we have been able to offer generic alternatives to patients generating savings of more than 8 million EUR for authorities.

How do you go about maintaining focus and harmonizing such a wide portfolio?

Once you have a portfolio of an important number of brands you always have to make choices and that is the focus where we should more and more go into it because of course, you have to make choices where you want to go and drive your business. Our generic portfolio is a solution for the affordability of patients and healthcare professionals while biosimilars is a new area where there is a lot of opportunity to grow. Moreover, Mylan is also the leading company in Belgium for HIV treatment. This is part of a global focus of Mylan on HIV area – worldwide, 40 percent of all adults and 60 percent of children who are HIV positive are treated with Mylan products.

It is always a matter of focusing when making choices but at the same time, these pillars will remain important not only from a business perspective but also to drive the challenges in the stakeholder environment of pricing, budget pressure, and patient needs.

What has been your experience balancing both the Belgium and Luxembourg markets and what are the similarities and differences that exist between them?

From a regulatory stance, the markets are quite easy to handle in parallel because dossiers built for Belgium can easily be used in Luxembourg as it typically follows the Belgian market. Of course, the market dynamic is a bit different but still very comparable as we see both are mainly prescription driven. However, some areas of substitution vary Belgium and Luxembourg, but overall it is not a different world. The authorities of the two countries are increasingly aligning together and what happens in Belgium is often used as an example also for Luxembourg to apply. Managing both countries is a complementary approach where some nuances may be different but overall we can manage both similarly.

Where does the Benelux fit within the EU operations of Mylan in terms of significance?

Mylan Belgium is a top ten player within the company's European operations. We are still small compared to other markets like Germany, France, or Italy where biosimilars have a high penetration percentage already. In these markets, biosimilars are already in the next phase of a more mature business meanwhile Belgium is still at the starting point. Therefore, the opportunity is to grow quickly and achieve high uptake as well. There is also opportunity in the generic sector. Looking at generic penetration in Belgium, there is a 35 percent volume based on publicly available data, which is low compared to other countries where generic penetration is at 80 percent. From that perspective, Belgium despite its challenges has plenty to offer and the portfolio of Mylan can further grow market share and achieve success locally.

How is Mylan Belgium keeping patient centricity as a value of its operations?

I would describe the culture at Mylan as patient-oriented and winning. My conviction is really that as an organization we can grow to a higher purpose than simply selling boxes, but instead providing patients with access to medicines. Mylan sells 70 million boxes a year in Belgium and we are a top five player by volume. However, our impact is not about units sold but the number of patients we can serve. The people who work in Mylan, myself included, are happy to come to work because we know that at the end of the day everything we are doing is for patients' benefit.

Any concluding words to share on behalf of Mylan?

Companies evolve over time and have to decide on which direction to grow. From a historically formal generic player, Mylan has chosen to evolve as a complete healthcare company. From that

perspective, I think what has been built is a unique model for the future that will deliver Mylan Belgium victories as we work to answer the challenges of the pharmaceutical industry.

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