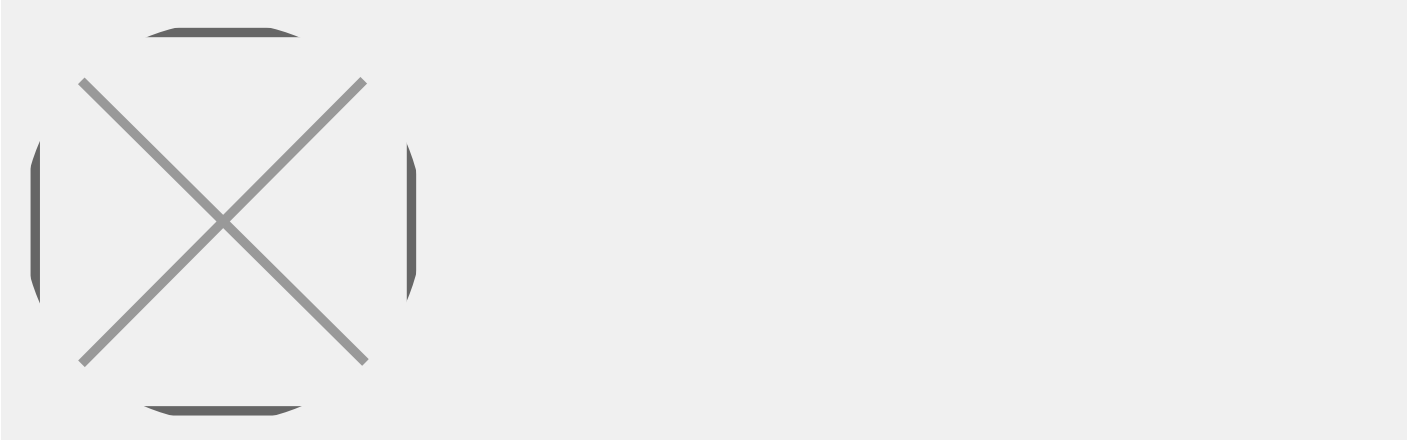
Interview with Pascale Engelen, Managing Director, Mylan – Belgium



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If generics market in Belgium do sn't seem to be at the level it deserves to be. Considering that Mylan controls about 14% of the local generics market share, how would you assess the authorities and physicians attitude towards the generic drugs in Belgium?

In Belgium, generic drugs are not being fully utilized to help manage the healthcare budget. There is no real policy or long term vision pertaining to incentivizing the use of this class of drugs. This is unfortunate because I strongly believe that generic drugs are complementary to their innovative counterparts. That is, generic drugs can serve as a tool to free up financial resources that can in turn be used to reimburse new and innovative drugs. In fact, since 2001, generic drugs have been able to create savings of €3.2 billion for the healthcare budget. There is certainly enough room in the market for both types of players; hence I do not believe we should be viewed as competitors.

Nonetheless, over the past years, we have observed immense pressure on the healthcare budgets not only in Belgium, but across the whole of Europe, stemming from both aging populations and the economic situation. Regrettably, the authorities seem to have passed on a significant proportion of the savings measures onto the post patent market. Therefore, instead of giving our industry more breathing room, we are left contemplating the sustainability of generics in Belgium. In order to be able to continue creating savings for the government, it is essential that we are allowed the volumes required to ensure our continuity. For instance, of the most recent product launches, only 10-15% are generic drugs following 3 – 6 months of their patent expiry. This illustrates the fact that there are no real incentives for physicians or pharmacists to truly utilize these drugs.

However, because the law states that drug prices must only be reduced when generic drugs are introduced, this presents a potentially dangerous situation because if the generics sector is no longer sustainable and new drugs stop being introduced, there will no longer be any savings. Hence, I believe it is of the utmost importance that necessary policies are put into place to incentivize the use of generics by both physicians and pharmacists.

To what extent is Mylan working together with other organizations and stakeholders to improve the positioning of generic drugs in the Belgium market and ultimately contribute to the overall healthcare systems sustainability?

This is indeed the primary task of FeBelGen (the Belgian Association of Generics Sector), of which Mylan is member of the Board. In this regard, our main goal is to be a true partner to the government to manage the healthcare budget over the long term by developing the adequate policies.

In doing so, we are for instance advocating the use of evidence based approaches to drug reimbursement as is being done in many other nations. More precisely, we believe that we should prioritize the use of first line products while keeping the incrementally innovative patent-protected drugs (the so-called me too's) for those patients that are not being well treated by the basic treatments. For instance, now that Lipitor (atorvastatin) has come off-patent, we could treat up to 90% of the patients with the statins that are genericized today while keeping the patented Crestor® (rosuvastatin) specifically for those patients that are not responding well to the former drugs. This is a cost effective approach that makes use of products that have demonstrated long term results (evidence based medicine) while reserving the more expensive drugs for patients that are not responding to the cheaper off-patent statins. This is simply a case of investing ones resources in a rational manner.

It is said that one of the reasons generics might not be at the level they deserve to be might be related to the fact that some buyers and consumers perceive them to be inferior to novel drugs in terms of quality. How is Mylan addressing this issue and educating stakeholders of the true situation?

Mylan is a worldwide Pharmaceutical company manufacturing and packaging products all over the world, with one unique mission: to provide 7 billion people access to high quality medicine.

Present in 150 countries in the world, our products go through the same quality process. Internal and external auditors inspect our facilities several times a year.

Before going under the country specific registration process, our products are submitted to some bioequivalence study.

The situation is improving day by day because more and more general practitioners understand that generic drugs are characterized by the same quality standards as their innovative counterparts. In addition to this, I believe physicians fully understand the role of generics in society and how they can create savings to be reinvested in the latest innovative drugs.

On the other hand, I think that specialists require a fair deal of information with respect to the standards of generics. The majority of primary care products have already genericized, next in line is a number of specialized drugs including those for the treatment of Alzheimer's disease and anti-psychotics, for instance. Hence, considering that we, as the generics sector, have not been so often in contact with specialists until now, we are presented with a new segment of stakeholders whom must be properly informed about the efficacy and safety of generic drugs as a whole.

2012 marks Mylan Belgium's 6th anniversary since the acquisition of Merck KGaA's Generics business as well as Matrix Laboratories, which propelled the group to becoming one of the world leaders in the production and distribution of generic pharmaceutical products. What synergies were realized by Mylan following these acquisitions?

The fact is that we have become a global group and having this new global scope is the biggest difference. Prior to the acquisition, Merck Generics was mainly European focused. However owing to Mylan, we now enjoy the reach and scalability of a large group. In addition to this, we were also able to achieve vertical integration through the acquisition of Matrix Laboratories. This represents a critical advantage for us since we are now able to control quality levels across the entire value chain. Furthermore, as Mylan was a leading generics company in the US, the acquisition granted Merck Generics access to the company's operational and technical standards and knowhow, helping it to streamline and consolidate its operating processes worldwide.

Ultimately, Mylan has grown from an entrepreneurial company to a globally established and recognized company. Considering the high standards of today in terms of quality, pharmacovigilance as well as regulatory, I believe this is the right heading for the company to follow, since such structures have become absolutely necessary. The ability to offer such high quality and standards, a personal prerequisite for me, will also help to shine us in the same light as the innovators industry.

Could you highlight one of the affiliate's main milestones since you assumed control in early 2011?

The integration of the Merck Generics and Docpharma's portfolios is certainly a cornerstone in my tenure at Mylan which has endowed Mylan Belgium with a more comprehensive and complete products portfolio. Prior to the acquisition, these were two completely different companies with dissimilar client pools and market approaches. I believe that integrating these structures together was an essential step forward for the organization. Indeed, Mylan now has a clear strategic vision

and direction and our resources are focused on identical goals and this is certainly important in the framework of sustainability.

In addition to this, by integrating our portfolio of products under the Mylan brand name, we have simplified the routines of many people including the authorities, pharmacists and physicians and helped the company's overall efficiency.

Looking ahead, the next step would be to prepare appropriately for every new product launch and prepare for the future. Although this is no easy feat, I am quite optimistic following this year's installation of substitutions for antibiotics and antimycotics. This measure clearly demonstrated that if the appropriate incentives are put into place in the market, and substitution is encouraged, then the market is significantly more accommodating to the generics industry and I believe this is precisely what our industry needs to ensure its future growth.

What would you say is the strategic importance of the Belgian affiliate to Mylan's regional operations?

Belgium always has been an important country for Merck Generics which is now Mylan of course. In fact, when Merck Generics was acquired, the company was ranked second in Belgium in terms of market share. Indeed, our history in the country has created a legacy of still being an important contributor to the success of Mylan in Europe. This is reflected in the fact that the Belgian affiliate ranks among the top 7 affiliates of Mylan in Europe. Considering Belgium's small market and population size, especially compared to the big five (UK, Germany, Italy, France, Spain), being ranked among the top 7 is rather impressive and serves to strengthen my confidence in the country's capacity to being a strong contributor to the company's regional operations.

Does Mylan engage in collaborative initiatives with academic, commercial or regulatory organizations to strengthen its scientific or commercial capabilities for a more sustainable business environment?

On an international level, we are performing R&D activities in the domain of galenic formulations with the Mylan Group, driven by Matrix Labs in the US. For instance, Mylan is well reputed for its strength in ARV's (Antiretroviral drug, used to treat infections by retroviruses, primarily HIV) where we developed a heat resistant formulations for ARV's so that the products can be transported to warm climates such as Africa without having to abide by cold-chain requirements. Hence, contrary to popular belief, generic companies do engage in notable R&D activities which broadly aim to improve existing drugs.

In Belgium however, Mylan is commercial organization that distributes its drugs to the market. Naturally then, our main collaborative initiatives are those with the FeBelGen association which are broadly directed towards creating a more sustainable business environment. In addition to this, we

also work closely with a number of doctors' and pharmacists' association to educate them about generic drugs. Likewise, we also help the government raise awareness of the post-patent market and promote the good use of medicine. In addition to this, we have good and frequent contacts with the regulatory and social affairs agencies to demonstrate to the authorities that we are abiding by the highest quality standards that are expected of us.

In conclusion, what goals would you like to achieve as the Managing Director of Mylan in Belgium over the next couple of years?

Our main goal today is to shape the company into the preferred partner of healthcare professionals. Not only do we aim to achieve this by delivering high quality medicine, a prerequisite in today's society, but also through our role in providing added value services. This involves providing professionals with accurate and up to date information as well as expert training that goes beyond informing them about the various drugs or diseases to also educate them about the professional environments they operate in. Put differently, our main focus in this respect is to become the healthcare professional's main business partner, so they can indeed be most efficient in their daily work. We will strive to achieve this goal by paying careful attention to the concerns and requests of our stakeholders and responding to those accordingly through tailor made solutions.

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