

Interview: Jacek Glinka - President, Europe; Tomasz Buczek - Country Manager, Poland, Mylan



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Jacek Glinka, president of Mylan Europe, and Tomasz Buczek, country manager of Mylan Poland, discuss the intricate dynamics of the European and Polish pharmaceutical ecosystem and the steps required to find a sustainable balance between government and industry to ensure patients receive world-class healthcare. Furthermore, they highlight the importance of the biosimilar boom for European healthcare budgets and the importance of the Polish market for Mylan.

What does it mean to be an independent global generics company within Europe in 2018?

Jacek Glinka (JG): In fact, today, Mylan in Europe is not a generic player anymore, but has evolved into a diversified healthcare company. Mylan entered the European market in 2007, with the acquisition of Merck generics, giving us access to around 20 markets, and this presence was strengthened throughout the years through sound acquisitions, such as the 2014 purchase of Abbott's mature brands portfolio outside the US, and the 2016 purchase of Meda.

This has transformed the company to being omnipresent throughout Europe - in 35 markets - and more diverse in portfolio; therefore, now only 30 percent of our European business is generics, with our focus based increasingly more around branded products and OTCs.

If you look at the overall market, for years, the innovative and generics companies experienced a turbulent relationship, with generics companies stressing some of the practice of innovators - while

in the meantime – innovators marginalised the generics products due to concerns about quality and safety. Additionally, over the last decade, there has been a convergence between different business segments in big pharma as they attempt to establish their own generics unit, with many companies deciding later on to sell off their generic branches.

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Mylan chose to take an innovative approach by building our presence in many segments under one roof – very different to the past. We understand that, from a supply chain perspective, generic and innovator organizations function in the same manner, and all aspects of pharma are interconnected. Furthermore, Mylan is investing deeply into innovation, like generics companies have done over recent history. Our all-inclusive business model is unique, and Mylan is truly pioneering the next evolution of the pharmaceutical industry. We now are a truly diversified global healthcare company focused on making high quality medicines available to everyone who needs them.

There are many factors working against the traditional business model of a global generics company. Do you believe that the market can still accommodate such an approach?

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JG: There is always room for generics organizations! If you analyse European healthcare markets, 60 to 80 percent of therapies are generics, and it is the segment of the pharmaceutical industry that is strongly responsible for the health of people. Definitely, the generics ecosystem is becoming more competitive than ever before, despite European governments being exclusively focused on cost containment measures towards generics, rather than innovative therapies.

This, in many cases, is being done in a non-sustainable manner, that in the long run impacts the supply of drugs into a country. For example, when drugs prices are drastically lowered, countries run the risk of only a few companies being able to match this price. Therefore, organizations pull out of the country, and patients do not receive the therapies they require. It is a vicious cycle that in the end results in the patients losing out.

How has the generics industry been able to cope with these enforced pricing pressures?

JG: Overall, the generics industry has shown its strength by being able to survive such drastic price drops by national payers.

Nevertheless, the generics market has had to reorganize operations, and Mylan is no different. Previously, API's were outsourced; now, approximately 80 percent of the product volume we sell is produced through internally controlled manufacturing, in one of our approximately 50 plants around the globe which adhere to stringent quality standards regardless of location.

Local authorities have put pressure on generic pricing, putting at stake the European pharmaceutical industry competitive situation. Despite this, Mylan has continued to invest in Europe and we now have 12 plants on the continent, responsible for manufacturing and packaging, as well as R&D centers.

All in all, Europe should take a more holistic view of the importance of the generic sector. If the generic volumes in Europe were replaced by innovative products, it would cost Europe 100 billion EUR (122 billion USD) annually. It is not sustainable! Governments must start looking at the generics industry as the saviours that help them achieve their healthcare goals.

As the President of Mylan Europe, what would be your message towards the authorities when they are forming decision to find a balance between the needs of the government, industry and patients?

JG: The most important task for the payer and pharmaceutical industry is to create predictability and sustainability. Therefore, in many nations, such as France, UK and Belgium, the entire pharmaceutical industry has signed sustainability agreements with Ministries of Health that lays out the healthcare spending over the following years.

This does not prevent a price reduction in drugs, but allows the industry to have knowledge in advance of any policy shifts, rather than discovering the information the day of such an important decision. We are then able to discuss how to achieve a balance in healthcare budgets, and develop an effective solution that is sustainable for both industry and governments, so in the end patients can receive the treatments they need.

A clear example of the importance of mutual agreements occurred in Romania. The Romanian payers aim was to offer the cheapest prices possible, believing this was the best way to get as many therapies as possible to the patient. The problem is companies allocate the volume of a therapy to the nation offering the most sustainable pricing. Therefore, when issues occur in a treatment's supply chain, countries that offer incredibly low prices, such as Romania, miss out, and there is a supply shortage for the patients.

Romania is facing critical issues in healthcare now – they got the lowest prices, but are facing serious challenges in providing the volumes needed by patients. Therefore, nations must develop a sustainable business environment for all companies to be present in the long term, rather than just look at the short term financial impact of driving down therapy costs.

How would you describe the European results for Mylan in 2017?

JG: In 2017, I would say the major success has been our ability to positively navigate the market under one organization umbrella after a period of acquisitions. This brought us new opportunities in various therapeutic areas, serving our customers better than ever and providing better access to the 740 million people in Europe.

What have been your best performing markets, and what are your up and coming stars?

JG: Mylan Europe consists of 35 countries, and from a size perspective the big-five are our largest markets: Spain, Italy, UK, France and Germany. From a growth aspect, Poland is absolutely an important market for us in Europe, and equally so are Germany and Italy. Additionally, Mylan’s greatest example of creating a sustainable market position occurred last year in Portugal, where we were able to become the number one company in the market!

Where do you see the areas of growth moving forward?

JG: Our goal is to grow in every sector that we are present in. Due to the fact that Mylan in recent years has grown inorganically as a result of acquisitions, this growth will differ in every country as we have differing levels of assets.

Looking ahead, Mylan observes an outstanding opportunity in the field of biosimilars, and this area is set to develop massively. In Europe, for more than ten years, patients have benefited from the availability of biopharmaceuticals; over the next three to five years, the market in general will experience top performing original products coming off-patent – a great opportunity for biosimilar players and healthcare systems. In fact, just as generics save Europe EUR 100 billion (122 billion USD) annually, in the next five-years, there is the potential for Europe to save EUR 50 billion (61 billion USD) annually due to biosimilar launches – based on Medicines for Europe data.

The unsolved question is: how will governments promote and increase market share uptake of biosimilars? Patterns indicate in some European nations biosimilar penetration six to twelve months after launch is 60 to 80 percent – while in other nations – for the same product two years down the track the penetration is a mere two to five percent. If these biologic generics are not rewarded, healthcare professionals will continue to prescribe the original therapy, and payers will continue to

be paying for the original drugs, missing out on the opportunity to offer the biosimilar product for a significant amount less.

The perfect scenario is the day following a drug coming off patent, 100 percent of the market share comes from generics. For example, in Poland for many years the country lacked market access of innovative products, as the governments could not afford such treatment solutions. Though with the promotion of generic and biosimilars, this has freed funds for the introduction of innovative solutions – it is all interconnected.

Finally, in the last decade, governments have been overly cautious about not increasing the percentage of pharmaceutical spending in the healthcare budget. Why? The amount spent needs to be assessed as a larger picture, and based on what is the overall impact of pharmaceuticals on the healthcare budget. As a healthcare community, we must look long-term.

Poland is a generics market, and offers huge potential for companies. What is the strategic importance of Poland in the region?

Tomasz Buczek (TB): Polish generics penetration is 78 percent of volume. This shows the potential for the nation to give to the patients the treatments they need, and I am proud to be leading Mylan Poland and helping the nation fulfil this healthcare goal.

Mylan, unlike pure innovators, is able to generate substantial savings for Poland, while providing excellent access to patients of necessary therapies. In-turn, these saved funds can be redirected to other areas of healthcare, or facilitate the oncological tsunami Poland is experiencing.

In fact, it is a pleasant surprise for Poles to witness that our government improved market access of therapies to oncology patients, despite at times this being limited to drug programs, consisting of limited patient numbers or treatment period. Nevertheless, the aforementioned saved funds, facilitated via the huge market share of generics and biosimilars, will help amplify the patient recipients in the drug programs and extend their treatment period in the future.

JG: Poland is an important market for us in Europe, and in recent years has been one of the most successful. After starting from scratch only a few years ago, to jump to number 15 in the market is huge – according to IQVIA data. Moreover, Mylan has a good position here as the Polish government values generics – additionally – Poland is one of the region’s top OTC markets and the government’s approach toward this sector is quite advanced and well appreciated by Mylan.

What are the growth drivers for Mylan Poland?

TB: In the retail sector, we are number 15 in the market – according to IQVIA data, and still have a long way to grow, though have extremely encouraging signs and per annum, we are supplying around 20 million packs to Polish patient.

The cardiovascular sector makes up 40 percent of our volume and is Mylan Poland's number-one area. This therapy is along the entire chain of cardiovascular disease, going hand in hand with our treatments fighting diseases associated with environmental factors and the ageing population, such as statins to reduce patient's cholesterol.

Finally, we strongly believe Mylan Poland can create an immense footprint in HIV treatment, and globally the company is responsible for providing therapy to more than 40 percent of all HIV patients. In Poland, generics can offer this treatment and lower the overall costs in the therapeutic area by 70 percent. If you take into consideration the ten thousand patients that require drugs, this is a huge amount of savings that can be redirected into other areas of healthcare or expand the access of treatment solutions to Poles.

Mylan has a biosimilar partnership with a local Polish player, Mabion. How did this come about?

JG: Partnering with Mabion was a natural fit. Polish entities have been improving their R&D developments over the years and we are proud to have this partnership here in Poland.

Do you feel the pharmaceutical industry is investing enough into Poland, especially considering the great potential of the market?

TB: Mylan is proud to have a strong footprint in Poland for more than ten years, and to be an important employer locally. Furthermore, Mylan Poland is home to many regional and global employees, and is an important hub for the company in developing its European market.

What are your future aspirations for the company moving forward?

JG: Throughout Europe, once we have reorganised ourselves after all the asset movement, we will look to grow all business areas. Furthermore, over the next two to three years, we will focus heavily on delivering more to our customers, so patients can receive the best possible access to therapies.

TB: In Poland, we've been equally working to reorganize our business structure after the asset acquisitions and have already finalized this process, while in the short to mid-term, we look over into creating higher visibility for our highly diverse OTC portfolio. Linked to this, we see it as an important aspect in Poland to have increased patient's access to the OTCs, which can help improve

the health status of our people every day. Therefore, it is also very important for us to continue to present our mature Rx portfolio to healthcare professionals, as well as broadening the visibility of the products we've acquired from the latest acquisition Mylan performed.

Additionally, we will look to integrate Mylan's HIV and biosimilar treatments into the Polish healthcare ecosystem. Regarding biosimilars, we have numerous options we can provide, especially to oncology patients. In-turn, this will drive forward the overriding goal of Mylan: to provide better health and increase access to high quality medicines, so that Poles live healthier lives.

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