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***The Czech Republic is a perfect example of how the generics industry can ensure the sustainability of the healthcare system and reduce costs***

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*Milan Černek, country manager of Mylan in the Czech Republic*

*, provides expert insights into current trends in the Czech Republic's generics and biosimilars markets, describes the affiliate's strategy to continue growing and reinforces the company's commitment to providing high-quality modern treatments.*

**Milan, you have more than 20 years of experience in the generics industry, especially in the CEE region. How has the generics industry changed in the Czech Republic from when you first started to now?**

When generics first entered the market, healthcare professionals and patients questioned their quality and efficacy. However, today, they are well accepted and an essential part of the healthcare system. Market penetration of generics in the Czech Republic is very high – roughly 65 percent in volume – and one of the highest in the CEE region.

The Czech Republic is a perfect example of how the generics industry can ensure the sustainability of the healthcare system and reduce costs. The money saved through generics opens the door to the introduction of innovative therapies. In addition to the reduction in the cost of treatments, generics have allowed more and more patients to benefit from modern therapy. For example, twenty years ago, statins were only prescribed by specialists for a limited number of patients, whereas now they are commonly used by GPs, even for primary prevention of cardiovascular

events. To put it into perspective, the number of patients treated by statins has increased from less than 100,000 two decades ago to about 1.4 million patients today.

As one of the key players in the market, we strive to maintain a healthy, sustainable and stable healthcare system. Mylan's mission is to increase patient access to high-quality modern therapies.

**Could you introduce the footprint of Mylan in the Czech Republic?**

Mylan's affiliate in the Czech Republic posted sales of two billion CZK (approximately EUR 80 million) a year based on publicly available data, IMS data Dec 2019. We offer a robust portfolio of more than 140 products in the market, including generics, branded products, biosimilars, vaccines and over-the-counter (OTC) medicines. Our diverse portfolio gives us an opportunity to address many needs in the healthcare system. We also bring forward innovative therapies to improve the quality of life of patients.

Our generics portfolio spans many therapeutic areas: cardiology, neurology, pulmonology, dermatology and more. Furthermore, among our innovative treatments, we launched Dymista in 2017 for patients suffering from seasonal allergies.

Mylan also works with authorities and other companies to increase flu vaccination coverage in the country. The flu vaccination rate in the Czech Republic is still low relative to other EU members. As a result, in the flu season of 2018-2019, a total of 996,000 people in the Czech Republic sought out a general practitioner for acute respiratory infection and flu. Of these, 625 had to be hospitalized under intensive care and 195 died. Today, one out of three people are vaccinated for the flu with our product. Saving the life of a single patient makes Mylan's work worth it.

As for our OTC drugs, we provide Brufen, a very popular ibuprofen, and Allergodil, a nasal spray to relieve the symptoms of allergic reactions. In the previous year, we have launched Endwarts for the treatment of warts.

Finally, we entered the biosimilars market at the end of 2018 with the launch of adalimumab for patients suffering from autoimmune diseases under the name Hulio. Adalimumab is the biggest biologic molecule in the Czech market with one billion CZK (EUR 40 million) in sales; by using biosimilars instead of the reference product, the Czech healthcare system creates everyday savings of at least 50%. Adalimumab is used for the treatment of certain immune-related diseases like rheumatic arthritis, Crohn's disease and psoriasis. More recently, we launched trastuzumab, a biosimilar to Roche's blockbuster anticancer drug Herceptin, under the name Ogivri – very

important in the treatment of breast cancer in women. Overall, biosimilars are a game-changer for healthcare sustainability, as we have the potential to improve the treatment of patients, reduce hospitalization rates and avoid disease complications in a more cost-effective way.

**What is your assessment of the biosimilars landscape in the Czech Republic now and in the future?**

While the Czech Republic may not be the biggest market for biosimilars, the perception of biosimilars is very positive, and I believe the country is setting the trend in the region. While in other markets there are ongoing debates regarding their quality, safety and efficacy, key opinion leaders and specialists in the Czech Republic recognize the value of biosimilars.

Market penetration of certain biosimilars, like infliximab and filgrastim, is high. Nonetheless, many areas remain unknown. We are now discussing with key stakeholders and the authorities about the possibility of developing incentives to promote faster uptake of biosimilars.

The lower prices due to biosimilars may also increase patient access to these medications – for example, we see that adalimumab use has grown by ten percent while the cost has dropped by 50 or 60 percent. Overall this means the healthcare system is achieving the benefits of significant cost savings while more patients have access to these medications, but not in full yet. We need to increase awareness and shape the legislation to promote the value of biosimilars to the key stakeholders administrating them.

Furthermore, market statistics show that the treatment of patients can start much earlier. For example In the case of idiopathic intestinal inflammations – Crohn’s disease and ulcerative colitis., patients started often treated biologic products eight years after diagnosis when they reach very serious stages, even though biosimilars entry allow the treatment to start three years after diagnosis./ nearly three times sooner!

Finally, biosimilars will bring savings to the healthcare system which can then be used to bring new innovative treatments.

**When we met with Jacek Glinka, at that point President of Mylan Europe, he said that “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.” In your opinion, what should be done to create a more sustainable environment in the country?**

I fully agree with this message. We need to strive for a sustainable healthcare system that benefits patients and the community as a whole. This is one of our key priorities.

Blindly cutting down prices is not the solution for a sustainable and stable system, as low prices will push many companies out of the country. In extreme situations, where very few companies remain in the market, the country may suffer from drug shortages. According to analyses of the Czech Association of Pharmaceutical Companies (CAFF), where Mylan sits in the board, the country needs at least four suppliers of the same active substance to guarantee product availability and meet patient demand. We may also see a lower investment in education.

Biosimilars are a case in point. A decrease in the price of biosimilars does not mean more patients will suddenly be treated. We need to find a balance between savings and the number of treated patients. Here, we can leverage our experience from the past, when generic statins first entered the cardiovascular segment. While total costs rose, the increase in the number of patients treated with the modern therapy resulted in a significant reduction in cardiovascular mortality, which ultimately has a beneficial impact on the overall economy and reduces social costs.

**In addition to having one of the lowest prices in Europe due to the reference pricing system, in the Czech Republic, the pharmacy market is consolidating and large pharmacy chains like Dr. Max and BENU have increasing bargaining power. What would you say are the key success factors to operate in this environment?**

In terms of success factors, first, we need a robust and diverse portfolio. Second, we need to remain active and bring new projects to our partners, with the patient’s benefit in mind. In our partnerships, we have to speak about propelling changes in the market and finding solutions that both parties will benefit from. We endeavour to become active partners that bring new ideas and new projects. One of our missions is to become *the* partner of choice. We believe that when our partners are successful, we can better diagnose and treat patients, manage stock levels and bring savings to the healthcare system.

**Regarding shortages, the government has proposed an Amendment to the Act on Pharmaceuticals and the Act on Public Health Insurance to tackle the issue. How will**

**this amendment affect your operations?**

This amendment draws inspiration from changes implemented in Slovakia (emergency system), so we can leverage our experience there to adapt to the market impact in the Czech Republic.

The main goal of the amendment is to improve the availability of medicines by restricting the export of medicines intended for Czech patients. However, parallel exports are only part of the problem. As you might be already aware, shortages have many roots – being linked to pricing, consolidation in the retail pharmacy sector, or production issues.

Another proposed change is the introduction of the so-called emergency system of supplying pharmacies. If a pharmacy cannot find a product at the wholesale level, they can directly contact the marketing authorization holder (MAH), who has the obligation to provide the product within 48 hours, which means additional stocks and costs for manufacturers.

Overall, we believe this is a good step forward to improve the availability of drugs for Czech patients.

**As a new year and decade begin, what are your ambitions for Mylan in the Czech Republic?**

Our ambition is to increase patient access to high-quality modern therapies. At the same time, we want to consolidate Mylan’s position as one of the key players in the market `. We also want to remain the preferred partner of choice for healthcare professionals, distributors and authorities.

In addition, we still see great potential in the field of flu vaccination, as we prepare for the next wave of seasonal vaccines. We would like to change the market to favour patients and ultimately, increase flu vaccination coverage.

In 2019, we launched ten products in the market, and we want to do the same in 2020 as new products represent a significant part of our total revenue.

Our priority moving forward is our biosimilars segment, for which we still have a relatively small percentage of the market share. Mylan has a strong pipeline of biosimilars – we have 20 products in the market and in the pipeline, so this area will continue to be a strong focus for us locally.

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