Jasmien Coenen – Managing Director, Medaxes

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Medaxes - the Belgian industry association for companies producing generic and biosimilar medicines, as well as other off-patent medicines and self-care products - welcomed a new CEO in 2022, Jasmien Coenen. Here, Coenen describes how the growing awareness of generics and biosimilars in Belgium is not yet translating into a rise in prescriptions; a situation which she feels threatens the healthcare system's sustainability. She also speaks candidly about the limitations of a localised manufacturing push in Europe post-COVID and rebuffs some of the innovative industry's harshest criticisms of new EU pharma legislation

Please begin by taking a moment to introduce Medaxes and the goals of the organization in relation to Belgium's pharmaceutical landscape.

Medaxes is an organization representing 15 member companies, primarily involved in the off-patent industry. Initially focused on generic medicines, our scope has expanded to include biosimilars as well. With the evolution of the industry, we now see a broader portfolio, as generic companies engage in merger and acquisition strategies, acquiring parts of the portfolio from originator brands.

While most of our member companies operate in the off-patent arena, we also have companies with innovative medicines in their portfolios. This indicates a changing landscape. However, the common ground for all our members is ensuring access to affordable and quality medicines. This is the core focus of Medaxes. With the increasing diversity in the industry, our member companies are well-equipped to guarantee accessibility and prioritize baseline care.

Medaxes holds a significant market share in the area of baseline care within the Belgian market. Our members cover over 70 percent of the volume of medicines while accounting for only 25 percent of the cost to the health system. Our member companies provide a cost-effective solution for medical needs, emphasizing the importance of balancing the innovative industry with affordable baseline care.

How effective are these arguments in your discussions with the authorities and where does the off-patent market stand in Belgium today?

In terms of market share, we are witnessing the growing importance of our sector, and there is an increasing awareness of the importance of the off-patent industry in Belgium. However, this does not translate into an increased prescription of generics and biosimilar medicines within the country. Currently, the prescription market share for generic medications is dominated by originator brands, and the situation is even worse for biosimilars, with very low market penetration compared to other European countries. Belgium is not an attractive marketplace for biosimilars, and there is no incentive for biosimilar companies to enter the Belgian market unless the originator brand has disappeared. While policymakers acknowledge these challenges and demonstrate a willingness to address them, there is still a long way to go in making the Belgian market more competitive for our member companies in the off-patent segment.

At Medaxes, we have been successful in conveying our message to various stakeholders. Our advocacy efforts have focused on two key aspects: highlighting the importance of our sector in generating savings and emphasizing the need for a competitive marketplace. Historically, there have been hurdles created for a competitive marketplace, and our goal has been to raise awareness about the value of competition in generating savings. We believe that savings should come from competition rather than relying on the introduction of one biosimilar that lowers the price of the originator brand. We emphasize that our sector is responsible for supplying medicines to a significant portion of the population, approximately 80 percent, through the off-patent sector. While innovation is important, especially for niche markets and unmet medical needs, relying solely on innovation without considering the importance of baseline care is not a sustainable approach. It is essential to create awareness that the off-patent sector plays a crucial role in providing access to basic medicines, particularly as the population grows and ages. In Belgium, there has been a focus on paying for everything within a closed budget envelope, neglecting the role of off-patent drugs in supporting the cost of innovation. We need to emphasize that a competitive and sustainable marketplace requires adequate pricing for essential medicines. Our primary objective is to raise awareness of our sector's significance and the need for its survival to ensure the continued supply of medicines.

Our association's main focus is to shift the narrative and emphasize the importance of future-proofing the off-patent sector. While we recognize the importance of innovation, we also highlight the potential consequences of solely focusing on innovation at the expense of access to basic medicines. This is the message we aim to convey to everyone. Fortunately, we see initiatives emerging that align with our perspective. The recent royal decree on tendering in hospitals, for example, reflects a desire for a competitive marketplace and acknowledges the need for competition to ensure sustainability. We are pleased that our message is being understood, but still, major improvements can be made to render the market sustainable and competitive for generic and biosimilar medicines.

In your opinion, what have been the impacts of COVID on these conversations among pharmaceutical and healthcare stakeholders especially given the medicine shortages which occurred during this time?

Looking back, I believe that the conversations among pharmaceutical and healthcare stakeholders have been influenced by the COVID-19 crisis. The government, being responsible for supply during the pandemic, experienced firsthand the challenges and difficulties in securing medicines. They

realized the importance of addressing supply issues and recognized that pricing was often a significant factor contributing to shortages. This shift in perspective by the Medicines Agency, which previously considered pricing outside its jurisdiction, was a significant development. The COVID-19 crisis highlighted the accomplishment of companies in supplying hospitals with essential medications at the very low prices prevalent in Belgium. It brought awareness to the critical role played by the off-patent sector in ensuring baseline medication availability. While I don't view COVID-19 as a positive event overall, it did serve as a catalyst for initiating these important discussions.

However, it's important to note that the repercussions of the COVID-19 crisis have also posed challenges. The pandemic has affected industries at various levels, leading to increased resource costs. As a generic industry, we are unable to incorporate these price increases into our pricing structure, which exacerbates the problem. Medaxes has been successful in creating awareness and advocating for legislative changes that allow for price corrections to account for rising costs. The mindset has shifted towards recognizing the need to correct prices, but the urgency to address this issue has become more pronounced due to the impact of COVID-19.

Additionally, the government's experience during the pandemic has provided a broader understanding of the entire value chain within the therapeutics and medicines sector. They have recognized the importance of the relationship between physicians and patients, which has always been a focal point in healthcare policies. Furthermore, COVID-19 shed light on the challenges faced by the industry, including supply chain issues and the accessibility of pharmacists. As a result, policymakers now have a more comprehensive understanding of the entire value chain and recognize the value and contributions of each stakeholder involved. This awareness is crucial for shaping future policies and decision-making processes.

Although there are practical limitations of manufacturing all the medicines that a country needs within its own borders, do you believe there should be increased efforts to relocate some manufacturing closer to home or reduce supply chain lengths, even if not necessarily in Belgium?

It is true that not every country can manufacture all the medicines it needs within its borders. It is not feasible from a practical standpoint. Our member companies would agree with this assessment. While it may not be necessary for all manufacturing to take place in Belgium or Europe exclusively, it is important to have a risk mitigation plan that diversifies the supply chain and reduces

dependency on other countries.

The reason why the generic industry primarily manufactures in certain regions is that it has been the only viable option to supply medicines at a price that governments are willing to pay in Europe. Companies do not have an inherent ambition to manufacture solely in distant locations. It ultimately comes down to the willingness to pay and the value placed on the products.

Local production is certainly beneficial, and it is essential to consider the societal choices involved. If there is a desire to keep industry and manufacturing within the country, there needs to be a willingness to pay the prices that align with a sustainable model in Belgium. It is important to recognize that blaming companies for sourcing from China, for example, overlooks the fact that they are supplying medicines at low prices as per the requirements. It is a complex issue that requires a balance between societal expectations, investment choices, and government responsibility.

At Medaxes, we contribute to raising awareness of these issues. We advocate for Belgium’s need to have a reliable supply of medicines. However, it is also important to convey to the government that if they want to ensure supply, they must be willing to pay for it. We strive to provide medicines at the most cost-effective prices within our business model, but it is crucial to sell them at a profit, even if it is a low-profit margin.

The EU Commission has recently launched a new Pharma Strategy and many innovative companies have criticized the proposal to reduce the IP for innovative medicines to 8 years from 10. What do you see as the possible impacts of this regulation in Belgium?

The possible impact of reducing the IP protection for innovative medicines from 10 to 8 years in Belgium could be positive for the generic and biosimilar medicine companies. It would enable them to have quicker market access without hurdles such as backup patent linkage. Additionally, increased transparency about managed entry agreements would provide more clarity for the off-patent sector, allowing them to calculate a value business case and improve access to the market. These initiatives align with the Belgian health roadmap and are expected to facilitate easier and faster access to generics and biosimilars, which is positive for our industry.

Can you empathize with the concerns expressed by innovator companies regarding this issue?

We understand the concerns raised by innovator companies regarding the reduction of IP protection for innovative medicines. They argue that it may hinder innovation and result in less access to new treatments.

While we recognize the importance of innovation for the pharmaceutical landscape and the need to address unmet medical needs, we advocate for a fair and equal level playing field for both innovator companies and generic/biosimilar medicine companies. We believe in a balanced approach that does not create an unequal situation between these sectors.

Medaxes acknowledges the importance of protecting intellectual property to incentivize innovation. However, we are critical of the abusive use of patents that hinders accessibility and competition. Hurdles that impede market access should be removed to the benefit of a sustainable and competitive marketplace.

In our opinion, claims that reducing IP protection may lead to less access to innovation, do not hold water. Innovator companies will still have the opportunity to protect their intellectual property.

Do you have a closing statement you would like to deliver on behalf of Medaxes and its members regarding what comes next for the Belgian’s off-patent and generic industry segment?

In closing, Medaxes and its members are committed to safeguarding baseline care and ensuring the availability of affordable medicines. We believe there is a need for a societal debate on the willingness to pay for healthcare, including medicines. It is crucial to raise awareness that baseline care should not be taken for granted and that investment in our quality of life is essential.

We urge stakeholders to see the off-patent industry as more than just a cheaper alternative. We promote healthy competition, which benefits price dynamics and fosters various forms of innovation beyond new molecules. Incremental innovations in dosage and other areas within the off-patent and generic sectors can contribute to cost-effective and high-quality medicines.

Medaxes and its members stand ready to contribute to the ongoing dialogue and collaborate with all stakeholders to ensure a sustainable and competitive marketplace that prioritizes patient access and the delivery of affordable healthcare solutions.

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