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Between the ageing population and the cost of innovation which will continue to rise, the burden being put on healthcare will only become heavier

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Joris Van Assche, managing director of the Belgian association for accessible medicines, Medaxes, highlights the need for a stronger policy to create a more positive environment for generic and biosimilar medicines. He also outlines the important role the off-patent sector plays in the long-term sustainability of Belgium's universal healthcare system.

According to IQVIA, generics accounted for only 17 percent of drugs sold in pharmacies and five percent in hospitals by value in 2018. What factors that have resulted in such a low market penetration in the country?

Apart from the mechanics of the healthcare system, we should also take into account the significant footprint of the originator industry here in Belgium. There is a strong contribution of investments from these companies, for example through job creation, which has been translated to the attitudes of policymakers in some way. Even in the off-patented segment, there was a desire to create a very favourable environment for the brands.

The system, of course, needs generics and biosimilars to create competition and lower prices, but we are instrumentalized for the purpose of lowering costs and nothing more. Since we are seen as a lever of triggering competition rather than a permanent driver of cost efficiency in healthcare, this translates to the system, which is designed in favour of the originators, allowing them to have

majority control of the market.

I will admit that this attitude has both positive and negative consequences. On one hand, it has prevented authorities in the past years to have an off-patent policy that made the same mistakes as in the Netherlands which has a pharmaceutical ‘preference policy’ and aggressive tendering system resulting in instability and shortages. However, the negative impact on our segment is the very low uptake of generic and biosimilar medicines which is unhealthy, and in the long run, detrimental to the cost efficiency of the entire system. If we want a sustainable healthcare system in the future, the Belgian policymakers should definitely take greater advantage of the opportunities offered by generic and biosimilar medicines.

Have there been any other policies put into place within the past five years or so to help support generic manufacturers in Belgium?

When the Minister of Health Maggie De Block entered the position in 2015, a stability pact with the pharmaceutical industry was signed, which included a budget trajectory. This trajectory was based on the assumption that generic and biosimilar medicines would be able to create the necessary budgetary headroom for innovation. However, after several months, there was a realization that the cost of innovation was going much higher than anticipated when the document was originally signed. In response to cover this cost of innovation, we have seen on the one hand an unprecedented rise in the use of Managed Entry Agreements (MEAs) for in patent medicines whilst on the other hand, the off-patent segment has been the subject of permanent price erosion, which was not compensated by a higher uptake of generic and biosimilar medicines. Moreover, in Belgium generics and biosimilar medicines pay clawback taxes at a level that you do not see elsewhere in Europe. The sustainability of this system is coming to its end and we will absolutely need a reset with the new government.

What role can generics play in managing costs and creating sustainable healthcare models, all while maintaining the country’s high level of access to innovation?

Between the ageing population and the cost of innovation which will continue to rise, the burden being put on healthcare will only become heavier. Yes, the generic and biosimilar segment will continue to relieve some pressure, and much more can be done, but it will be impossible to create all the headroom necessary for innovation. This is not only the case for Medaxes and Belgium but a

paradigm shift globally. Especially in countries like Belgium with generous healthcare systems that try to cover all costs, the system cannot bear it anymore. We need to explore new approaches, for instance by rewarding Belgian patients and their healthcare professionals, including the hospitals, for cost-efficient use of medicines.

The business model of our segment is simple; we must have a sustainable environment that has the right equilibrium between price and volume. The higher volume generic products have the lower their price can be. However, we are currently facing too many barriers for a more flexible pricing policy as well as a very low volume.

What opportunities do you see then for improving generic penetration in the market?

What we first must focus on is pricing. Belgium is one of the rare EU countries where generic and biosimilars drugs are systematically subject to high claw-back taxes and other INAMI taxes, as a way to compensate the cost of innovation, which represent in total more than 11 percent of turnover. In the case of generic drugs, these taxes are a real brake on a dynamic that could directly benefit patients and health insurance. Medaxes estimates that having the tax exemption on generic companies will lower the price of generic medicines by tens of millions of euros.

Speaking on volume, only 59 percent of the drugs currently dispensed in public pharmacies are cheaper drugs. In this segment, it should be possible to globally prescribe up to 75 percent of the cheaper drugs through a system of prescription objectives of cheaper drugs. The current program of prescription targets only refers to cheaper drugs rather than specifying generics. Therefore, there is room for improvement to have higher, more ambitious targets especially in Belgian hospitals where the use of generics is the lowest in Europe.

The new government must create specific regulatory pathways for generics of complex drugs, generics for orphan drugs, generics for drugs which are managed by MEAs, etc. If we create a new Pact for the Future which will support the growth of generics and biosimilars, we will be able to re-invest in reducing prices and creating more competition within the market.

How would you asses the current biosimilar landscape in Belgium, and how does it compare to other sophisticated EU markets?

Like generics, the uptake of biosimilars is very slow and there is a lot of hesitation from the policymakers. The conditions of this segment in Belgium are quite alarming and there have even been three biosimilar molecules that manufacturers have decided not to introduce to the market. Of course, many factors go into consideration when examining in which market to launch products, but the fact that Belgium is not even being considered in these cases is a major red flag indicating the local conditions.

A special task force has been created to work more closely with biosimilars, presided over by INAMI. The deliverable of this task force is to draft a report with concrete proposals that will help drive the uptake of biosimilars. This is a positive indicator that the health authorities are realizing the need for action in this segment.

The biopharmaceutical forum does not focus on creating impactful local policies for pricing and reimbursement but rather in foster the overall Belgian positioning for investments such as clinical trials., Medaxes so far has not participated in the meetings of this forum, but we are definitely ready to reach out if ever the uptake of biosimilars in Belgium is on their agenda.

In terms of the incentives that were implemented, we have seen an increased uptake for anti-TNF molecules but going slowly. Belgium is still much farther behind some of our EU peers in this area. I do not high hope that these outcomes will improve with time alone, therefore, we have to ask the question of whether the incentives are attractive enough or if the system should be radically reviewed all together.

How are biosimilars viewed among Belgian stakeholders – authorities, physicians, patients?

There is absolutely still an information gap about biosimilars among healthcare professionals and patients. One initiative Medaxes is advocating for is to set up a biosimilar champion of sorts. This would entail developing a specific program for each biosimilar that enters to market to inform healthcare stakeholders about the molecules. Additionally, specific incentive programs and targeted would be set for each product.

Biosimilars are biological medicines, therefore we cannot rely on a one-size-fits-all solution to promotion. These are complex therapies that cannot be treated the same way as a standard generic, they are unique and require a specialized approach.

What recommendations can you offer health authorities to cultivate a more desirable biosimilar ecosystem in Belgium?

Biosimilars have been on the market for over ten years, and as the conditions are today, it is quite a dramatic situation. To put it plainly, the market is not functioning well and there is a major need for intervention. Therefore, there must be positive uptake measures introduced specifically for biosimilars, exclusive to even originator products that have lowered their price to the same level. This will be the key point in creating a favorable landscape., Hence, we should also look at solutions to further enhance conditions such as prescription quotas or financial incentives for hospitals.

We already see that some biosimilars are not coming to the Belgian market. If the dynamics continue, the way they have been, I have a deep concern that companies will even begin to disinvest in Belgium. It is time to act and we must close the information gap, establish specific biosimilar policies, and improve the hospital tendering system. Currently, tenders are not sufficiently open to biosimilars when they enter the market. There should be clear legislation stating that when these products enter the market tenders should be open in addition to providing more guidance in the way tenders are designed so that biosimilars can compete with originators on equal footing.

What goals are you hoping to achieve within the upcoming five years as managing director of Medaxes?

Achieving a sustainable equilibrium between price and volume so that we can create the best-added value system of the Belgian market. This should translate into a higher uptake of both generic and biosimilar medicines. I truly believe this will be to the benefit of the entire healthcare system as it will bring greater dynamism to the pharmaceutical market.

Is there any final message you would like to deliver on behalf of the association and its members?

The future lies in a collaborative approach to healthcare. Both the challenges and opportunities are so significant when it comes to access to healthcare. All stakeholders, especially in the industry, have a real societal responsibility to be partners and deliver the best access possible to Belgian patients. Like in the Medaxes mission, we must create the best possible healthcare for as many

patients as possible.

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