

Marc Gryseels â?? Managing Director, BACHI



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Marc Gryseels of BACHI, Belgiumâ??s over-the-counter (OTC) medicines association, highlights the organisationâ??s mission and vision, the key trends at play within the Belgian consumer healthcare market, and his industryâ??s significant role within Europe.

Why is it necessary to have an OTC medicines association in Belgium given the relatively small size of the market?

Having an OTC medicines association in Belgium is necessary for several reasons. The first is that the association provides a way to reach out to consumers. Even if consumers donâ??t necessarily recognize that they are using an OTC product, it is important to understand the consumerâ??s perspective. In Belgium, one out of every two boxes sold in a dispensary is an OTC product. This highlights the importance of the OTC market in terms of contact with consumers and healthcare providers. In addition, there are extensive regulations in Belgium for OTC products, which means that lobbying is needed to influence regulation in a positive way. This can include informing and educating consumers, as well as finding the best solution to meet their needs. Ultimately, the association represents both the needs of the consumer and the industry and seeks to inform and influence politicians who make decisions about regulations.

What are the top items on your agenda for the association today and how has the COVID-19 pandemic influenced them?

COVID had a significant impact on BACHI's agenda as well as the way we communicate, market dynamics, and consumer habits more broadly. With Belgium being a highly regulated market, the association has many priorities starting with over-regulated areas with drug and food supplement labeling and claims, which require careful translation and interpretation to comply with local laws. Another priority is the freedom of pricing for OTC products. It is important to note that Belgium is one of the last countries in Europe where OTC prices cannot be altered, meaning that any change in price during the lifecycle of a product requires approval from the Federal Public Service (FPS) Economy.

The association also needs to lobby for balanced relationships with the authorities to ensure that the needs of both the industry and consumers are met. As an independent association without any products or vested interests, BACHI can represent the market segment fairly in discussions and negotiations with the authorities.

Have you witnessed any changes in the high level of regulation that characterizes the Belgian OTC market?

There have been some positive changes to the heavily regulated nature of the Belgian OTC market, including the industry being accepted as a representative in various commissions for discussions. Nevertheless those consultations are not always evolving at the desired speed, effectively changing regulations in Belgium is a lengthy process which poses significant challenges.

In general, while there have been some changes and gradual movements towards less regulation in the Belgian OTC industry, it is still heavily regulated and changing legislation is a slow process due to the political system and culture embedded in our country. Belgium possesses a complex system with deeply embedded habits and difficult political decision-making processes. Unlike other countries, like France, where decisions can be implemented more quickly, in Belgium, compromises need to be made on everything to achieve changes in legislation. This can make it challenging to achieve change, especially if some stakeholders are generally happy with the current situation and do not want to see it changed. Therefore, BACHI must work hard to generate awareness for changes that are beneficial to the OTC industry and consumers, even if it may take time to see their impact.

How has the Belgian OTC market been performing in recent years?

The OTC market in Belgium has had its ups and downs in recent years. Due to the COVID pandemic, there was a decrease in sales in areas such as cough and cold, and gastric problems. However, pain relief products were still in demand during the pandemic. We lost a predominant streamline of revenues in some areas but had some increases in others areas like vitamins. Overall, our members performed well in 2021 and 2022 and the market currently has an overall value of around EUR 1.5 billion, as well as a relatively large market size per capita.

However, it's important to consider the cultural context when evaluating the Belgian OTC market. In Belgium, it is common to go to the doctor when you are sick and get a prescription for treatment, because our primary care network and access to doctors is rather high. This is ingrained in our culture, and people have the habit of seeking treatment when they are ill. This is different from other countries like the Netherlands, where people can simply inform their boss that they are ill without

needing to see a doctor. The culture of a country plays a significant role in shaping the OTC market.

The doctors and pharmacists play a crucial role in the initiation of a treatment for self-care products, including medicines and medical devices, as well as food supplements. The healthcare system in Belgium is quite secure, with a strong primary care system and people have trust in their pharmacist and general practitioners. The advice of healthcare professionals, including pharmacists, is highly valued by consumers, and the initiation of treatment is mostly done thanks to a doctor's prescription or the advice of a pharmacist. Therefore, I do not see this infrastructure being susceptible to any significant changes in the future, as it is deeply ingrained in the culture and healthcare system of the country.

What are the major roadblocks within Belgium's OTC system?

The main challenges in Belgium's OTC system are the lack of European harmonization in regulations and the fact that consumers have access to information through the internet. Regulation and health claims may differ across European countries, which can lead to unfair competition. For example, the use of the word "probiotic" is forbidden in Belgium but authorized in some specific products at the European level. So, if you're looking for products that have these properties online you will be taken to websites from countries like France and the Netherlands. Therefore, there is unfair competition where Belgian retailers are not having the opportunity to capture consumers.

Additionally, there is an urgent need for European harmonization around communication, claims, prices, and distribution. E-commerce regulations in Belgium require that the owners of these business be licensed pharmacists. However, this is not the same for all countries in or around Europe. If some consumers in Belgium do not realize this, then they can be purchasing low quality products or products with false claims from ecommerce businesses internationally without even knowing it.

For patients accessing medicines and OTC products, Belgium counts on an incredible network of pharmacists. Is there an opportunity for industry consolidation?

The 4,800 pharmacies in Belgium represents a dense network that ensures easy and quick access to healthcare products for consumers, which is a crucial aspect of the system. This stands in contrast to the situation in the Netherlands, where there are around 2,200 pharmacies, and some areas may have a significant distance between them, leading to lower accessibility for consumers.

However, despite the high number of pharmacies in Belgium, the government has recently passed legislation to increase accessibility for consumers concerning medical devices. The new regulations have allowed for medical devices to be sold in places other than pharmacies, such as supermarkets, similar to the situation in the Netherlands.

Despite the convenience of being able to purchase healthcare products (non-drugs) anywhere, the advice provided by pharmacists is still a crucial aspect of the system. For pharmacists to provide good advice to their patients, they need to know their patients well. This includes understanding what medications and supplements they are taking, as well as any potential interactions or health concerns. Therefore, purchasing healthcare products from a variety of sources can potentially lead to a lack of understanding of a patient's full health profile, which can have negative consequences.

What impact can, and is, digitalization having on the relationship between pharmacists and patients in Belgium?

Digitalization can have both positive and negative impacts. On the positive side, digitalization can provide access to digital health support and internet sales, which can help grow the pharmacy industry and improve access to healthcare products. However, it's important to ensure that the quality of advice and information provided to patients remains high, as this is crucial to ensuring patient safety and compliance with treatment. The current system in Belgium is reliable, with access to healthcare products mainly through pharmacies and prescriptions, but there is room for improvement in terms of facilitating consumer access while maintaining high quality advice and information.

Overall, I consider the most important question to ask regarding digitalization is whether it helps to improve the quality of the service and advice that patients receive.

Are there any focal points that need to be addressed in Belgium regarding the OTC medicines market?

Firstly, one of the major focal points is price. I believe it is high time for Belgium to have price freedom in the OTC medicine market. The current process of getting approval for prices from the commission is time-consuming and does not add much value, as we are already competing with other countries. We need to find a way to average out the prices, rather than maintain regulated prices.

Another opportunity is to transition some of the currently reimbursed products to OTC medicines. We need to reconsider which products should be reimbursed and which ones should require a prescription. Our focus should be on the process of switching products from prescription to OTC, which currently has a negative connotation. We need to improve this process by changing indications, not ingredients, so that we do not disrupt the balance between products in the market. If we can identify a pathology that allows for self-medication and products that are safe enough for OTC sale, then we should switch it from prescription to OTC. We should not continue to reimburse basic self-care treatments, which can be costly. Changing indications to OTC will allow everyone to access the products and help improve self-care, while also freeing up funds for new drugs. We could when necessary maintain a negative list of products that should remain on prescription due to safety concerns within that indication.

I believe the role of pharmacists should increase in the future, and not decrease as it is happening in some other European countries. This is because most of the side effects of products are not coming from the drugs themselves, but from combinations of products and overdosage or misuse. Hence, proper use of drugs is important, and pharmacists can play a crucial role in educating the consumers on the right dosage and proper usage of drugs.

In addition to the pricing and cost issues, we also need to address the harmonization of dosage across Europe. Currently, there are two types of harmonization that are important for us: amortization of dosage and upper-level dosage. Europe is currently working on the upper-level dosage, which will determine the maximum and minimum dosages of an ingredient to have medical claims. However, this process has been ongoing for close to 20 years, and we still don't have harmonization of dosage across Europe today. This is a problem for companies because they must produce products with different dosages for each country. This process is not efficient and can be

expensive for smaller countries. We need to harmonize dosage across Europe so that companies can produce products more efficiently and cost-effectively, regardless of the country they are selling in so that all countries can have a fair pricing scheme.

Given the agenda points you have highlighted, what do you see as the momentum for some of these opportunities to be realized?

It's important to keep in mind that some of these changes require collaboration and agreement at both the national and European levels. While progress is being made, it's a slow process that takes time and involves many different factors such as regulations, culture, and mentality. For example, the issue of shortages during COVID has been acknowledged by all European countries and the need to produce more active ingredients and final goods within Europe has been identified. However very little has been actually done to bolster API manufacturing so far. It takes time for companies to re-address their production processes and for agreements to be reached on a European level. Ultimately, while I wish the process could be faster, I understand that these changes require careful consideration and execution.

Do you have any final message you would like to offer on behalf of BACHI?

As we approach the next government elections in Belgium (2024), it is an important time to address a political message. Belgium will also take on the presidency of the Council of the EU in the first six months of 2024, so there is an opportunity to share our perspectives and priorities on a larger stage.

In terms of the pharmaceutical industry, there are a lot of ongoing issues that may not be well-understood by the general public or politicians. For example, pricing is a topic that is frequently discussed, but it is important to remind people that the cost of medications is not just about profits for the industry. Our products deliver high-quality, life-saving treatments, and we have rigorous safety systems in place to ensure that they are safe and effective for years to come. It is also important to emphasize the need for European production of active ingredients and final goods, as this can increase supply chain resilience and reduce the risk of shortages.

Overall, I believe that the pharmaceutical industry has a crucial role to play in improving public health and driving innovation. However, it is important that our priorities and challenges are well-understood by policymakers and the public, so that we can continue to deliver safe, effective treatments for patients in Belgium and beyond.

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