Filip Van de Vliet – CEO & Gérard Lefèbvre – Country Head PI Pharmacy Sales & Operations Director, Alter Pharma, Belgium



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Filip Van de Vliet and Gérard Lefèbvre of Alter Pharma Group discuss the value that parallel importing is bringing to Belgian patients and the evolving relationship between parallel importers and the wider pharma industry. They also offer insights into Alter Pharma's planned launch of generic medicines in the US market and their strategy for success.

Can you briefly introduce Alter Pharma and its purpose?

Alter Pharma's purpose is a very simple one – making affordable medicines available. In the Alter Pharma Group, we have two businesses. The first is our parallel import (PI) business, which sources products from Europe, and repacks and sells them in Belgium. The second business is a more international business in which we develop, supply, and distribute generic medicines for patients all over the world.

Our turnover is close to EUR 100 million. Just over half of that total stems from our PI business, which is reinvested entirely in our generic developments. From the generics side, we are a truly virtual company, working together with partners in manufacturing, out-licensing, and distribution.

We have a number of large names in our generics portfolio, where we partner with some big names in the industry who bring the generic products to the market under their generic brand. Consequently, while our name recognition may be lower with patients, it remains high within the industry, mainly under our well-recognised trade name *Neogen*¸ but we are planning to also launch generic products under our own brand in specific areas.

In addition to our headquarters in Belgium, we have a large presence in Ireland and the USA, the latter being a key target market for Alter Pharma's generic business.

How does Alter Pharma's parallel import business create value for the industry?

It is a fact that nowadays, there are a substantial number of drugs unavailable in Belgium, but readily available in other European countries. Through parallel imports, we are able to safely repackage and make these medicines available to Belgian patients. This also adds convenience to pharmacists who are less frequently required to identify and source an alternative to an unavailable product, which they often don't manage to find. Thanks to parallel import, we enable the pharmacists to focus on their key function, advising patients, and patients can continue the treatment they are familiar with. Those are the first two value creators, on which we have been collaborating with the Belgian Association of Parallel Importers and Exporters (BAPIE) as part of a campaign called *#FillTheGap,* surveying pharmacies to determine the value that parallel imports bring.

The numbers speak for themselves: over a recent period of eight months where the Belgian market was confronted with shortages, as it still is today, we were able to import around 814,000 months of missing treatment. That equals more than 100,000 patients who every month received their monthly dose of medicine, which they would otherwise had lacked. Hence, by our parallel import activities, we live our credo: making affordable medicines available.

Besides that, as a third way to create value, within Belgium, there is often only one provider of medicine with no incentive for the price to deviate. Alter Pharma introduces competitor products into the Belgian market in order to drive prices down and increase availability. If all pharmaceutical companies could meet the requirements of all patients in each European country and at a similar standard, there would likely be little room in the market for parallel imports. However, that is not the case, so the need for competition is real.

A recent success story and a perfect example of our value creation for the industry but also for society, in general, is the Paracetamol IV initiative we took during the COVID-19 crisis. We have leveraged both aspects of our business to fill the gap. Through our parallel import supply chain, we were able to bring a large volume of our generic paracetamol IV (intravenous use), destined for a foreign market, into Belgium with assistance from the health authorities. As one of the products used in the fight against COVID-19, hospitals were facing a shortage. Thanks to our operational excellence in our supply chain, conceived to quickly move products across the EU under strict compliance standards, we were able to bring the product at very short notice. Within one week, we made 36,000 vials of paracetamol IV available for Belgian hospital use. This was delivered for free as part of our contribution to society.

How has the relationship between parallel importers and the industry evolved?

In general, we have limited disputes with the industry. Nonetheless, a small number of companies still attempt to control the market and prevent the increased competition which parallel imports create, usually through legal obstacles. However, we are strictly utilising the free movement of goods and trademark legislation across the European Union. Moreover, parallel imports can often indirectly benefit the supply chains of other countries, increasing access to smaller markets, such as Belgium. In this regard, we are able to rebalance the supply from other countries across Europe.

One of the challenges that we encounter every year is working within the finite resources of the healthcare budget. Belgium is a small country and becomes less and less attractive for the big pharma players who are optimising their manufacturing and supply chains. One of the main challenges we must overcome is the constant lowering in price of off-patent drugs, which rather than making them more affordable and accessible, has made them often unavailable: through reducing the prices of the old drugs to the benefit of newer drugs for which the government closes secret price deals, fewer become available annually and thus there are a larger number of gaps that arise. Moreover, such shortage leads the patient to the more expensive new drugs, dramatically increasing the healthcare budget. Consequently, some of our problems are self-created in Belgium through counterproductive policy.

Given the stiff competition and difficulties in gaining a foothold within the US generics market, why is this the time to take the risk and enter the US market?

Indeed, competition and entrance hurdles make that the US market is challenging. Over the past 4-5 years, the number of abbreviated new drug applications (ANDAs) in the US has doubled and the quantity of generic products and players in the market has dramatically increased. This is not only true in the US but is a worldwide phenomenon.

Alter Pharma anticipated and has been investing heavily in lining up products for the US market. We are planning our first successful launches in 2020.

In order to be successful in the generics business anywhere, one must be successful in every facet of the business, from the selection of the product, to development at the right pace with the right manufacturers. There must also be commercial partners in possession of suitable contacts who can introduce the products to the right customers.

Our aspiration is to be different. We are looking for niche markets that we can target and are examining how best to leverage our unique capabilities into our generic product selection and development. We try to be smart by experimenting with combining drugs and different dosage forms. Our main specialism is in liquid forms and injectables. We are assessing a number of options that would increase the convenience for patients and hospitals. We believe that is our competitive advantage.

How do you foresee the balance between the business divisions in the future?

We have internationalisation projects and a growth path for both generics and PI. We envisage strong revenues from our planned launches in the USA through our generics business. Similarly, on the PI side, we are looking at how we can expand. We see opportunities both inside Belgium and within Europe to strengthen the parallel imports business.

What is the importance of partnerships?

We have a number of key stakeholders. First on the list are the health authorities. We are still very much shaping the PI environment. Thus, the legal framework in use remains outdated and needs to be refreshed. We are advocates of taking guidance from effective ideas of best practice developed outside of Belgium. It is our job to be a partner for the health authorities in order to realise these improvements and look forward to the new regulatory framework, that is being prepared.

Secondly, building mutual understanding with the government is going to be critical, looking ahead. They must understand the value of both the PI business and the generic drug business, and how together we can build a more sustainable approach to the market. The present policy of seeking annual price decreases for older drugs is unsustainable and will further stretch the market.

On the generics side, we bring an ability to act and select successful products quickly, based on years of expertise. We are ambitious, and partnerships are important throughout the value chain. We always look to add something to already existing generic products. We look for partners who can work with us in order to achieve this. Despite the fact that the generics business is under pressure, there are a number of gaps that the industry is leaving behind, which an agile, flexible, and intelligent businesses like Alter Pharma can bridge.

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