Tanguy Schmitz – President, Belgian Association of Parallel Importers & Exporters (BAPIE)

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Tanguy Schmitz, president of the Belgian Association of Parallel Importers & Exporters (BAPIE) outlines some of the recent work that the parallel distribution industry to ensure the supply of medicines across Belgium and Europe during the COVID-19 pandemic, rebuffs some of the negative stereotypes that the industry has garnered, and explains the vital role that BAPIE plays in defending the interests of parallel importers and exporters in Belgium.

The COVID-19 pandemic has affected all aspects of the healthcare value chain, with some EU Member States banning parallel exports of certain “essential” drugs. How are BAPIE’s members adjusting to the current extraordinary times?

As Belgian citizens wanting to provide an active contribution to this extraordinary crisis, our members have offered their purchasing and logistic capacities in reaction to the demands for help of our health authorities.

We have quoted from our pan European network – at purchasing price – for the medications asked for by the hospitals and the Federal Agency for Medicines and Health Products (AFMPS). However, the quantities we were able to provide were limited, as each country was rapidly closing its borders for the common products being sought worldwide.

One success story, however, was the supply of Paracetamol IV. We were informed that this product ranked high on the list of medications in scarcity and was much needed for the COVID patients lying unconscious in hospital beds. We shared this with our parallel importation members and the information escalated at a group level. The Alterpharma group, the owner of both a parallel import business and a generics company, was able to provide a solution as they were manufacturing this product. As a contribution to society, 36,000 doses, primarily destined for foreign markets, were given for free to AFMPS.

Thanks to the cooperation of the parallel import supply chain, conceived to quickly move products across Europe under strict compliance standards, and manufacturing capacity, the group was able to bring the product from abroad to Belgium at very short notice. Within one week, 13 pallets of this medication, were rendered available for hospital use. Other members helped, on-demand, several local actors in the provision of alcohol gel and masks, even though the medical equipment sector is not our members' business.

To what extent does the COVID-19 crisis represent an existential threat to the parallel distribution industry?

If every country closes its borders, this will cause a problem for the parallel distribution industry. However, this is not only a problem for our industry, but for Europe as a whole! Some countries will be in deficit for some medications but in excess for others. No country is self-sufficient in all sectors; every country needs the contribution of its neighbours to "fill the gaps". If there are no trade flows between EU member states, there will be shortages (as well as surpluses) everywhere.

Regarding exports, several countries have put disproportionate restrictions in place after COVID-19 that limit or prohibit the trade of medicines. While controlling the exports of medicines in times of shortage are justified, the criteria for these medicines to be banned from trade should be clear, proportionate and consistent. Export restrictions should respond to actual shortages, when there is no generic or alternative treatment available, and be removed once the problem is solved.

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The EU parallel import market was worth EUR 5.5 billion in 2018, representing 2.9 percent of the total European market. Moreover, a recent Affordable Medicines Europe study showed that the total amount of annual savings from parallel imports in Germany, Sweden, Denmark and Poland totaled EUR 3.2 billion. How is BAPIE attempting to communicate the importance of this field to government and other key stakeholders?

BAPIE takes part, with other stakeholders, in a “shortage group” installed by AFMPS.

Parallel import (PI) sales in Belgium amounted to a modest EUR 60 million in 2018. We could import much more if AFMPS granted us import licenses as comparable countries such as Denmark, Sweden, Germany, and the Netherlands do. We even have applied for licenses of products in shortage, where for two years we got no answer. Almost 60 percent of parallel import sales originate in other high-income countries. The UK, Romania, and Germany are the main sources this year, so it’s clearly a misconception that parallel import is predominantly a flow going from low-income to high-income countries.

The Belgian Parliament recently backed broad restrictions on parallel exports of pharmaceuticals. This law of 7 April 2019 was clearly against the principles of the single market, as it effectively banned parallel exports. This is especially dogmatic for a country, where parallel imports are an important source for the alleviation of shortages. The Belgian Constitutional court has in the meantime decided the law to be unconstitutional with reference to the EU Treaties (Resolution 146/2019 of 17 October 2019) and suspended it.

How would you characterize BAPIE’s relationship with the traditional pharmaceutical industry? Are there attempts being made to restrict the increased competition that parallel trade brings?

Generally, there are limited disputes with the industry. As an example, during the ten years of my governance of Impexeco, on the 200 registrations gained – with polite exchanges with the industry – we had only one legal case that a North American reference laboratory lost in the first instance and on appeal.

However, we have more problems with the administration and the government (potentially as a result of the heavy lobbying by the industry). To name a few: in Belgium, it is much more difficult and time-consuming to get a parallel import license than in other countries. Whereas normally, it should only take roughly about a month to obtain a license, average lead times for getting new

licenses exceeded 200 days in 2019. Moreover, to obtain a price and reimbursement, we face the same and lengthy bureaucratic process. Why do we have to rebuild a whole file for an imported product when the reference product, identical in all aspects, has already received this price and reimbursement? In other countries, a mere notification is enough.

On the legal scene, I already spoke in the previous question of ill-inspired laws banning or threatening parallel exports. We were forced to let them reform by the constitutional court as contrary to the EU law.

On the tax scene, one of the main challenges we must overcome is the constant lowering in price of off-patent reimbursed products, which rather than making them more affordable and accessible, has made them often unavailable (and replaced by new and expensive products benefiting from “secret price deals”).

How do you counter concerns around parallel trade’s impact on the R&D-based industry?

There is no evidence that parallel trade has a negative impact on R&D in Europe. The costs of all parallel imported products are paid to the manufacturer at the price requested in the source market pricing principles, allowing for the recouping of R&D costs, hence every market pays for R&D.

Parallel trade represents only a very small part of the total European pharmaceutical market, accounting for only around three percent of total sales. Whilst innovation in the pharmaceutical industry is vital for the development of new medicines, R&D represents only around 15 percent of the budget of most pharmaceutical manufacturers. Manufacturers have higher expenditure in other areas, such as sales and marketing, where they spend almost twice as much as they spend on R&D. Finally, their margins after R&D, marketing and taxes are still often above 50 percent!

Christoph Stoller of Medicines for Europe explained to us the severe challenge that medicine shortages pose in Europe, with 86 percent of pharmacists having experienced difficulties in sourcing medicines at some point. This is especially true in Belgium, where a substantial number of drugs are unavailable but are readily available in other European countries. **What do you see as the role of parallel trade in addressing this issue?**

The Belgian wholesalers, importers or exporters respect their obligation of public service by not exporting vital medicines in shortage at home. On the contrary, Belgian parallel importers buy medicines in Europe when they are declared by our Agency (AFMPS) to be in shortage locally. From Dec. 18 to Jul.19, the “parallel” industry imported 814,000 monthly treatments that were in shortage in Belgium.

The shortage crisis in Belgium would be much more serious without this constant and silent contribution of parallel importers.

Thanks to parallel importers, 814,000 patients (100,000 per month) were able to be supplied in accordance to their doctor’s prescriptions. Adherence to treatments could be maintained towards the prescribed medication; reinforcing treatment compliance. The industry should be delighted!

For the 4,800 Belgian pharmacists, 814,000 difficult and lengthy searches abroad were avoided.

It is in crisis time, when the Belgian pharmaceutical industry is out of stock, that one notices most the beneficial effect of parallel importation: we offer a ‘second chance’ to provide the missing product! This result could have been much better since it has been achieved with only fifty (50!) medicines on shortage for which an import license was received, while 550 (!) packages were on the official shortage list. So, the achievement of more licences would mean fewer shortages… our Agency (AFMPS) should help us to get quicker registrations. In the Netherlands, Germany, the Nordic countries, and England, the registrations are obtained in a few weeks – by notification. In Belgium, the cumbersome process to obtain an import license often lasts more than a year… reform is urgently needed.

What are the aims and outcomes of BAPIE’s #FillTheGap campaign?

#FillTheGap is a Twitter campaign to illustrate how parallel distribution reduces medicines shortages in Belgium and explain how it works. Over the last few years, medicine shortages have become a disturbing trend both in Belgium and in Europe generally. In Belgium, we have seen many cases where patients simply could not access the drugs they needed. Why does this take place? There are several reasons, which involve how the pharmaceutical industry approaches price-setting and competition in Europe. But most fundamentally, these shortages take place due to disruptions in manufacturing and supply chains and a general limited global supply of medicine.

For example, medicines produced in a country like China, with a growing population and demand, will be allocated to fulfil those needs before being shipped elsewhere. Parallel distribution is one of

the most efficient means we currently have, to address and mitigate medicine shortages. But what is parallel distribution in laymen's terms? It's simply the process of a company purchasing medicine in one European country and selling it in another, all the while complying with the strictest EU standards that we all enjoy.

How can parallel distribution reduce medicine shortages? Say a Member State has a medicine shortage. When that happens, this country can look to another Member State with a surplus to #FillTheGap. In other words, the Member State with more medicine than it needs helps the one with not enough. And of course, both Member States benefit from this transaction. Parallel distribution is what enables this process to take place.

Here's a real-world example: as already indicated before, during a recent shortage in Belgium (Dec 18 – Jul 19), parallel distribution brought in 335 thousand boxes of medicine from other EU countries—equal to 814 thousand months of treatment. This enabled Belgians all around the country to get the medicine they needed. Of course, parallel distribution only deals with surplus medicine in Member States. Never will it force one Member State to give up medication it needs to supplement supplies elsewhere in the EU. This is part of the Public Service Obligation, which is a foundational and important part of European law. Removing the obstacles to parallel distribution in each European Member State is vital. Thus, mitigating shortages becomes a much more challenging endeavour. Breaking down these trade barriers that parallel distribution currently faces is the first step to a reality in which Belgians always get the medications they need.

Conversely, the European Commission has identified that parallel trade of medicines is leading to shortages in certain Member States. How are BAPIE's members managing to fill the gaps in certain states while not depleting stocks elsewhere?

First and foremost, the EU Commission have never presented any data or proof. We have confronted the Commission several times with this. Now they admit that in theory, it could – but they have no reason to make any conclusion. We, therefore, welcome an in-depth study from the Commission, so we can have our name cleared.

The fact is that more than half of the parallel imports of pharmaceuticals are sourced in the 12 highest-income countries in the EU. Norway, for example, is the largest exporter per capita, and Germany the top exporter to the Dutch, Danish, Swedish and Norwegian market. The UK is by far the largest exporter to Belgium with one-third of all our imports coming from the UK.

The flows of PI are similarly distributed across the continent, as the proportion of medicines sourced in northern, southern and eastern countries are comparable. Medicines do not solely go from the south to the north or from east to west; trade flows occur in many directions, and many traditionally considered importing countries are at the same time, big exporters. A higher percentage of the parallel imported medicines come from countries like the Netherlands or Austria than from Poland, Spain or Bulgaria. France and the UK are the main source countries at the European level.

Price levels are not homogenous among and within markets. Although the general price level of medicines in one country might be higher than in another, there are very often particular cases in which a particular medicine is still relatively less expensive. Every country can potentially benefit from parallel trade. The objective of parallel importers is not taking medicines from poor countries to sell them in richer ones to the benefit of the latter and detriment of the former, but identifying opportunities and promoting competition. It is key to remember that parallel imports are the only competition to the pharmaceutical manufacturers for medicines under patent protection.

Given that you sit on the board of the Belgian and Luxembourgish medicine verification organizations respectively, to what extent do you feel that the parallel import industry acts as an effective filter of falsified medicines or medicines with production errors in circulation within the EU? How much the industry is given the credit it deserves for this crucial role?

We are part of the industry in this common fight, and even bring an additional security check to the supply chain. We, and the industry, consider falsification as a common enemy. Therefore, you will not be surprised to learn that we were very active in the foundation and in the financing of those verification organizations in Belgium, Luxembourg and in Europe.

Thanks to those efforts, very few falsified products succeed in entering the official and hospital pharmaceutical circuit in Europe. This situation in America, Asia and Africa is totally different and much more dangerous for the patients.

How did you come to work in the parallel distribution industry and what keeps you motivated?

18 years ago (2002), I founded Impexeco, today the oldest parallel importation company still active in Belgium. This creation occurred after 20 years of experience in the pharma “corporate life” where I enjoyed successively the functions of product manager, market research manager, line manager, business unit, general manager and CEO. I also experienced mergers… the latest one led me to take the decision to create my own company. I made it in parallel trade as it was for me the only way to own my product registrations. In 2013, we decided to sell the company. After this, I was asked to chair BAPIE to defend the interest of the parallel business. In 2019, the (parallel) exporters joined the association and we have now as members all companies which count in parallel distribution, exportation and importation. We form the national association for Belgium of Affordable Medicines Europe.

Now, what motivates me to do this job? I would name three main motivations: 1) The pleasure of defending small/medium entrepreneurs (like I was) in the pharmaceutical sector; “With BAPIE, I am not alone anymore” is a quote that I hear often. The psychological, political and legal support given by BAPIE is of great importance for the life and survival of most members. 2) The ideal of free circulation, of open competition in Europe. In the health sector, this ideal must be defended constantly against monopolistic deviations such as secret agreements, the fragmentation of markets (limited quotas of products per country) which ends up in higher prices and shortages for the customers and the social security. 3) The satisfaction of enhancing the ethical standards of our members: by regular and compulsory audits, we upgrade the behaviour of the members far above the legal requirements of Good Distribution Practices. A strong accent is put on the safety and verification of their supply chain. By doing so, we try to eliminate the risk of entry of falsified medications in the supply chain. By adding several safety layers (in standard operating procedure forms), we provide extra insurance for our members and a title of proudness for our association.

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