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Orifarm is the largest supplier of parallel imported medicines in the EU and a fast-growing supplier of generic pharmaceuticals in the Nordic countries.

Christian Vallentin, country manager of Orifarm Sweden, explains the intricacies of the parallel import business and generics market in Sweden, how to successfully compete in both areas, and the crucial role the company plays in providing savings to the Swedish healthcare system.

Could you start by introducing the business model of Orifarm?

Since its foundation in 1994, Orifarm's mission is to challenge the pharmaceutical industry and to provide a better deal for healthcare by creating an alternative to Big Pharma. Through our two business areas, parallel imports of pharmaceuticals and generic medicines, we foster competition and deliver great savings for both society and consumers.

Orifarm is among the top five companies in Sweden in terms of revenues. What makes the Swedish pharmaceutical market so important for Orifarm?

In the eight European countries where we operate as parallel importer, our ambition is to play a significant role in the domestic pharma market, and ultimately be the market leader within this field. In terms of turnover, Germany is our largest market, followed by Denmark, the birthplace of

Orifarm. Sweden is also one of the main revenue drivers for the company, and we invest a lot of effort to be one of the top players here.

Parallel imports represent about 80 percent of our revenue in Sweden with SEK 1.5 billion (USD 160 million) in sales, which makes us the dominant player in the market. This year, we average over 40 percent market share. Our market share has been growing steadily since January to close to 50 percent share of the parallel import market in Sweden. Our key strength in parallel imports is our smooth-running machinery that is unrivaled in the industry.

As for the generics business, it generates a revenue of SEK 300 million (USD 32 million), which makes us one of the main players in the domestic generics industry. Our growth in the generic business is driven by many low revenue generic pharmaceuticals and specialty products.

Could you explain the key market dynamics in the parallel import business in Sweden?

As a parallel importer, we sell products through three different mechanisms. For patented prescription medicines, pharmacy operators can negotiate a price that is lower than the list price set by the Dental and Pharmaceutical Benefits Agency, known as the TLV. Pharmacies can choose to go with a parallel importer or a direct importer, normally they choose whoever offers the lowest price. However, we do not only compete on price but bring value in other ways. As a large established player, we can provide a better service level in a broad assortment and bring more visibility to the pharmacy operators about what is going to happen in the coming months.

Overall, pharmacy operators benefit hugely from the competition we provide, but it also benefits society because the TLV takes it into account when determining the margins, they, ultimately the society, pay to the pharmacies. Since the deregulation of the pharmacy market in 2009, the number of independent pharmacies has grown from around 1,000 to around 1,400 today. Parallel trade has definitely contributed significantly to this growth.

Orifarm also parallel imports generic medicines. In Sweden, pharmacies are required by law to substitute prescription medicines with the cheapest available alternative. The exchange frees up millions that can be used for urgent areas within Swedish healthcare. This substitution is ruled by the TLV's Periodens Vara system. Each month, the TLV designates the generic exchangeable medicines with the lowest price for the period and chooses two spare products that the pharmacies can switch to if the cheapest are not available. As both a parallel trader and generics business, we also compete within this model, providing direct savings for payers and society.

Finally, we are also active in public procurement of requisition medicines at the regional level. In this field Orifarm also delivers direct savings within both parallel import and generic medicines for payers and society. Orifarm is by far the dominant parallel import supplier in this field due to our size and ability to take on the high risks and complicated framework of regions contracts. This framework could however be simplified to open up for more competition and thereby public gain.

Before joining Orifarm, you have worked for a large Swedish pharmacy chain as well as a community pharmacist. How have you leveraged these experiences in your new role?

Coming directly from the customer side has helped me a great deal when I started working at Orifarm because I understood the needs of pharmacies and what is important to them apart from price. After the deregulation, I helped to build the parallel import logistics system and pharmacy exchange system for Kronans Apotek, one of the largest pharmacy chains in Sweden. So I understood the key success factors in procurement of parallel imported goods, the importance of being a LEAN company and accepting the role we have to support customers pursuit of savings

Regarding generics, Sweden has the second lowest pharmacy prices for generics in Europe after Denmark. How do you successfully compete in this pressurized environment?

Orifarm supports low prices for generics as our mission is to provide a better deal for healthcare. The key to success in this environment is to continuously optimize our portfolio by monitoring the market trends and identifying opportunities. As Orifarm cannot compete on the same playing field as the global generics giants, we need to differentiate ourselves. We are not active in the biggest generic substances. Instead, we have been increasingly active in more niche, specialized generic products which have been driving the growth.

Though it is a success that the system for generic substitution, "Periodens Vara system", generates good savings for payers and society I do need to stress that this system also has many flaws. The total focus of the system is on "lowest price bid", but it thereby doesn't mean that the payers get the optimal solution for supply and value for money. Some products are under unhealthy price pressure that is not long-term sustainable and price ceilings set by TLV can cause long-term damage, e.g. risking that products are discontinued, or competition put out of play. The implementation of the Falsified Medicines Directive and delivery demands that are very rigid is

putting extra pressure on costs as well and risk that products need to be scrapped or even discontinued in the market.

The parallel import business is heavily influenced by currency fluctuations. How has the depreciation of the krona impacted your business in Sweden?

The key is to act fast, for instance by stopping the purchase of products that do not make sense anymore. Dialogue with customers is also crucial to find the optimal balance for us to continue to generate value to the customers. At times when the currency gets weaker, we need to show them how much more volume they can get by lowering the discount.

How does Orifarm ensure the quality and safety of the medicines it imports on the market?

Orifarm takes great pride in its extensive and thorough quality control system throughout the supply chain. We work very diligently with auditing and are assessing any supplier from which we purchase good, and tracing where products come from. We continuously keep track of the alerts coming from EMA or other health authorities.

Moreover, we have prepared early-on to meet the serialization requirements of the EU's Falsified Medicines Directive by rebuilding our IT structure. In fact, this has allowed us to gain an edge over some of our competitors who were not as quick to adapt and has been an important factor behind our outstanding growth since the beginning of the year.

In many ways, the parallel import industry acts as an effective filter of falsified medicines or medicines with production errors in circulation within the EU. Regrettably, this crucial role is not given the credit it deserves by political stakeholders and health authorities.

Do you feel authorities realize the importance of parallel imports to generate savings for the healthcare system?

Unfortunately, I think that politicians and other stakeholders do not realize the contribution of the parallel import industry in providing both direct and indirect savings for the healthcare system. On the pharmacy side, parallel imports have contributed direct savings of approximately half a billion

kronor (USD 53 million) each year. However, indirect savings, which represent the majority of total savings, are difficult to assess. What would the price level be if competition from parallel imports did not exist?

In public procurement, the difference between the direct import price and the parallel import price is normally rather small, hence the direct measured savings also are. The competition puts a lot of pressure on the overall price level though and the indirect savings are therefore a lot higher. In this area parallel import suppliers are lately facing obstacles to compete, and healthy competition is now under threat, due to the way demands from the county councils are formed on production conditions. We support that more is done in the environmental area, but as parallel import supplier we cannot have the traceability back to where the active ingredient was produced and under what conditions.

In all sales via open care pharmacies, assessing indirect savings is a difficult exercise to perform. However, the parallel import industry also provides savings, thereby bringing products for which there is low competition.

How do you cooperate with the relevant stakeholders in order to promote parallel imports and communicate their importance for the healthcare system and patients?

In the past, companies in the industry did not collectively invest enough resources to drive these questions in the public arena and make ourselves more visible. One important action we took as an industry was to hire Fredrik Skepp as full-time CEO of the parallel trade association (Läkemedelshandlarna) who will work to make our voices heard and defend our interests. Since then, Fredrik Skepp has been very active in meeting with politicians and communicating on the importance of parallel imports for the healthcare system.

Moreover, Läkemedelshandlarna is a member of the European Association of Euro-Pharmaceutical Companies (EAEPC) which is in the process of conducting a study on indirect savings.

A recurrent criticism of parallel imports is that they threaten product innovation. Do you feel this accusation is warranted?

I think this is an unfair criticism. Parallel imports create competition where it would not exist otherwise. Competition is fair as it helps payers and society get the most out of taxpayers' money.

There is no evidence that parallel imports hamper research and development. A lot of money from payers already goes back to the Pharma industry today that could be used to finance new medicines. Once products have been on the market for some time, there should be some price pressure, otherwise taxpayers are paying too much for their medicine.

What do you think could be done for Sweden to get even more out of parallel trade and generics?

While the Periodens Vara system for substitution of generics is quite an effective system, it could generate more savings and prevent stockouts by being more flexible. For instance, by making it possible to sell smaller volume instead of only selling one-month supply at a time, which is more difficult to achieve through parallel imports but also occasionally hampers generic products sale. In this regard, the Danish system is something to look at for inspiration.

Moreover, for parallel import the model with the list price focus today means that if a direct importer lowers its price insignificantly, even by a single krona below our price on a product that costs 10,000 krona all direct savings are lost. This happens often and ongoing month by month for some products, the pharmacies are then not allowed to exchange the product because the list price is higher. The parallel importer is not allowed to change its price until two months later to get lower than the insignificant price change. As a result, the pharmacies, and society as a whole, cannot maximize the savings from fair competition. From my perspective, all price cuts should have to be above a certain significant level if they should have this effect. Price competition should be fair, but today the system can be used to make competition imperfect and as a result big direct savings are lost.

Unfortunately, the government's pharmaceutical review under Toivo Heinsoo did not address the flaws in the price model. Even though we believe that parallel imports could work on many different models, the most important thing is to have a model that is transparent and foreseeable so that we can predict how much volume we can get if we have the lowest price on the market. We felt that this proposal was not completed, it only presented a brief outline of how the new model would work. The rest of the work was left to TLV to take care of. As an industry, we would like to play a bigger role in generating savings for Sweden. But we need to know what the alternative is and what it means for the industry. In the case the government decides to conduct a new investigation, we would be happy to work with the investigators and see how parallel imports could contribute.

In public procurement Sweden currently risk limiting both parallel import savings, but also generic competition via too difficult to obtain data demands on traceability and production data. We support that more is done in the environmental area, but demands need to be implemented with a better understanding of consequences and aim to make real change. E.g. by as a start be limited to antibiotics where the production is a potential real risk factor.

Going forward, which areas do you plan to disrupt to bring even more savings to Sweden?

Orifarm is on a journey of growth and our ambition is to further develop as a respected player in several niche areas and expand the business in areas where we are not today. We have a full team dedicated to investigating new or adjacent businesses where Orifarm could further disrupt the pharmaceutical industry.

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