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Teun Grooters, co-founder and CEO of Arega - the exclusive distributor of Teva generics in Belgium - tells the story of the newly founded pharmaceutical company and shares his future ambitions to grow the organization into a multinational player delivering comprehensive solutions in areas with unmet medical needs. Grooters also offers insights into Belgium's challenging generic segment.

Before you founded Arega you had an extensive career in the MNC pharma space. What motivated you to take the leap and start your own company?

To be frank, it was frustration. Due to the unfortunate outcomes of acquisitions made by Teva, when the current CEO Kare Schultz joined the company in 2017, he was forced to implement a restructuring and cost-cutting period. As part of this exercise, it was decided that the company's generic business in Belgium would close because of the complexity of the market and high operational cost from the large sales force necessary for success. Therefore, it was decided that these costs were not justified in the new model of the company.

This frustrated me because the reality was that Teva generics was doing very well; we were outgrowing the market and gaining headway in Belgium. For eight years Teva had been losing market share but a year after I arrived at the affiliate, we grew by three-fold in the market. Unfortunately, this appeared not to be enough to save the business.

One day on the way to work I came up with the idea of taking over the affiliate's generic business and pitched it to a few of my colleagues. I then suggested the idea to Teva's head of Europe who supported the plan. After several months of reorganizing Teva Belgium internally and preparation for the new business, we established Arega Pharma in April 2019.

What were the initial challenges you faced in getting Arega up and running and how did you overcome the hurdles?

Of course, such a procedure goes through phases. I had the idea to take over the generic business in December 2017, but first needed to reorganize the affiliate which concluded in June 2018. After being asked to restructure again that August I decided it was time to put the Arega plan into action.

This kind of transaction takes time as a term sheet must be drafted which defines the conditions for the negotiation of a contract. By January 2019 we finally signed the term sheet and at that point, it was time to build a new business from scratch. From the end of January to the beginning of April we managed to build Arega with all the necessary systems to run a business – a major accomplishment and testimony to the dedication of our team without whom this success would not have been possible.

Looking back at 2019, how did the company perform during this time and what are the goals you have set for Arega in 2020?

The first months of Arega's operations were focused on execution; making sure that the product and clients' data were transferred, orders continued to be fulfilled, and proper invoices were sent. After this initial transition, we began to think about what our next steps would be as a company given that we were only the exclusive distributor of Teva. As a distributor, it is never practical to be entirely dependent on a single client. Therefore, we began an extensive business development campaign and had 30 ongoing projects within just the first three months.

Arega now has several agreements which are in the finalization process that will bring new products into our portfolio such as a food supplement for the prevention of migraine and a medical device which was originally produced by Teva and marketed through another partner.

We have been able to be this successful in establishing deals because partners like not only the Arega story, but also that we are a company that started operations immediately with a 50 person-strong sales force visiting GPs, hospitals, and pharmacists.

What differentiates Arega from other distributors in the market?

What sets Arega apart from the average distributor in the Belgian market is the extensive industry experience that we have. I am a medical doctor by training and did clinical development for ten years and helped to develop blockbuster drugs in HIV for example. After, I moved into global marketing and was also the European head of Teva's CNS business – a EUR one billion business. While I have extensive experience launching products in Europe, Arega's entire management team has the same caliber of expertise. Our marketing director has vast experience in global marketing and our medical director was the head of a therapeutic area in clinical development in Novartis, for example. Moreover, we have a highly dedicated and motivated team, who have chosen to join us on this exciting journey.

What market strategy have you determined for the company?

In our strategic vision for the company, we have identified an ambition for our first year of operations to create partnerships for ready products in the generic and OTC segment which are currently not being marketed in the Benelux region. Second, we will explore if Arega can engage with foreign companies from the US or Asia who are aiming to bring their products to the European market.

Finally, we will engage in R&D in the rediscovery of old medicines for new indications and create a proprietary portfolio of food supplements and OTC products. In fact, we are already in talks with a Dutch university for establishing a research collaboration to develop new products.

We are discussing with the university on a new kind of concept where targets are developed based on genetic profiles and the protein expression of those genes. What we are specifically aiming for is the repurposing of old drugs. Many new targets can be addressed by old molecules and even some past blockbuster drugs were repurposed medicines. Arega's ambition is to develop these drugs and make them available at an affordable price.

When deciding what products Arega will represent in Belgium, what are the top criteria are you taking into consideration?

Arege is particularly focused on niche markets with smaller target groups which include orphan areas. Additionally, to help build the business locally we are building an OTC portfolio as well. We have encountered products for muscle wasting in elderly patients as well as several in wound care. These products fit into our mission of care to deliver on high unmet medical needs and are also a niche area which can be managed with a smaller sales force. With about ten products in woundcare that are being considered, we have decided to set up a new woundcare group to offer integrated solutions to help improve the treatment of patients with all types of wounds.

In building our portfolio we take a solution approach rather than an individual product approach. In wound care for example, we aim to deliver a full range of products which include creams, dressings, and technologies to help patients heal. Furthermore, we want to partner with societies and patient organizations in this field to come to new treatment strategies and build better solutions.

Arege's name is based on the Greek word "arego" which means to help or support. Our business philosophy is about helping people to feel better and deliver quality care. Moreover, as a trained medical doctor, all our products must have a valid scientific claim behind them.

The Belgian generic segment faces challenges with a low penetration rate - hence Teva decided to not market these products on their own. What is your assessment of the current conditions?

The generic industry in Belgium is a very unhealthy business for several reasons. First off, just from the market structure, we see that the first company has 50 percent market share, the second has 28, and we are third with 12. With the first two players holding such a majority it is difficult to compete for the rest of the players, Arege included.

Next, Belgium has a government that is very focused on innovation. Having spent 25 years of my career in innovative pharma, I agree with the importance of this segment, however, it is clear that without generics there is no innovation. If innovators are not pushed by generics and patent loss to create new products, then there is no innovation. Having been in charge of COPAXONE, Teva's blockbuster CNS drug, I can attest that the competition generated by generics after a loss of patent is essential for creating urgency to deliver new molecules.

With a drug budget of EUR five billion, more than the Netherlands, Belgium is constantly under pressure and notorious for the difficulty in price setting. As a solution, the Minister De Block has come up with Article 81; secret managed entry agreements which include new immunotherapy products. The overshoot of this budget was EUR 300 million last year while the total generic budget was less than EUR 500 million. It is impossible to make up for this overspending with cost-cutting and price erosion of generics.

Due to the size, Belgium is not a hugely influential market within the European business of international pharma. Therefore, as we have seen with Teva, the costs are high, and the profitability is low which leads it to be one of the first markets to be abandoned by generic players.

What do you see as the most important changes need to improve the generic sector?

First, there needs to be more consistency and transparency about how prices are set in the innovative segment. Next, the authorities need to stop protecting the off-patent products of innovators. In Belgium, innovators can still ask for a supplement of up to 25 percent of the price up to EUR five per pack of medication – charging more money for the same product as a generic. With this pricing structure, the margins are high, and they can continue promoting and maintaining brand loyalty. Forcing generics to invest more in sales forces, but penetration remains the lowest in Europe.

I would also like to point out that there needs to be an improved adherence to the regulations in Belgium. Substitution at the pharmacy level is not allowed in the country but is still done by many pharmacists as they often do not have all products like they are supposed to. Therefore, it is necessary to have a large sales force to have these discussions with health professionals; in Teva, our team was the same size as Germany which had ten times the sales of Belgium.

Given local challenges, is establishing operations outside of Belgium also a future strategy for Arega?

Absolutely. Of course, with Teva we have an agreement to only market their products in Belgium and Luxembourg, but the opportunity exists for other partnerships and our eventual self-developed portfolio. To maintain the typical Benelux region, we are currently in the process of setting up an organization in the Netherlands. Additionally, if some of the deals we have on the table come to fruition, Germany could also be a potential market for expansion. In the long-term France would

also be a natural move because of the proximity and shared language. While we are ambitious and things are moving rapidly for us, we must also keep our pace and take things step by step.

As CEO you have to create a new identity for the organization and set a path for your team. What is the corporate culture you are aiming to establish at Arega?

I have always tried to surround myself with people who do not need to be told what to do. I bring in people with expertise, experience and drive, who can run their own business and take responsibility. It is very important to have a strong management team that works in the same direction.

A philosophy we also have is to put responsibility in the hands of the people who execute the continuum of patient care. Through our sales force, we visit the pharmacists but also GPs and specialists where prescriptions are generated. In effect, these professionals now must manage their business and ensure that the pharmacy next door has the products they are prescribing.

Moreover, we are moving towards a system in which the sales force will benefit from the profit of Arega rather than working in a bonus structure which I do not believe in. All sales territories are different, but as a company, all our employees are working to achieve the same benefit for patients. So instead of competing against one another, if Arega does well we all do well.

Looking forward to the next five years, what vision do you have for Arega?

My vision is for Arega to be a multinational company with several self-developed repurposed drugs in areas of high unmet medical need. I hope that Arega will be seen as an atypical pharmaceutical company delivering on its promise to be a reliable partner for patients and health stakeholders. Finally, I also want my colleagues in the company to have this same ambition and feel empowered and passionate about the work they do. Of course, we also want to have success in the market!

What do you hope that people will think when they hear the name Arega Pharma?

I want to work for that company!

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