

# Interview: Isabelle De Walsche - Managing Director, Gedeon Richter Benelux, The Netherlands

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*Isabelle de Walsche, Managing Director of Gedeon Richter Benelux, provides us with an update on the development of this striving and ambitious player in the women's healthcare field and shares her multi-country experience in market access and innovation perception.*

## **The Gedeon Richter Benelux affiliate only opened in 2012. What were the main rationales behind the decision to set up an affiliate in this territory?**

In 2010, Gedeon Richter acquired Grünenthal's oral contraceptive portfolio and PregLem, a Swiss-based biotech company. At this time Gedeon Richter was a well-established pharmaceutical company in Central and Eastern Europe; but with a very small presence in Western Europe. To better benefit from the commercial potential of these two new acquisitions, the company thus decided to strengthen its position in the West, opening a first affiliate in Germany, then in the UK, Spain, France, and Italy, while smaller geographies like the Benelux and the Nordic countries were grouped together.

## **Starting from scratch in May 2012, what has been your strategy to build up a solid presence in your territory over the past four years?**

Opening and putting this affiliate on the right track has been a very intense and enriching adventure! Beside logistics matters, one of my first tasks was obviously to build up a talented team

and start establishing Gedeon Richter's footprint on our three markets. Given that I have been working in women's healthcare on the Belgian market since 2000, I was fortunately able to rely on a well-established network, both to hire collaborators but also to access KOLs, hospitals and clinics. Nevertheless, for the Dutch market, I started from a blank page by first mapping all the local important stakeholders and potential partners, and then met them one by one to truly understand their needs and expectations.

By the end of 2012, I managed to pull together all the key internal competencies that we needed to move the affiliate forward, from regulatory affairs to marketing and finance. The first product launch of the affiliate occurred in 2013, and the first challenge that our sales team met was obviously to put Gedeon Richter on the map in these three new markets. Our first main objective was to clearly explain our vision to the local stakeholders, and to build the basis of a long-term partnership. In this regard, being a relatively small affiliate has been an indisputable asset, as we are able to meet the needs of our clients and partners with great flexibility and rapidity. Furthermore, doctors and healthcare professionals know our entire team by name, which creates a very personal approach in the way we engage with our partners.

**Beside gynecology, the Gedeon Richter Group is also strong in therapeutic areas such as the Central Nervous System and cardiovascular fields. What are the main rationales behind the focus on women's health of the Benelux affiliate?**

It is strategic headquarters' decision to initially concentrate our efforts on women's health. From a mid-term perspective, we will continue to deepen our portfolio in this field, as we plan to launch two new women's healthcare products in 2016 and 2017. Firstly, thanks to our license and distribution agreement with Bayer HealthCare to commercialize their transdermal contraceptive patch, we just launched these products on the Belgian market during the third week of January 2016. These products will be available for the Dutch patient around March or April 2016. In 2017, we will also launch a completely new Hormone Replacement Therapy (HRT) in the Benelux.

Recently, Gedeon Richter massively invested in a cutting-edge biosimilar manufacturing plant in Debrecen (Hungary), which notably is able to manufacture many oncology and other specialty products that are about to go out of our pipeline. Nevertheless, it has not yet been decided whether they will reach the Benelux market through our affiliate or if these upcoming products will be outsourced. As Managing Director, the opportunity to broaden our portfolio obviously seems like a very exciting challenge, as we would become a multiple-country affiliate with different specialties!

## **What is the development curve of women's healthcare products across the region and in Benelux in particular?**

First of all, our portfolio is split between two specialties: ESMYA, our innovative treatment for the fibroid, and our contraceptive portfolio (Bellina, Daylette, Lisvy). As the volume of the contraceptive market is not rising particularly highly in the Benelux region anymore, our growth strategy on this relies specifically on being more creative than our competitors to ultimately gain their market share! For contraceptive pills, Belgium clearly represents a higher business potential than the Netherlands, as generics have now reached a very low price on the Dutch market; drastically hindering our profitability. In Belgium, we have brought different contraceptives onto the market, and we strategically decided to closely engage with local gynecologists and GPs, who have a very important role in the prescription of contraception. As we started from scratch, our sales volume on the Belgian market was obviously quite low at the beginning, but our GP network is quickly expanding now, and since the beginning of this year we have had a dedicated GP-team in charge of the whole contraceptive portfolio for the Belgian market.

For ESMYA, the situation is completely different, as it is an innovative product without any similar competitors in our market so far. This product has been established since its launch as our main growth driver,

In terms of sales, after only three years of activity, we are about to reach break-even level and with product launches already planned for the coming years and the potential opening of new therapeutic areas in the Benelux region, we are particularly optimistic for the future!

## **Given your two-country experience, how would you compare Belgium and the Netherlands in terms of market access and innovative products?**

Talking specifically about the procedures and according to my past experiences, market access is probably smoother in the Netherlands than it is in Belgium. To engage and cooperate with Dutch public authorities is particularly easy, and procedures are shorter and clearer, while the different specialty clusters really help to ramp up the overall process. In a nutshell, market access in the Netherlands is more transparent.

On the other hand, I feel there is still a huge reluctance from Dutch public authorities when it comes to innovative products. As a consequence, the use of innovative products in the Netherlands is continuously decreasing, and is now among the lowest in Europe in percentage terms. Furthermore, new products have to follow medical guidelines precisely, while an important part of the clinical trials are also expected to be conducted in the Netherlands. It is particularly surprising

and also contradictory in a context where healthcare stakeholders are looking for more harmonization within the European environment. In this vein, Nefarma and Pharma.BE, the Dutch and Belgian innovator associations, are pushing for adopting “EMA-like” market approval expectations at the national level, in order to allow pharmaceutical companies be more efficient when they penetrate their local markets.

**For the Dutch Presidency of the EU, one of Minister Schippers’ priorities is to foster European cooperation on drug pricing and reimbursement, particularly between Belgium and the Netherlands. As a Benelux GM, would you welcome this initiative as an opportunity to faster reach your target markets?**

Considering that I currently deal with three almost completely different regulatory systems, I would obviously greatly welcome a certain alignment at European level, as soon as it strictly implies pricing and reimbursement. Nevertheless, a joint-procurement initiative between multiple-EU states would be particularly risky for the pharmaceutical industry, as it would probably provide public authorities with too much bargaining power when it comes to negotiating treatment prices.

We will also then have to find the right balance between the price of the treatments and the timeline to access the markets. From a Benelux point of view, it would be particularly satisfying if a joint approach in terms of reimbursement and pricing could also allow us to bring our products on the market within an average time period of what currently happens in my three different geographies. As an example, in the Netherlands, the whole reimbursement procedure for our products usually lasts around four months, while it usually takes between nine and twelve months in Belgium.

**What are your three key goals for the upcoming five years in Benelux?**

Firstly, from a short-term perspective and looking at the contraceptive side of the business, we want to further extend our GP network and increase our sale volume based on GPs’ prescriptions. This business is still particularly new for us, and we absolutely want to make it a success. Furthermore, we want to ensure new product launches at GP as well as SP level but also potential new therapeutic areas should follow the same successful development curve as our recent products have.

Finally, we really want to have a greater and broader impact on our patients, mainly through disease education. Although we often say the world is evolving extremely quickly and people obviously now have access to the Internet to get information; some diseases and symptoms unfortunately remain taboo even in developed countries, specifically in women’s healthcare.

Considering our unique position in this industry segment, we want to foster information transfer but also provide both patients and healthy women with the most accurate information available. As a company, it is really challenging to engage patients without being too intrusive, but as always, we will strive to be creative to ensure women can benefit from our know-how and better use their treatments. We certainly have a great role to play in this effort, but a broader cooperation based on a win-win partnership between the industry and public authorities appears to be the best option to maximize the impact of such initiatives.

**In the pharmaceutical industry, we see a lot of women in lower or middle-management positions; but the situation remains completely different for higher positions, such as Managing Director or CEO. What is your assessment of the situation?**

Unfortunately, this assessment is quite true, but the situation is probably better in the pharmaceutical sector than it is in many other industries. Nevertheless, this situation has improved tremendously in recent years. In my career, I have never been questioned in my ability to handle leadership positions just because I am a woman, which might seem obvious today but would have been extremely likely a decade ago. On the other hand, things are maybe moving faster from a corporate point of view than from a social one; as women remain more frequently in charge of children and household jobs on average. This leads to a situation where finding the right balance between long working hours and family obligations could be trickier for a woman than for a man. If there is still huge room for improvement, I however don't feel isolated as a woman, and am confident we will see an increasing number of talented female CEOs in the pharmaceutical industry in the upcoming years.

In collaboration with Gedeon Richter (2016-004)

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