Emmanuel Eumont – General Manager, Gedeon Richter France

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Emmanuel Eumont, general manager of Gedeon Richter France, discusses the group's leading position in women's health, its external growth strategy, notably through the acquisition of Finox Biotech in 2016, and the upcoming product launches that will strengthen its portfolio. Finally, Eumont shares his thoughts on the 8th edition of the Strategic Council of Health Industries (CSIS) that took place last July.

Last time we met with Gedeon Richter France, then-CEO Ksenija Pavletic was very proud about the integration of PregLem within the company and the success of the product ESMYA® (a drug used to treat symptoms of uterine fibroids in women who have not yet reached menopause.) More recently, you joined the group through the acquisition of Finox Biotech. Could you tell us more about this acquisition and what it brought to Gedeon Richter?

The rationale of the acquisition was to enlarge the product portfolio and to strengthen our position in women's health by entering the fertility and biosimilar fields. In that respect, Finox Biotech was a unique opportunity. Through this operation, Gedeon Richter also acquired BEMFOLA®,a recombinant-human Follicle-Stimulating Hormone (r-FSH) that has been developed as a biosimilar to Gonal-f®, an already-marketed and established reference product. BEMFOLA® is hence a biosimilar, fertility drug and a very strong seller for our group today.

How was the process of integrating a mid-cap Hungarian pharmaceutical company with a more humble Swiss biotech startup?

While the acquisition was confirmed in 2016, the real integration in France and abroad started in the beginning of 2017. Thanks to the acquisition of PregLem in the past, the group had all the tools to conduct a smooth integration. On top of that, Gedeon Richter was well organized: it had used external growth as a strategy several times before, and had an open mindset for such integrations.

Not only was it smooth overall, but it was also particularly easy in France. I was personally responsible for the integration due to my experience in setting up Finox Biotech in France. Here, we merged the two companies into a single entity and we now have a unique salesforce whereas in the other countries, it was established as a separate fertility business unit (which would then include Finox). This local decision was related to the peculiarity of the French market, both for our employees and the patients. The results were excellent: we had a double-digit growth in BEMFOLA® just after the acquisition, so we can say that it was the good choice. On top of this, it showed Gedeon Richter could follow different strategic paths in different markets.

What does France mean today for Gedeon Richter?

France is our eighth most important market, recently gaining one place in our rankings. It is also the second strongest in Europe for us, behind Germany. The performance in this country is critical and promising. Not only is BEMFOLA® growing precipitously, but also the fertility business in France is the largest by far in the Gedeon Richter overall group: the sales of BEMFOLA® in France constitute one third of the sales globally.

France is also one of the best-performing countries for the sales of ESMYA®. Hence, revenue-wise and strategically, France is crucially important. The footprint of the Group is growing consistently. We are going to have new products too for which the group has already signed some licensing agreements. Hence, in the future, the adult women healthcare offer, now representing nearly 40% of the group’s healthcare, will be even more complete.

France is as you mentioned, the eighth largest market within the Gedeon Richter group, but it is the fifth largest pharma market in the world. How do you explain this gap and how would you describe your strategic priorities to narrow the gap?

Even if the Group was established for decades in France through Medimpex France, the foreign trade company established by the biggest Hungarian pharmaceutical manufacturers, Gedeon Richter on its own was only set up five years ago in France. We are still a very young player and we

are still in the learning phase, growing daily and gaining ranking consistently. This is perhaps the reason behind the mismatch of the market size and the ranking of the French market for the group. We are moving in the right direction, though. In particular, for us, moving forward means a strong focus on Women's Health, enhancing the performance of existing products (mainly ESMYA® and BEMFOLA®), and enlarging the portfolio to serve more patients'. Also, biosimilars are considered in the future of the whole group.

How does Gedeon Richter differentiate itself from established players in the field of Women's Health, and how do you raise awareness towards healthcare authorities, the medical community and patients on our great portfolio?

To be honest, it is very straightforward. We do two things: we launch innovative products, like ESMYA®, and we build customer intimacy. We consider all the stakeholders within the industry and especially patients, and that's absolutely central in our corporate ethos and vision.

As Philippe Lamoureux from the LEEM (The French Association of Pharmaceutical Companies) mentioned, delays in market access are considerable in France: an average of 530 days while the European directives prescribe an amount of time lower than 180 days… Could you tell us your experience with market access in France, and how might the announcements made during the Strategic Council of Health Industries (CSIS) change the picture ?

In France, market access is indeed lengthy and complex. Luckily, the CSIS gave some sort of visibility to this issue, especially concerning delays, which is going to be extremely beneficial for the whole pharma industry and will help attract more investments. This is the key for the industry: to have visibility.

Regarding complexity, it is extremely lengthy to navigate the French regulatory ecosystem, as several steps are required to have a product on the market: a product must pass through the ANSM to get the marketing authorization, then the HAS and the Transparency Commission, , and finally the CEPS for the pricing. Each of these steps require discussion with the public sector. However, this discussion aspect might also be beneficial, as it allows us to have a true conversation with the authorities about a product. For example, ESMYA® has two indications; a short-term one in preparative settings and a longer-term use. For the first indication, we have full reimbursement, while for the long-term use we are still under discussion with the authorities, knowing that ESMYA® is reimbursed for both from all the other European countries. We are working with authorities to give access to ESMYA® to the whole patient population. We will have to adjust the price and to find

the right balance for the two indications for the targeted populations with the CEPS.

In the UK, pharmaceutical companies truly work in close partnerships with the healthcare authorities. How does Gedeon Richter approach these partnerships in a country like France?

We work in the same way. We work in partnerships with the French governing bodies. In particular, we try to understand their priorities and to make them understand the final, concrete, benefit of our products for the patients. Once the respective priorities are communicated, it is just a matter of finding a balance between price and reimbursement. It is all about focusing on the patients and their benefits, and then working together to maximize those.

Recently, the Comité Consultatif National d'Ethique (National Committee for Ethics or CCNE) gave its stamp of approval for the Medical Assisted Procreation. How do you anticipate this news is going to impact your business?

That is important news, but it is just a statement for the time being. It will need to be endorsed by the authorities and the government. To be effective, it is necessary to see concrete steps. If this is the case it will give women access to fertility services, which means giving them the same access already granted to the women of other European countries. These patients will not have to travel to other countries to have a baby. However, practical steps need to be taken by the authorities, but this endorsement by the CCNE is already a big step forward. Now, we need to explanations as to how it will be reimbursed. Obviously, this cannot be done overnight. Only after this we, as a pharma company, will play a role in helping the patient conceive, but it is way too early to comment definitively on the mater.

You have been in the industry for 25 years. Do you see the CSIS 2018 as a true game changer?

It is giving more visibility to the pharma industry. In the past, the French market suffered so much for this insufficient visibility, but the proposed changes make it easier to plan investment and the attached ROI. All the comments from the proponents of Big Pharma confirm this. This is the game-changing aspect. The Pharma Industry is a "long-run industry": ten years are required to develop a product marketed for at least another ten years, so it is a cycle of roughly twenty and plus years. If you do not have any visibility then you do not invest. It is different for the shorter-cycle OTC market, that needs much less visibility than traditional pharma.

What would you like to achieve in the next 3 to 5 years for this affiliate?

The most important thing is to continue developing the team, not only in terms of numbers but also in image and competency. We want to be recognized as one of the leading companies in Women’s Healthcare. Another aspect is to reinvent ourselves with patients, physicians and all stakeholders, as it is the only way to move forward. Inertia is the worst thing in this business.

A few words to conclude for our international audience?

France is important, especially as it attains more and more visibility. We will keep establishing ourselves in the Women Healthcare business in this country, and we will continue to perform stronger and stronger.

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