Brigitte Calles – General Manager, Ferring France

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Brigitte Calles, newly appointed general manager of Ferring France discusses the important role the affiliate plays as a market leader in reproductive medicine & women's health, gastroenterology and uro-oncology and goes on to highlight the company's exciting period of transformation as a renewed focus is placed on science and innovation at the group level. Additionally, Calles shares her expert insights on the complicated market access dynamics of France and the possibilities that exist to evolve the issue into a more patient-centred process.

On a personal note, you have had a very diverse career, starting in the consulting world, then moving to drug policy at the national level, and finally entering the pharma industry several years ago. After working closely with many top industry players, what was it about Ferring that stood out to you and motivated you to join the team last November?

After entering into the pharmaceutical industry through my position with LIR (France's Association of International Research Laboratories), I worked for several pharmaceutical companies, in charge of market access & government affairs in France and in Europe. With these different experiences, I wanted to join a company with a strong portfolio in specialty areas such as women's health as well as strong values in terms of ethics and patient centricity.

What have been your initial priorities since taking on the role of general manager several months ago?

Of course, my first ambition was to continue learning more about Ferring and understand the business model of the company by listening to both the internal team and our customers. As a doctor myself, I enjoy engaging in conversations with other healthcare professionals to better understand their needs and perception of the company. My priority is to create a strong bond with gynaecologists, gastroenterologists, and urologists in order to identify opportunities to improve the services Ferring can offer.

With my experience in biotechnology companies, many of my roles were revolving around launching products which allowed me to enter into discussion and negotiate market access with the health authorities. Ferring will launch a new fertility treatment this April – a project for which my experience will be critical.

What is most exciting about the role is the diversity that exists in each day. Being a general manager requires a hands-on involvement in all areas of the business, ranging from finance and HR to pricing and marketing.

How has your experience as a medical doctor benefited you in this role?

Thanks to my medical background, establishing a dialogue with our customers is easier. I am able to relate to their experiences and concerns – speak their language so to say. Moreover, science is the most important asset of Ferring and my education has encouraged me to be science-driven. In fact, Ferring's new president and chief science officer, Per Falk, is a scientist and doctor which I believe speaks volumes to the values and vision of the company.

How is Ferring positioned within the French market and how do you expect Ferring to evolve in the coming years?

In the pharmaceutical industry, change is absolutely essential in continuing the momentum of an organization. As the environment changes, being able to adapt and having a clear vision for the future are key assets of Ferring. In my view, the future of pharmaceutical companies is based on innovation and science. Without innovation, it is difficult to survive, which is the vision of Per Falk. In addition to our new fertility treatment, we have a non-antibiotic treatment in phase 3

development for the treatment of Clostridium difficile infection (CDI), which has the potential to be the first human microbiome product approved anywhere in the world. We also have the potential to commercialize a novel gene therapy for bladder cancer. Our commitment is to drive Ferring forward through innovative drugs which will in turn boost revenues in France of course.

In France, we have three therapeutic areas: reproductive medicine and women's health, which includes fertility and obstetrics, urology and gastroenterology. Ferring is the only company involved in obstetrics research and a reference player in the area. Furthermore, we are a market leader in gastroenterology and first for the treatment of irritable bowel syndrome. We will continue the growth in France, but we are concerned about market access in the country, especially for our lifecycle management portfolio.

In my role, I act as an 'ambassador' to France for the global management of Ferring. I work with the domestic stakeholders to help build a case for why international companies like Ferring should invest in France and I bring these arguments internally to convince global operations that France is a key market. Unfortunately, this has been a very challenging task in recent years.

How have you seen the attractiveness of France as a pharmaceutical market evolve in the past years and in the scope of the Macron administration?

I fully believe that President Macron realizes the importance of France as a market for international pharmaceutical companies. However, the current reality of France does not align with the vision of creating a competitive environment.

The ATU system is actually a major asset in making innovative drugs available for patients with an unmet need, often in France before other major countries in Europe. For patients, this is an essential advantage to get access to innovative treatments. However, the ATU process is becoming increasingly difficult and complex. For example, there are many cases of medicines being registered through the ATU system that are over 500 days in negotiation. The purpose of pharmaceutical companies is to bring innovation to patients and countries, but this disconnect is a real concern in France compared to other European countries.

What are your expectations from the government today in terms of reforms for market access?

All innovations regardless of the therapeutic area they are in are critical for patients, but as a health decision maker, it is difficult to choose how to prioritize between them. I understand this challenge, but I do believe there must be clear rules to determine efficacy and safety. Sometimes, during the assessment carried out for very innovative drugs, the evaluator is not always specialized in the given therapeutic area they are reviewing. In terms of the risk-taking process, if there is considered to be any amount of risk, rather than giving an ASMR5 the assessment should be postponed to be reviewed based on real-life data a few years later. These challenges make negotiation very difficult, so it is the assessment system that should be examined as a whole notably for disruptive innovations.

There is a lot of hope with the current administration. This is actually a tipping point for France, but these matters need to be applied for real improvements to happen. At the CEPS level, negotiations are often blocked because only the Social Security expenses are mainly being thought about, but a broader vision is necessary to create an environment in which the industry can continue bringing innovation to France.

As an expert in market access, what changes do you see as most necessary in improving these conditions?

Pharmaceutical companies should not forget that they also hold some responsibility in the current situation. The industry has to contribute to providing drugs through strongly executed clinical trials. The requirements of the EMA and the demands of the FDA are not the same. The design of trials should be able to meet any standard from the beginning, especially when there is a plan to distribute across various markets. When conducting clinical trials, we must not forget to consider the requirement of France to demonstrate the efficacy of drugs, but this can be applied to any European country.

On the other hand, the HAS should also be more flexible with trials. For example, when there are very innovative drugs in oncology which have new ways of proceeding, sometimes the commission may have to accept to be more flexible with methodologies or grant conditions ASMR to review the drug with real live data.

Both sides need to find common ground and work in partnership to find the right way of making a drug accessible and affordable. Today in France we still operate in silos and it is time for these walls to fall down. Access is beyond just reimbursement and pricing. Access is about being a partner to physicians, pharmacists, patients, and the overall health environment.

What can be the role of France and the affiliate in bringing disruptive innovations to the group – a priority of Per Falk, the new president and CSO of Ferring?

We are actively working to forge partnerships with research institutions to cover new therapeutic areas and drugs that we have in our pipeline. This will be my first step to increase the scientific value of the affiliate while also building the innovative reputation of Ferring in France. Ferring is and will continue to be a company driven by science as we move forward in developing the medicines of the future.

What final message would you like to deliver on behalf of Ferring France?

I joined Ferring at the right time. The ambition of the company to move to something new is very exciting. At the local level, I would like to create a new momentum in the company structure based on scientific values, employee mindset, and the embracing of industry disruptors like digitalization and a patient focus.

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