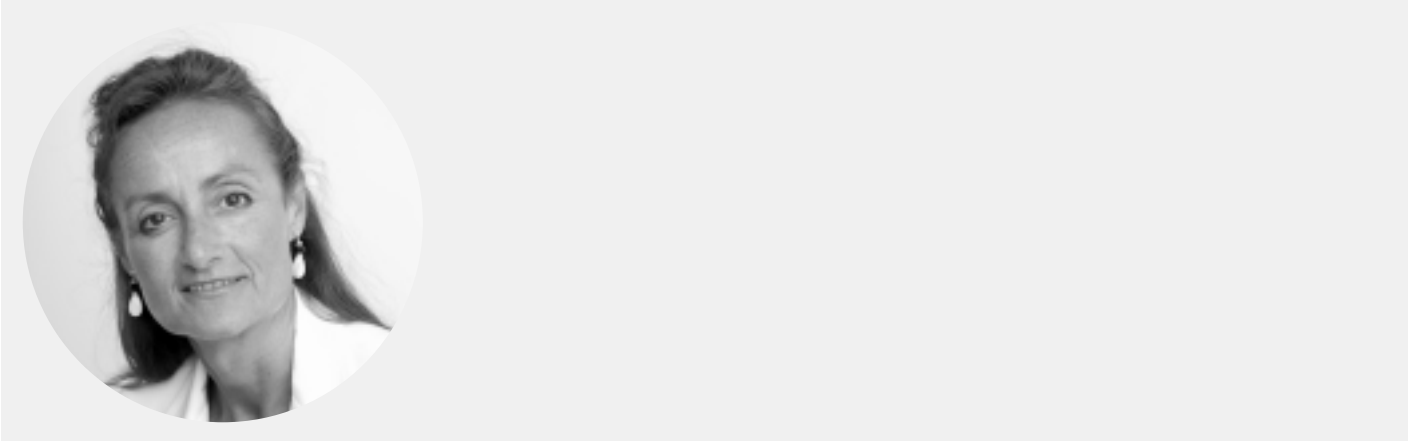
Interview: Simona Falciai – General Manager, Shionogi, Italy



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Simona Falciai, General Manager of Shionogi, provides insights into the launch of the Italian affiliate, how the company is catering to a key unmet medical need with Ospemifene, the first oral, non-estrogenic drug in the field of vulvar and vaginal atrophy, and the central role of partnerships in the company's R&D strategy.

The Shionogi Italy affiliate only opened in 2015. What were the main rationales behind the decision to set up an affiliate on this territory?

We have a long history in Japan with over 6,000 employees globally. Over the last 15 years we have also developed a solid base in the US where we now have multiple products in the market and conduct a number of clinical trials. In addition, we have a presence in China and South East Asia. In Europe, we started building our base in 2012, primarily focusing on developing and registering innovative medicines for the European market, focusing on Germany, Spain and Italy. Shionogi has decided to enter and to invest in Italy for three reasons. First, it is among the largest global and EU Pharma markets, respectively as number six and number three, so we can serve many patients directly. Second, it has high quality research standards (within the top ten in the world) and key opinion leaders with whom we collaborate to develop innovative clinical solutions. Third, Italy is one of the most challenging countries for market access policy. Here, we can collaborate directly with the Italian payers to learn and reapply what we have learned in other markets. In late 2013, I

joined Shionogi to start up the Italian Affiliate. Since we opened the office we have created an agile team (about 30 people) to prepare for our entry in Women's Health. In October 2015, we launched our first product, Senshio (Ospemifene).

Speaking about Ospemifene; it is a significant innovation for women with vulvar and vaginal atrophy, which was a response to a key unmet need in the area of menopause. How was the product received in the market?

Ospemifence has been around in the USA for three years already. In the beginning of 2015 it was also approved by the EMA and Italy is the first market where we launched the product with an out-of-pocket strategy.

The reason this is such an important product is that people are living longer and longer and for women, this means that the majority of them spend more than a third of their lives post menopause. More than 70% of post menopause women suffer from atrophy of the vulva or vagina. This is a serious condition in that it causes dyspareunia (pain during sexual intercourse) and damages healthy relationships with their partners. Many women live in fear that their partners will not be satisfied and that their relationship might break down. It is a rather taboo subject and women and clinicians are not openly talking about it (e.g. EU Revive survey). The innovation thus comes from understanding this patient need and offering a solution that is non-estrogenic as women tend to be scared of estrogen, particularly in Italy. Ospemifene is the first oral, non-estrogenic drug that can significantly address the problem of VVA.

The first results we received after the launch were very encouraging and it is great to see that doctors are now starting to get patient feedback. It is one thing to hear the impact of a drug from us as a company, but another thing to hear the results from actual patients. Patients say that this product has truly changed their life and they are able to engage in intimate relationships again. In addition, KOL's have been very thankful, not just because we have launched this product but also because we have been supportive in diagnosing this condition.

Shionogi's portfolio is very diverse, covering infectious diseases, oncology, cardiovascular, CNS and women's health. What is the next step for the Italian market? Will you be introducing further women's health products or focus on other therapeutic areas as well?

In Italy, we are very much committed to helping women and clinicians start the conversation on various issues in women's health and find appropriate solutions to restore their healthy life and confidence. For example, last year we launched EVEs, an epidemiological study across Italy with

over 20 sites, studying the prevalence of VVA (vulgar and vaginal atrophy) and current practice of helping women with this condition. The aim is to raise awareness of our clinicians and find an approach with our doctors to solve this important health issue for women over the age of 50. The study will also have sites in Germany and Spain.

Importantly, Shionogi is investing in additional research programs in Italy, with three clinical studies in our new product development pipeline, which involve over 30 hospitals. Additionally, we will soon start with the market access strategy and collaboration early on with payers for our new specialist pipeline (chronic pain and anti-infective).

Finally, while we are investing in the Senshio LCM, we are also aiming at broadening our women's health portfolio through in-licensing of effective patient-friendly solutions. In May 2015, we have re-launched a Food Supplement with strong clinical evidence (Femal), which is addressing a strong need among women for non-hormonal solutions for menopausal symptoms.

The rest of our pipeline is going to be more specialist. We have a gram negative resistant antibiotic in development, for which we get a lot of support by governments to conduct research.

Furthermore, we are starting with clinical research for an additional very promising product in Italy. It is important for Shionogi to conduct clinical research in the country that we will be launching the product in, so we are fortunate to be collaborating with research centers all over Italy. We expect this product to launch in 2020 but we need to start now with our market access strategy to understand what will be required from the payers in order to get optimal access to this drug.

Shionogi has also developed a new drug that targets the side effect of constipation related to the consumption of opioids. The impact on patient life is amazing and we expect to start the market access program in Italy soon, we have an advisory board in Europe with two representatives from Italy and we expect to launch it in 2019.

Overall, we will focus on women's health in the first few years of our presence while working on the clinical research and market access strategy for our new specialist pipeline.

How easy or difficult has it been to navigate the regulatory environment in Italy?

AIFA has made important improvements. The timing for centralized approved drugs is much faster now. If you want to have reimbursement it naturally takes longer to go through the reimbursement process. However, the timelines for reimbursement have also been shortened from over a year roughly to six to nine months nowadays. I think a remaining challenge is the predominate regionalization in Italy. Because the national health system in Italy supports healthcare for

everybody, which is an admirable thing to do, it puts pressure on the available resources to reimburse innovative drugs. Nevertheless, things are moving in the right direction, which is encouraging.

What role do partnerships play for Shionogi, today and in the future?

The concept of partnerships is the essence of Shionogi's R&D strategy. We believe that good ideas no longer can just come from internal R&D. Thus, the company has really reached out to different companies, from small biotech to big pharma, to create various partnerships. Currently we have a partnership with the Cambridge Therapeutic Consortium as well as a big pharma player to develop an anti-flu drug. One of the best examples is our partnership in commercializing Crestor, where we partnered with AstraZeneca all over Europe.

Speaking of the Shionogi brand, how has it been perceived so far?

The brand stands for our values: accuracy, balance, honesty, and fairness and our passion for patients. Another thing that I have never heard of in a pharma company is humbleness. We are a humble pharma company in the sense that we listen and try to collaborate and support. The concept of honesty and being a fair partner to doctors, researchers, clinicians, and patients is what sets up apart. Clearly, we are at the beginning of our journey but the feedback that we got so far since our initial corporate event was very positive. The feedback from the experts is that we are different in that we are focused on patient needs and try to approach things in a different and innovative way.

What is your vision for the next three to five years?

I would like Shionogi to be seen as a company that is becoming an important patient-centric player, offering innovative solutions, particularly in the women's health arena but going forward in chronic pain and anti-infective area as well. By 2020, we should have our short- and medium-term pipeline in the market. I want Shionogi to be a partner for doctors and patients. Europe is a country for the long-term – you cannot invest in Europe and expect short-term results. Thus we are in Europe and in Italy with a long-term strategy.

Despite the fact that we are a public company, we are very much still a family, value-driven like company. Our values of accuracy, balance, honesty and fairness are really what characterize us and make us stand out among our competition.

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