Interview: Erin Gainer – CEO, HRA Pharma, France



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Erin Gainer, the CEO of HRA Pharma, reveals how the company has significantly grown its business in the fields of women's health and endocrinology over the past decade to become a leading European pharmaceutical company with a global product presence and local operations in 11 European countries. She goes on to talk about how they have transformed from a primarily R&D focused organization, to a full-fledged R&D and commercial pharmaceutical organization; and how HRA is at the forefront of making products available on an OTC basis, a key industry trend.

In 2009, you became CEO of HRA Pharma, a company specializing in women's health and endocrinology. How have you stamped your own vision on the direction of the company?

When I took over as CEO of HRA Pharma in 2009 the company was already on a successful growth path. We are an R&D driven organization and I myself have a R&D background. In 2009 we had a license-out R&D business model. One of the first strategic decisions I took was to develop our own commercial infrastructure. Our first presence outside of France was in Germany, and today HRA Pharma is a leading European pharmaceutical company with a global product presence and local operations in 11 European countries. Last year our turnover was 70 million euros (USD 74.02 million). This year our growth has accelerated. For the first half of 2015 our top-line sales were up by over 30 percent versus the first half of 2014. Over the past decade the company has significantly grown its business in the fields of women's health and endocrinology. We are able to serve patients' healthcare providers and pharmacists across much of Western Europe directly. We

have transformed from a primarily R&D focused organization, to a full-fledged R&D and commercial pharmaceutical organization, something which is rather rare for a company of our size.

My second key objective over the last six years has been to continue in our R&D drive to develop new and innovative products. We are not only interested in developing innovative medicines but also in ensuring that they are accessible to as broad a range of patients and consumers as possible. A key trend we see in the pharmaceutical industry when it comes to access, and something that HRA Pharma is at the forefront of today, is making products available on an OTC basis, i.e., without the need for a prescription. Innovative Rx-to-OTC switches of medicines is something that we have been successful with on two occasions, starting with *NorLevo*, an oral emergency contraception pill that can be taken up to three days after unprotected sex or contraceptive failure and more recently with *ellaOne,* an emergency contraception pill which contains 30 mg ulipristal acetate*.* We believe that moving forward, when you look at the pressures on pricing, the enhanced consumer access to information online and general patient awareness, what we call self-care medicine, medicine available directly in a pharmacy, is an area of high strategic interest and one where HRA Pharma is already well positioned.

Your ellaOne product received the Prestigious Nicholas Hall & Company Award for the most innovative European product to be introduced on the European market as a non-prescription product in 2015. What did this award mean for HRA Pharma?

Receiving such an external recognition was certainly rewarding and has helped to increase the visibility of the company. The *ellaOne* OTC switch was in itself a great achievement. The whole of the European Union, through the centralized procedure, has switched *ellaOne* to OTC. This was the first time that a centrally approved product was fully switched, something very innovative from a regulatory point of view. This category of emergency contraceptive OTC products had been categorized as an OTC product in a number of countries for a while – in France this happened 15 years ago. Yet there were a number of large European countries where, up until this *ellaOne* OTC switch, a prescription had been required, including Germany and Italy. When we speak of accessibility, due to this switch, we have now made this category of important products more readily available to women across numerous markets.

Is there not a danger of abuse now that such products are more readily available? How do you ensure that this remains a product for emergencies?

Numerous studies have been conducted and demonstrate that there is no abuse of these products taking place. In France, the UK, and the US, these products have been available for a number of

years and there has never been any sign of inappropriate behaviour. There are political undertones to this debate, but over the years it has been demonstrated that increasing the number of contraceptive options for women has only a positive impact on society. Ensuring that such products are available for women is good for public health as a whole, and all of the data that is available today converge to say that this is something important and beneficial for families and for women.

HRA Pharma is a market leader and pioneer in the area of female reproductive healthcare and is also active in endocrinology. With 15 percent of revenue invested in R&D, how would you describe your innovation strategy?

The starting point for all our R&D activities is unmet needs. We believe that we have created a unique positioning in terms of tackling neglected areas. Not neglected diseases per se, but areas that have been traditionally overlooked by other players in the pharmaceutical industry, emergency contraception being a good case in point. We have a strong understanding of women's healthcare and are able to identify neglected needs and then design and develop products that are focused and targeted on meeting these needs. From our pipeline, we still see significant opportunities in the contraceptive space. We are looking at alternative methods of administration, moving beyond the need to take a pill each day, by considering alterative dosage regimens. Beyond our focus on contraception, we are also active in the area of fertility. From a demographic point of view, we see a decline in fertility, with couples waiting longer and longer to have children. We have a number of projects internally looking at approaches to enhance the chances of pregnancy success.

Two years ago we conducted an internal review of our gynaecology-oncology activities, to identify unmet needs where we could make a difference. We know that oncology is a very broad and competitive field, yet in endocrinology, HRA Pharma has the only approved product for adrenal cancer. We have identified ovarian cancer as an area with a particularly high unmet need. Indeed, HRA Pharma acquired the IP for a cancer vaccine approach to ovarian cancer from a Dutch pharmaceutical company that has focused on women's health.

How do you explain the fact that Big Pharma has tended to neglect the area of women´s healthcare and how has this presented HRA Pharma with an opportunity?

There is a perception that women´s health is a declining market. The contraception market remains large, valued at over seven billion dollars globally. Yet it is perceived as being a market that is shrinking in value as it becomes increasingly genericised, reducing the room for future blockbusters. The fact that big pharma is no longer so engaged in women's health has created

opportunities for companies that are very focused on developing innovative approaches in this area.

How would you describe your international strategy and what role is there in it for partnerships and collaborations?

HRA Pharma has its headquarters in France, but we are an international company. We are not only a European company. While Europe does account for the majority of our sales, our products are marketed in over 80 companies across the world. Our commercial strategy is a combination of our own infrastructure in Western Europe alongside a network of international distributors and partners. The next big stage in the evolution of our business will be to establish a stronger presence in the US. America accounts for only a small percentage of our sales today. We have a number of FDA-approved products, alongside a couple of products in our pipeline with great US potential. Over the next three to five years breaking through in the US market will be a major objective.

Collaborations are core to our business model: from our research activities, through the supply chain, and even our commercial and marketing strategy. Building relationships, forging longstanding partnerships and fruitful collaborations is a part of our DNA. We have recently created our own incubator and have a team dedicated to reaching out to academics and start-up entrepreneurs. The key is to be proactive. *Dream, dare, share* is our slogan and by sharing we are referring to the partnerships that we foster and develop.

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