Interview with Adrienne M. de Waal , Country Manager, Ipsen Farmaceutica BV

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Within our reports we typically like to highlight the personalities of the industry and the stories behind the executives that we meet. As you are still relatively new to Ipsen, what has been the professional trajectory that has brought you to the head of this local affiliate?

I came here out of an interest for the Dutch market. In my previous company I worked in the Netherlands as well as throughout the rest of Europe. I headed the new product introduction team in “new” Europe including Russia, Middle East parts of Africa – a very large region of partly emerging markets. It was a very international job and due to restructuring in my organization in which launch procedures were more centralized, my position was abandoned. After being offered a position that did not necessarily spark my interest, I decided to leave behind the international travel, hotels, and airport lounge culture and come back home to spend the last part of my career in the local market.

Has your interest in the Dutch market sustained itself in contrast to experience in emerging markets? What have you learned from those markets that you are now applying to the Netherlands?

Markets such as Russia, Turkey, and the Middle East are very interesting with their high growth rates, interest in new products, and also demand for products that already existed in other European countries. There is lots of growth, new initiatives, and progress in professionalism as well as eagerness to seek best practices from other markets.

The learning that I took from those markets and bring to my new role is that innovation is also present in small things for small budgets, that through customer focus is a mindset and relationship is an art. Despite the fact that the emerging markets are overloaded of generics, branded or specialty products still have a strong presence. So perhaps we should not be afraid that generics have only a damaging effect on innovation; perhaps we should be more creative in finding solutions.

We are hearing quite the opposite from Nefarma member companies – that there is not always space to bring innovation to market in the Netherlands. Are you finding that this is a receptive market to Ipsen innovation?

It first has to be clear what the definition of innovation is. Is it pure product innovation? Or is it innovation in a way to approach customers and to enter a market?

If we begin with technical innovation as such, then it is tough. Our company does have a very innovative reimbursed orphan drug product on the market. The issue we encounter, however, is that there is a lot of hesitation from physicians to start using it. In this case we did not experience the trouble of getting innovation to market, but instead to get it actually marketed and overcome the conservatism. So, unfortunately, still an access issue.

We do not have any products at this time going through registration procedures so we are not “suffering” at this moment by the serious delay in filing and/or reimbursement approvals. As soon as we have new products to register then surely those issues will come.

What is the orphan drug on the market and what does it treat?

It is called Increlex and is a new treatment for children who do not react to traditional growth hormones. It treats severe IGF-1 deficiency.

Ipsen’s global strategy focuses on a three-pronged approach: grow in the traditional therapeutic lines of oncology, neurology, endocrinology, and hematology; expand into large markets such as the US and China; and further develop primary care market. Considering that the Netherlands is a small country with a rather unprofitable primary care market for R&D based companies, two of the three growth strategies do not apply here. What is the strategic role that the Netherlands plays for Ipsen globally?

Ipsen originally started in France as a family owned company with primary care as start-up business. The company extended to other markets and it was a strategic decision to shift the balance from primary to specialty care. It is the core focus in most countries now.

A few exceptions to the above are found in markets such as Eastern Europe or China given their different dynamics and the potential growth for primary care.

We do indeed focus on oncology, neurology, and endocrinology in our portfolio. Hematology is not present yet; it is more of a future-oriented therapeutic line.

We see a lot of companies moving into oncology as a core therapeutic priority for the future and have learned that there are over 300 oncology compounds in various phases of development. What is the added value that you see Ipsen offering in oncology in the future?

Our role in oncology is divers. In the field of Neuro Endocrine Tumors (NET) we are highly experienced and present with Somatuline, a somatostatin analogue. Strategically we position this indication in our endocrinology franchise. In our oncology franchise we have Pamorelin, a LHRH agonist for the treatment of prostate cancer. This market is pretty satisfied and mature. Our brand had a late entrance and is still relatively unknown. In contrast to other Ipsen markets where the brand (named differently; Decapeptyl) has been introduced early and is leading. Despite the fact that we have a small share at the moment we are highly motivated to build a broader presence as we have identified this area as a strategic pillar for future new product introduction.

What do you consider your flagship lines to be here?

Our flagships are in neurology with Dysport and endocrinology with the already mentioned Somatuline. For the treatment of neurological indications like f.i. spasticity and dystonia we have a botulin toxin A with a strong position and substantial research and development programs. The other focus is endocrinology with three products marketed. Two in growth disorders in children. We offer a unique continuum in treatment with both a basic growth hormone therapy and the new option for severe IGF-1 deficient patients with our orphan drug. The other one is for specific neuro endocrine disorders targeting the previously mentioned endocrine tumors and acromegaly. These diseases are difficult to diagnose and characterized by small patient numbers with a high need for specialized treatment and patient care.

Ipsen does not have any products in the registration process yet. However, as you invest in the future and prepare to bring more products to market do you consider yourselves to be in an advantageous position because you can observe and, ultimately, learn from the regulatory difficulties that competitor companies are currently going through?

I am not sure if it is a pro or con, that we are not registering anything now… but it is certain that we can learn from other experiences. We have time to be well prepared. Demands like cost-effectiveness and pharmacoeconomic proof certainly will be driving part of the composition of new dossiers. We highlight these needs to our corporate organization and pro-actively try to define as much as possible what characteristics needs to be built into programs from scratch. There is a certain limitation as to what we can do given that the direction of the research is not generated from the Netherlands.

In our market we work to optimize the value of our current specialty products. And new products are essential for sustainable growth. Not all output of our rich research pipeline will stay with us. Some innovative drugs do or will not fit in our strategic focus and are or will be licensed out to other companies with a better strategic match. If our research does bring a molecule that treats diabetes it could go to 'big pharma'. We are always looking for partners and very open to debate possibilities. For now we have our focus defined and will not introduce products that need a whole new franchise around it. We are better off generating some cash flow and continue the investment to detect solutions that enrich treatment options in our current indications.

While research strategy is implemented from corporate headquarters, the Netherlands is endowed with a very cutting-edge research culture and infrastructure through its various university hospitals and bioscience parks. To what extent do you try to serve as an integrator between the corporate research initiatives and the local industry strengths?

Very limited to be honest. We are a local affiliate and we are definitely not in the driver's seat for research. But we do have a medical department focused on Phase 3 and 4 developments. They are in touch with key opinion leaders who propose suggestions and establish links with our corporate headquarters. Erasmus University, for example, is very top end with endocrinology research and closely worked together with Ipsen corporate research people on early developments. Researchers are sometimes more familiar with the Ipsen's corporate research agenda than we as local Ipsen staff.

As the financial books close on November today and we head into the final month of 2010, how has the yearly performance of this affiliate gone so far?

Ipsen in the Netherlands is doing well and exceeding the 2010 target showing strong double digit growth from a volume perspective. Bringing in the Euros and cents, although still ahead of budget, becomes more and more challenging with the ongoing and significant price decreases we have to absorb. One product lost 33% of its price in April this year and another 25% in October. Also parallel trade impacts our local performance. We have an ambitious plan for 20-25% volume growth next year, but, due to the price decreases we almost do not show any value and profit growth. Despite this we still see growth opportunities in the Netherlands and Ipsen corporate management is supportive to maintain and even increase local investments here.

More autonomy for the Dutch affiliate demonstrates the corporate belief in these opportunities. As the Dutch affiliate has always been a part of a larger geographical entity, probably the real potential has never been fully explored. It is our ambition to serve patients with our focus on value adding treatments and programs and positively contribute to the health care environment.

The "other" innovation that you referenced earlier draws on Ipsen's corporate motto – "Innovation for patient care." How have you creatively innovated patient care through your

outreach, communication, and stakeholder management activities?

We are a small organization with limited budgets so we must be creative to develop meaningful solutions. We developed specific home-care programs for patients. By now more common, but still important nevertheless, are home services in which nurses go to patients' homes with the medication to administer injections, give treatment follow-up, and report feedback to the doctor. We strive to be as supportive to the patient as possible. From a patient perspective it is very customer friendly to have dedicated home care, compared to the alternative of additional visits to a GP or the hospital. Innovation from this perspective translates in being very service oriented. We focus on the new technologies with many of our services being web-based. We try to be a bit more modern in the way we communicate.

Of course we try to be as innovative as possible with our medical devices so that they are user friendly and also appropriate for self administration.

We also cooperate in specific medical projects with doctors. In one we facilitate the construction of a database to collect historical and current disease and treatment information for a very rare and genetically inherited disease. By building this database and analyzing the information, the doctor can deduct the best treatment. Future patients will benefit from this information and receive the best treatment right from the start. The set up of this database has been judged as innovation for patients; without it they are treated by 'trial and error' now they receive best options.

The rich pipeline, the advantage of learning from other companies' registration experience for when more of Ipsen's products do hit the market, and new management autonomy all signal a very bright future for this affiliate. What are your ambitions for this Dutch affiliate going forward? Where do you see it being positioned in 5-7 years?

In 5-7 years we will have optimized the position of our current portfolio and the size of our local business. In line with this all of our business units will need new and follow-up products to make the growth sustainable. Patents are running out and competitive products, generics or biosimilars will take over.

We do appreciate, of course, that society needs savings to manage health care cots. But the process has to be fair and transparent. Even before the patent issue is at stake we already experienced a very tough case with an insurance company. Related biologicals and biosimilars were clustered and pushed into the preference policy concept were only one product will be selected and reimbursed (common now for standard generics). A therapy switch for all involved, chronically treated patients was at stake. This would have led to a lot of uncertainties, possible safety issues and a practical and logistical mess. As an organization with a focus on patient safety we strongly objected and decided not bid because we totally, fully, and principally disagreed with the process. More companies rightfully did so and up to now the whole theme has been delayed to

further notice.

What have been the challenges for you personally and professionally to reach an executive role as a woman in male-prevalent industry?

This is an interesting issue which is not specific to just pharmaceutical business but to the Dutch professional environment as a whole. In the Netherlands, women who decide to have children often stop working for some years or switch to a part time job, and end up with a broken or blocked career. We might look like a pretty modern country in several, even controversial perspectives, when it comes to appointing part-time directors there is reluctance and conservatism.

As for sure there is no lack of highly qualified women in the pharmaceutical industry. You will find them in all segments like sales, project and product management, regulatory affairs, and research. They are just missing in the boardroom. It is important to find a solution because we are losing too many talents and with that actually also a lot of investments. Time for innovative or more flexible management models I would say.

What would be your final message to our readers about Ipsen in the Netherlands and its ongoing agenda to contribute to the development of the pharmaceutical industry in this country?

My hope is that we, as a pharmaceutical industry, will improve our image. Right now this awfully negative and the general public are skeptical. Very different from, for instance, Belgium in which the industry is seen as a positive contributor to the economy, innovation and society. I hope that in the future, the contribution of the pharmaceutical industry will be more appreciated from the perspective that our drugs bring solutions, high quality and economical beneficial treatments and value to patients helping them to live a healthier or longer life. We invest a lot of energy, efforts, and intelligence in our products with a real and honest intention to improve healthcare. In my conversations with researchers, people on corporate level and day to day colleagues, I know that this industry is full of professionals who are highly motivated by the fact that they can bring something of value to sick patients, something impact full. However this is not always acknowledged in the media and general public, where we often are pictured as just money makers. My hope is that we at Ipsen can contribute to a positive appreciation of the pharmaceutical industry and convince society that we are a critical partner in improving healthcare; something that will become increasingly important with ageing populations.

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