Interview: Han Brouwer â?? General Manager, Actelion Netherlands

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Han Brouwer, General Manager for Actelion in the Netherlands, explains how Opsumitâ??s successful market launch has strengthened Actelionâ??s leadership position in the pulmonary arterial hypertension (PAH) field. He calls for a more comprehensive approach to the disease life cycle and for more transparency during market access procedures while the Dutch healthcare system is undergoing a deep transformation of its organizational and data management models.

When we met in 2011, you explained how you started the Dutch affiliate from scratch and turned it into a successful organization while keeping a young, dynamic and entrepreneurial approach to business. How has the Dutch affiliate evolved recently?

In the last five years we have matured to a team of 30 collaborators, almost equally split between field and office responsibilities. The share of people working in the office may seem surprisingly high compared to bigger pharmaceutical companiesâ?? affiliates. However, this is mainly related to the fact that we are still a small company and we need in-house resources for regulatory affairs, pharmaco-vigiliance, finance and marketing. From a sales point of view, we are doing very well, close to $33 million in revenues in 2015.

The launch of our new product Opsumit has been extremely successful. Opsumit is a new drug to treat adults with pulmonary arterial hypertension (PAH): a chronic, progressive and debilitating disease that can lead to lung transplantation or in the worst case, death.

As a consequence of the clinical results that our long-term study data revealed, we initiated a â??Change Perspectiveâ?• campaign, simultaneous to the Opsumit launch. This campaign was designed as a wake-up call to engage various stakeholders towards considering new strategic parameters as well as adopting new approaches to patient treatment in the context of PAH.

This success clearly highlights the exceptional work of our researchers in Switzerland over the past two decades. It is the first time that a company was able to present clinical trial results with long-term outcome data for the first time, which is absolutely remarkable. Furthermore, recently GRIPHON study results were published in the New England Journal of Medicine. This largest outcome trial ever conducted in PAH again shows long-term outcome data.

The outcomes of these trials are particularly positive and promising, as they have been able to showcase undisputable benefits with respect to mortality and morbidity.

What has been the impact of this long-term outcome data on public authorities, in terms of pricing and reimbursement?

Unfortunately, long-term outcome results donâ??t have the expected impact on public authorities regarding pricing and reimbursement procedures, as they still rely on a system that is mainly based on preset criteria, which cannot be changed during the evaluation process. The current evaluation system in the Netherlands is primarily based on short-term improvements without taking into account long-term results brought forward by companies like Actelion.

Furthermore, I am increasingly concerned by the decrease of transparency in the reimbursement process, including authoritiesâ?? activities that seem to contravene current rules and regulations. Despite the praise Dutch authorities receive regarding openness to negotiation, these negotiations remain out of the public eye and are thus non-transparent.

However, we really need consistent transparency in order for the industry to be able to understand and fulfill the requirements for drug approval and reimbursement.

If the overall process and its requirements are clear enough, companies can simply follow the rules and would not need an opportunity to negotiate in the first place. Negotiations should not become the new standard nor influence reimbursement procedures of drugs that are displaying satisfying clinical trial results.

Finally, recent drugs have frequently received conditional approvals, which creates substantial restrictions. Under a conditional approval pharmaceutical companies have to lower their prices, but they also have to set up a database and collect data over a period of one, three or even five years! Public authorities will then review this data and adjust the price of the treatment; sometimes they even eliminate the drugs completely! Conditional approvals create uncertainty in a way that they are fundamentally changing the approval strategy historically adopted by pharmaceutical companies. This can potentially result in a lack of incentives for pharmaceutical companies to obtain EMA approval local authorities can decide to eliminate the product due to their cost-containment agenda if in few years.

What is your position on the initiative Dutch Minister of Health Ms. Schippers has been championing to have joint negotiations of orphan drug prices between multiple EU member states?

The Minister is indeed pushing for a joint approach within multiple EU states regarding orphan drug pricing. Nevertheless, only ten percent of the overall drug spending in the Netherlands is related to orphan drugs. From an economic point of view, it seems more urgent to focus on the other 90

percent. Furthermore, this initiative seems to be in conflict with our current laws and regulations, based on established maximum prices and basket of reference countries.

Recent feedback from European regulators also shows that they are now more cautious in the way they want to move forward on this initiative.

Even if it may appear as a good initiative at first, the government should maybe concentrate its efforts on the drugs that represent 90 percent of our drug bill, especially if they want to be truly efficient in cost-saving.

The Dutch healthcare system is currently undergoing a structural transformation; based on a new re-partition of activities within academic and local care centers. How do you see this situation evolving and what will be the impact for both patients and physicians?

Following an economy-of-scale approach and a high-volume strategy, academic centers are taking over local and smaller peripheral centers in order to gain more leverage to negotiate with health insurers.

Nevertheless, the effect of this new organization will go far beyond the economic side, as the most complicated patients will be sent to academic centers while patients admitted for more conventional diseases will only remain in peripheral centers. Academic specialists will thus be forced to spend a certain amount of time in these peripheral centers, greatly changing the current breakdown of their responsibilities. As a matter of fact, they will have less time to conduct cutting-edge clinical trials or student training, while the time allocated to patient care will simultaneously increase. While overall care will improve due to more committed experts, future scientific and academic developments will suffer under this new paradigm. Adoption of new technologies and data monitoring will probably be the key success factors to optimize this new organization in the most efficient manner.

I expect that the transformation in patient distribution within peripheral and academic centers will tremendously change the role of doctors, transform organizations and also impact pay-for-performance models. Yet, these models are not well enough developed in the Netherlands, where we remain mainly focused on volume and prices.

Bringing the Dutch healthcare system truly into the 21st century could mainly rely on process innovation, as more patients would be able to receive treatments in their own homes due to new medicines and patient data monitoring for instance. Being a patient-centric company, Actelion has been a pioneer, particularly in terms of cooperation with patients and PAH experts, in maximising medical return. What kind of innovation has been already introduced by this Actelion affiliate and could benefit and inspire the overall â??Dutch healthcare system of the futureâ?•?

In a joint effort with Actelion International and numerous experts in the PAH field, we have developed a cutting-edge PAH data management system. Although we already have access to an incredible amount of data we are still far away from reaching the â??healthcare system of the futureâ?•. To move in this direction, it is crucial that companies like Actelion launch their own initiatives. Unfortunately, these efforts are too isolated to really influence and improve the overall system. In general, there is a lack of strategic direction on this matter that prevents us from transforming data gathering into effective data management.

All the initiatives coming from either smaller biotech companies or multinational pharmaceutical companies will never conflate by themselves to form a strategic policy. Thus, the Minister is currently gathering ideas to organize this revolution, which is of course a very appreciated initiative. Nevertheless, the industry needs strong and clear leadership that will allow the country to effectively

reach this new era.

The company is currently advancing its specialty immunology portfolio and accelerating its clinical development efforts in the field of immunological disorders. How do you ensure the Dutch affiliate will be ready to successfully take this strategic move?

The Dutch affiliate already holds several key people who have worked in the immunology sector for an extensive period of time, including myself. Thus, we already have in-house knowledge about immunology products. This knowledge will be extremely valuable to smoothly broaden our product portfolio when the time comes.

Actelionâ??s current immunology compounds are extremely interesting and promising. Nevertheless, we do not want to be too optimistic before these compounds officially reach the market. Fortunately, we know that the wait is always worth it for Actelionâ??s products!

What would you identify as the next big challenge that should draw the attention of healthcare experts and providers?

We absolutely need to deepen our management of the disease life cycle. We have to acknowledge that patients face different needs at different phases of their sickness.

We need to approach patient treatment holistically, taking into account aspects that go beyond the therapeutic treatment, such as socio-economic factors, and psychological or nutritional disease consequences. As a result of efficient data management, we should be able to predict that a patient with PAH showing certain symptoms will also need socio-economic support due to the inability to work for example. We need to provide patients with comprehensive support throughout the disease treatment period to maximize therapeutic effects. External factors in relations to specific diseases can create social costs and we need to improve our efficiency in the way we integrate these factors in order to either increase our savings or to improve therapeutic impacts of our treatment approach.

Furthermore, I fully agree with the Minister of Health regarding the importance of strengthening patient participation. However, as pharmaceutical companies in the Netherlands are not allowed to engage patients before they actively approach us, we also need to take into account the legal consequences of this effort.

How do you see the Dutch affiliate evolving in the upcoming years?

As a result of the increasing requirements from the Ministry of Health and the Federation of University Centers, we will probably end up with five PAH Experts Centers in the Netherlands. Their efficiency will vastly increase due to our data management initiative, helping to design better guidelines to improve daily practices provided in other supporting centers.

In the upcoming years we also want to introduce and implement support tools in order to shorten diagnosis timelines and engage patients as early as possible and most importantly, before disease progression. We will remain market leader for PAH, as we already represent more than 90% of total market sales in this field.

Moreover, I hope that we will have the opportunity to explore new therapeutic areas and contribute to other unmet medical needs. My biggest wish is to become a game-changer in disease life cycle management. Lastly, I sincerely desire that the Dutch healthcare system takes a step back from the current 100% cost-containment philosophy while our decision-makers increasingly look for adding quality to the provided care.

On the personal side, what keeps you motivated?

Actelionâ??s success story has been built on trust and teamwork. We are still a very entrepreneurship-driven company, even if we pursue a global strategy. We are as energetic, entrepreneurial, and drug-discovery-focused as we were 15 years ago. We are passionate fighters when it comes to improving patientsâ?? lives!

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