Interview: Maurits Huigen â?? General Manager, Chiesi, the Netherlands

24.09.2015

Tags:

Chiesi, Holland, The Netherlands, r&d, research and development, partnerships, reimbursements, innovation, CSR, healthcare, investment, pricing

Chiesi is preparing to market two first in class products: the first approved stem cell treatment in Europe, and the first approved gene-therapy, developed in the Netherlands by partner UniQure. General Manager Nether Maurits Huigen discusses the challenges his affiliate is facing to bringing these pioneering products to market, along with the importance of holding onto the companyâ??s heritage while developing a new highly innovative identity.

Chiesi is in the process of introducing two first in class therapies; how much progress have you made with commercializing Glybera and Holoclar in the Netherlands?

Holoclar is the result of a collaboration between Chiesi and the University of Modena, so we see it as a true Chiesi development as opposed to Glybera, which we are commercializing in Europe on behalf of our Dutch partner uniQure.

Holoclar is a very new and highly innovative treatment that can restore the eyesight of patients with severe corneal damage and is the first stem cell therapy to be approved by the EMA. This is a highly significant achievement, because Holoclar is much more than just a molecular compound; it is a personalized treatment where the entire process has been approved. The patient needs to be admitted at a center with specialized stem cell capabilities to collect samples of their own cells, the cells then need to be transported to the laboratory in Modena where they can be cultured, and, in the end, you have a tissue that has to be transported back to the treatment center to be implanted in the patient. Overall, this is a logistically complex process with a lot of steps, yet it has been registered and approved as an orphan drug.

At the current stage, we are working with the expert centers to assess the potential size of the market and to develop the expert centers where these treatments will be administered; we are considering developing up to three for Holoclar. We must collaborate with other stakeholders to build

experience in this uncharted area, and there are special requirements that have been set for the treatment centers to ensure all risks are minimized at present. We will be working closely with the experts and authorities to build a case for reimbursement as we proceed. The challenge is that as an entirely new treatment, it doesnâ??t fit within the existing processes and budgets, meaning that new structures and regulatory protocols are having to be developed; itâ??s an adventure for everyone involved, and any delays are purely due to the advanced level of this innovation.

Glybera has also created similar challenges, as it is the first gene-therapy product to be approved by the EMA and FDA, and is a treatment for the orphan disease lipoprotein lipase deficiency. The patient population for this disease is extremely small, perhaps up to twenty patients in the Netherlands, but as a gene-therapy with the potential to provide a lifetime cure for this disease, Glybera is effectively a one time treatment, making it a very interesting case from a pricing and reimbursement point of view as the one-time purchase price must be very high. However, due to the extremely small patient population size we have relatively limited clinical data and experience and are currently developing a patient registry and collecting additional clinical evidence. At present, there are still some uncertainties around how to value such a treatment from a reimbursement perspective.

The level of innovation represented by these products is phenomenal, and having to take a leadership position in helping to develop the new regulatory and reimbursement protocols and processes for these drugs is extremely valuable experience for Chiesi. From our heritage as leaders in the respiratory field, we are now emerging as leaders in regenerative medicine and an essential partner in gene-therapy, yet we are still doing things the Chiesi way; simply and honestly talking with our counterparts and keeping the focus of the conversation on our mutual interest: patient welfare.

In terms of that culture, how are you working to show the Dutch community who Chiesi is in the Netherlands today?

What we have been trying to do for eight years now is to go beyond selling pharmaceutical treatments and do our best to ensure that the patients in the fields we work within receive the best possible treatment. The main vision behind Chiesiâ??s innovation is not only the creation of new chemical entities; we invest significantly in studying where in the body the drug should be optimally placed to maximize the effectiveness of an API, while minimizing adverse effects, and, as such, we focus on innovation in formulation and delivery, a good example being the Chiesi Modulite inhaler. Innovation on the overall product level, as opposed to focusing solely on developing new chemical entities, is effective in terms of investment efficiency, and, as such, the added clinical value of such innovative products are also quite efficient from a pricing and reimbursement perspective.

However, we take this mentality a step further and also look for opportunities to help care for our patients on the prevention and care side. Chiesi Netherlands created the â??clean air for everyoneâ?• CSR initiative, which has grown substantially, to the point that we decided it needed to be transformed into an actual independent foundation; through this platform, Chiesi has worked to improve air quality in the Netherlands to prevent respiratory complications, as air pollution is a major cause of episodes of respiratory distress. We also operate Chiesi College, a professional education and service initiative working to improve diagnostic and treatment processes in the respiratory and neonatology areas at the physician level. In terms of the value Chiesi brings to patients, our goal is to be an overall healthcare partner helping to improve patient welfare in whatever ways we can, and if one of those ways is by supplying them with pharmaceutical products, then we can do that as well.

Talking about â??comprehensive healthcare solutionsâ?? is popular in the pharmaceutical industry; however, Chiesi may be the only one to try to include environmental policy.

Comparing Chiesiâ??s mentality to other companies that I am familiar with, there is always a lot of talk about such ideas, but action always lags behind. As a privately owned and family controlled company, Chiesi is able to prioritize such initiatives and act decisively; once started, you can learn from experience and develop and refine such projects, and, as we continue to improve, we build up unique skill sets that can create a competitive advantage. In the beginning, some respond to our effort with cynicism, arguing that a pharmaceutical company should stick with what they know, but now most stakeholders realize that cooperation and mutual collaboration are the way forward.

The Netherlands presents an interesting learning curve, and the market is somewhat like a smaller version of the UK, where the market is also in a very advanced stage. At the group level, we foresee the possibility that we may need to move away from the traditional â??share of voiceâ?? marketing model. The Netherlands was used as a test site for some new marketing initiatives. There is certainly the potential that some of these might be exported other affiliates.

Chiesi R&D spending reached a record high of EUR 237 million in 2014, almost 18 percent of total sales; what are some of they key R&D initiatives that Chiesi is pursuing here in the Netherlands?

We are investing heavily in another first in class treatment for the respiratory market, a triple combination product, where we now have a combination of an inhaled steroid with two bronchodilators, a long acting beta agonist, and a muscarinic antagonist. Several other companies are working on similar combination products, as patients have a strong desire and need for an effective all-in-one shot treatment, and at Chiesi we are developing it using our proprietary Modulite inhaler technology, which results in a much smaller particle size of the inhaled product so that it can penetrate more deeply, acting effectively with a smaller amount of API.

Furthermore, we partner a lot with the scientific community in general, and support non-product related research, relating to topics that seek to optimize treatment for patients overall. In a broad sense, we try to cooperate with all partners that have a role in our patientâ??s welfare, which as I mentioned earlier can include environmental authorities in conjunction with our â??clean air for everyoneâ?• CSR initiative, as well as physicians themselves through Chiesi College, and young scientists and researchers through organizations like the national respiratory society.

What is Chiesi Netherlands doing to celebrate â??80 years of people and ideas for innovation in healthcareâ???

This has been a special year for Chiesi to think about the future of the company, particularly as with our 2014 full acquisition of Cornerstone Therapeutics in the US we are now truly a global company for the first time. In developing our plans, we are embracing this new identity, while recognizing the importance of Chiesiâ??s history and culture and are working to ensure that the foundation for the future is built upon the strong roots of our organization. As a part of this, we have organized an array of events not just for our employees, but also for their families, and as a whole we are extremely proud to be a part of this unique organization and are very excited regarding Chiesiâ??s future.

Where would you like to take Chiesi Netherlands by 2020?

Iâ??d like to enhance and consolidate our partnerships with the therapeutic communities we work with. In terms of strategic planning, we have the target to double our presence in the Netherlands over the next five years. We will do this while preserving our identity, building on the roots of the Chiesi organization, doing things the Chiesi way and avoiding comparing ourselves too much to the pharmaceutical industry in general.

What do you see as some of the possibilities for healthcare reform at the EU level, and which do you expect the Dutch government will pursue in 2016?

The Netherlands has the council of Europe presidency next year, and given the recent announcement regarding and initiative for the Netherlands and Belgium to jointly purchase orphan drugs, it appears that the intention is to raise the issue of orphan drug pricing at the EU level. There will likely be other countries that support such an initiative and seek to cooperate, however there will certainly be a variety of opinions on the subject.

Overall, it is important to recognize that the pharmaceutical industryâ??s public perception is defined at present by behaviors of certain companies in the past, while the current behavior of the industry has evolved substantially. Also, while healthcare spending certainly should be contained, pharmaceutical spending represents only seven to nine percent of healthcare spending in the Netherlands and drug prices have been drastically reduced over the past five to ten years; given the highly genericized nature of the market, the potential savings from reducing spending on high priced drugs are very minimal when compared to the overall budget. Overall, the industry has accepted a mutual obligation to try to keep costs under control, and in fact by bringing innovation to market we help reduce spending on non-pharmaceutical items like surgery resulting from complications of a chronic disease. The Netherlands does recognize the value of this innovation for the most part, which is an important positive, but I think it is important that actors across Europe work to see the pharmaceutical industry as a partner in healthcare instead of a budgetary enemy, and focus on reducing spending in other areas of healthcare as well as in the pharmaceuticals budget; at the same time, the industry needs to, and largely has, accepted the need to keep pharmaceutical prices reasonable and proportion to their clinical value, instead of seeking to charge the highest possible price.

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