

Interview with Maurits Huigen, General Manager, Chiesi Pharmaceuticals BV

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The Dutch affiliate of Chiesi was established in 2007 when many changes were occurring in the local industry. The new healthcare system policy went into effect and the market was shifting towards a cost-containment structure. What drove Chiesi's decision to start-up in the Netherlands?

Our respiratory product, Foster, was one of the main drivers for establishing an affiliate in Holland. Some Chiesi products were already on the market, in more niche areas, through partnership with relevant local partners. Foster was our primary commercial driver and by integrating the licensed out products, we had an interesting portfolio to start an affiliate. The Netherlands was, in fact, one of the first countries where Chiesi established a start-up affiliate.

With your current management team you reorganized the affiliate to manage its expansion and to prepare for the rapidly changing pharmaceutical market in the Netherlands. In light of these changes, how have today's objectives and goals evolved since 2007?

I took over as General Manager in 2009 and the classic organizational issues came by. As with any fast growing company with a strong entrepreneurial behavior and a lot happening, our primary focus was on structure and processes. We wanted to restructure the organization and our processes to control our growth and to adapt ourselves to the changing healthcare environment.

Not too many things have changed in terms of our overall ambitions. But of all the potential market changes that we identify, we are assessing thoroughly which ones will be the structural changes on which we have to adapt our business model. The most relevant change today is the rapid decline of individual prescription behavior of healthcare professionals. The new framework moving forward in the primary care segment is shifting towards care groups of general practitioners (GPs). They are combining efforts and decision making processes to secure their role within the healthcare system dynamics. Health insurance companies are expected to take the driver's seat of a more market driven healthcare system and they are coming to discover how to best fill in their new role. This is all part of the new healthcare system.

Some measurements and activities came along such as the preferential policy – more or less a tender system – in which health insurance companies decide on the choice of preferred products based on a public price list. Others, however, opt for an –under the table– (non-public) tender system. Overall, the preference policy has been affecting mainly the generic markets, although some pilots have come by to move the system forward to therapeutic substitution. For the innovative pharmaceutical industry, especially in primary care markets, you can imagine that the GP care groups being formed are quite relevant in changing our business model from the traditional detailing

and sales approach to a more complex sales and marketing attitude. It is not always the individual doctor anymore, but a group of doctors who decide on choosing a group of products within a therapeutic class. Formularies, guidelines and health insurance company policies certainly affect this decision making process of the physicians.

Chiesi experienced very fast growth since it started. Year-on-year growth from 2008 to 2009 exceeded 180%. That is very impressive, but also typical of a new company penetrating a new market. In addition to Foster, what drove the success?

We have also been very successful with Bramitob – a tobramycin nebulization solution for the treatment of chronic lung infections with *Pseudomonas aeruginosa* in patients with cystic fibrosis (CF). The company was established in 2007 but the first two products were launched in early 2008, followed by Curosurf for the treatment of respiratory distress symptom (RDS) in premature babies. Curosurf was one of the products we took back from our partner Nycomed.

Having just broken into the market, your foundation of products can be seen as a reliable platform for the next several years. What are your realistic growth expectations going forward?

I believe that we will continue to grow with our respiratory products Foster and Atimos as our main drivers. Chiesi is quite good from an innovative point of view in the respiratory device area. Innovation in the combination of well proven – and new chemical entities with respiratory devices are one the unique properties of this Chiesi Group – we excel at combining the device and molecule to optimize treatment of airway diseases. With inhalation technology driven innovations you can target the disease with the right molecule. It varies from the disease itself, the location of the disease process and the location of the relevant receptor for the molecule how to target the molecule in the right way to optimize efficacy of the treatment and minimize side effects. I think it is a great asset of the company.

With Foster, we will continue to grow and the Next[®] dry powder inhaler will be launched within two years. It is a line extension and we are waiting for the COPD and pediatric indications. We also expect to expand our neonatal product portfolio in due time, so overall the scenario looks quite good. Within cystic fibrosis the product Bramitob is growing quite well, although the inhaled anti-biotic market is becoming quite crowded. But the foundation for success in Holland has been created. With our current commercial network and established partnerships and market share within the respiratory, CF and neonatal markets we serve, , I am confident that our current five products will all continue to grow. But now it is also time to look ahead at business development opportunities for 2012, 2013, and beyond.

The Netherlands is known for its regulatory hurdles that impose long lead times to get innovative products to market. With a niche area of pathologies in the Netherlands all of which you already have products on the market, do you consider yourself more favorably positioned than other larger competitors?

That is something that we definitely try to convince our people about. We are aware of what is going around in the industry. We know the stories about mergers, patent expirations, big job cuts in sales force areas. What you see in general are the dynamics of a declining market, while we here are a fast growing focused company. Our current network and continuous focus on and expertise in our key therapeutic areas may be of benefit to us in creating access to market also for our future products.

What I am really pleased about is that we have managed to have a proper penetration in respiratory, CF, and neonatology markets – the strategic focus areas for Chiesi. It speaks to your capabilities as a company.

On the other end, the Netherlands is also known for having active medical and pharmaceutical communities supported by strong research infrastructure. What types of local partnerships have helped Chiesi establish its position here?

We have spent considerable time strategizing this because it fits into the holistic vision of the Chiesi Group to do more than only sell and market our products. We try to establish partnerships, in the broader sense of the word. We have worked for instance quite closely with associations such as the Dutch CF Association, the Dutch Asthma Foundation and Lung Alliance Netherlands. We are one of the main sponsors of the Netherlands Respiratory Society which was founded two years ago and tasked with elevating scientific efforts in Holland to play a greater role in the global respiratory research area. Together with the NRS we have initiated a young researcher award for the NRS. We also support the neonatal community in leveraging local expertise by facilitating neonatal fellow meetings and an award to inspire the young talented researchers. In addition to supporting these associations in a scientific way, we are active with professional associations amongst relevant new industry stakeholders. Last year we began relationship building efforts with governmental and regulatory bodies by supporting a Healthcare Platform to liaise government and industry. The aim is for both bodies to learn from and understand each other.

Is this active integration across the value chain typical of Chiesi in other markets, or is it a unique Dutch approach?

I know that most Chiesi affiliates work hard to achieve this holistic approach. Chiesi has the strategic vision across her defined therapeutic areas. We really try to serve these related communities and in Holland we are now working, for instance, with care groups to understand local needs. We have allocated people to better understand how these groups think, what their role will be in the changing environment, and how we as a company can serve the care groups. We want to do more than just sell our products but also provide service and really contribute to care and quality of life for patients.

Your colleague in France who we met with, Eric Fatalot, spoke along similar lines of creating added value for the patient. This fits into the larger global challenges facing multinational companies, who have to be more innovative in their R&D perhaps by seeking partnerships. The Netherlands presents many opportunities to combine "big pharma" with SME strengths. Do you believe that the reputable research infrastructure in the Netherlands is of growing importance to Chiesi globally in order to strengthen future business developments?

Yes, and as a matter of fact we have been quite successful to roll out some substantial R&D projects in Holland. As mentioned before Foster was the major commercial driver behind the creation of a Dutch affiliate.. But indeed the reputable research infrastructure in the Netherlands contributed significantly in this decision for the Chiesi Group. Holland is seen from a scientific point of view as a top level country. Especially in the respiratory area we have some highly recognized scientific people and key opinion leaders. This can be of mutual benefit if we focus on innovation and R&D in the Netherlands. The headlines in the Netherlands might focus on the companies that are closing down or consolidating their R&D facilities, but there are companies, like Chiesi, who are increasing their R&D investment in this country.

Globally, Chiesi is targeting Central and Eastern Europe and Asia as its future growth markets. Will Chiesi Netherlands play a role in the internationalization process?

Yes, for sure. Although Holland is a small country on the commercial side, from an R&D point of view the scientific standards and the people in the big academic centers are well recognized. It is of mutual interest, especially for scientists, to leverage the research strengths of Holland. Chiesi can definitely play a role in this especially in times where other respiratory companies substantially

decrease their investments.

In less than two years you have built up a sizeable affiliate with close to a 40 person staff. How does your management style mix with the types of people that you look for shape the corporate culture?

We try to focus on the human value of the business since, ultimately, we are dealing with people. People are the greatest assets within the Chiesi Group vision. People make the difference and we are all about innovation and ideas which are fuelled by people. Aside from competencies, skills, and experience, what helps is true professional interest in and commitment to people in the therapeutic areas we serve. In the end, if you want to do more than just sell products, we believe that our people have to make the difference. We apply a highly professional "living room feeling" here. With globalization accelerating, companies merging and conglomerations forming, the business is becoming less and less personal. Due to our strategic focus, we are able to develop products while staying in close contact with the communities of the therapeutic areas that we focus on. We listen and develop the next steps together. Innovation, in the end, is the only way to survive. Especially when looking at market reforms you need to deliver added value as a company; with the products, the services and in the approach towards the communities served. Therefore we continuously invest in the development of our people and always have our eyes open for professionals who can make the difference.

We are a family owned company so we have short lines to communicate with management and fast response times in adapting to market needs. This is the way the Chiesi Group likes to do it.

What attracted you personally coming from a listed generic company to a family owned innovative company?

Above all, I was attracted to the entrepreneurial part of the job and Chiesi's strategic focus. If you know what you are good at, then focus on it rather than try to do everything. We do not want to be the biggest, but instead, the best in what we do.

Looking at the strategy of the Group you will see continuous above market average growth near the future. 2010 marks the 75th anniversary of Chiesi group with the past 20 years being mainly focused on internationalization. Europe is now covered and affiliates have been established in Asia, South America, and even the US through a strategic partner. It is a step-by-step approach which is partially due to being a family owned company who decides when and how to take the next steps in a financially healthy way.

What would be your final message to our readers about Chiesi in the Netherlands and its offering to the global pharmaceutical community?

Chiesi is a young ambitious, entrepreneurial respiratory company which can be considered as an attractive partner for foreign companies wanting to make the step into Europe. We have relevant commercial networks within our therapeutic areas of focus which serve as good gates to the continent for other companies. On top of that, we continuously strive to serve the patient. We are open to any input and any ideas which can help patients to increase the quality of their daily life. The fact that we are relatively small company generally gives us a step ahead in terms of flexibility, which is extremely relevant during times of reform.

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