Davide Dalle Fusine – General Manager, Chiesi China



We look forward to the acceleration of registration processes as well as the harmonization of China's regulatory requirements with more developed and mature countries

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Davide Dalle Fusine, general manager for Chiesi China, shares the key milestones for the company in the past five years, their leadership position in neonatology and strength respiratory franchise in China, the importance of the Chinese market for global operations, as well as his strategic priorities for the next few years.

Davide, what have been some key milestones for Chiesi China in the past five years that you have been general manager?

Given that Chiesi Pharmaceutical Shanghai Ltd was established in 2008, just ten years ago, the past five years have been crucial for Chiesi's journey in China. We have 'graduated' to a self-sustaining affiliate, which contributes organically to the Group strategy by pursuing excellence in three specific therapeutic areas: Neonatology, Respiratory and other Special Care and Rare Diseases.

In the area of Neonatology, we invested in our organization to build more access for healthcare professionals (HCPs) and patients to Curosurf ® (our life-saving pulmonary surfactant for prematurely-born babies suffering from respiratory distress). We also added Peyona®, the first caffeine citrate treatment in China for the treatment of apnea in premature babies. Other development projects are ongoing with the aim of providing more solutions for other unmet medical needs in this area.

In the area of Respiratory, we established a JV with a local partner to speed up the market access to our key products (Foster® and Clenil®). This has enabled these products to reach China's doctors and patients sooner than if Chiesi had undertaken the task alone. We are also applying to extend Foster®'s indications and to register new devices, formulations and products that have all already been approved in other countries.

Finally, in the area of Special Care & Rare Diseases**,** we are running other development projects too.

What does Chiesi's footprint in China look like today?

We have almost tripled the staffing of our organization from below 100 to approaching 300 employees. In addition, Chiesi has made a significant investment not only in a number of qualified people but also in the level of qualifications and experience of our people. A constant training program for our specialty areas is imperative.

Furthermore, we are especially proud that more than one-third of the employees who joined us in 2008 are still members of our team.

Last but not least, the value of our medicines delivered to the Chinese market has more than tripled to around CNY 700 million (USD 102 million) with the largest portion deriving from our two Neonatology products, as well as the growing importance of our two Respiratory products launched five years ago.

With China being the second-largest pharmaceutical market in the world today, what is the strategic significance of Chiesi China to global operations?

Since 2013, our China operations' share of the Group's global revenues has grown from 2 percent to the current 5 percent. We aim to maintain a similar pace of growth over the coming five years to double that to 10 percent. However, even 10 percent is relatively small in absolute terms and still represents only about half of China's 20 percent share of the global population.

There are many under-supplied areas calling for the pharmaceutical industry to develop further, especially for R&D companies – and Chiesi is very proud of our R&D investment because we invest 22 percent of our global revenues in R&D every year.

While we led in the introduction of new medicines for premature babies in China, we were not the first to enter the Respiratory area. However, our products for asthma and COPD patients do provide important additional benefits thanks to our innovative technology. Prescribers and patients in the markets of Europe have recognized this higher efficacy in recent years.

We are committed to the further development of our respiratory franchise in China. We are working to extend the indications of Foster® from asthma to chronic obstructive pulmonary disease (COPD) and we plan to launch our NEXThaler®, an innovative dry powder inhaler delivering an extra-fine fixed combination. We are also applying to introduce our Trimbow®, which was the first fixed triple combination for COPD to be launched in Europe.

Our inhalers have been developed with the innovative Modulite® technology, which delivers extra-fine particles of active ingredients to treat not only the large airways but also the small airways of lungs. The Small Airways Disease is highly prevalent in patients whether they are suffering from asthma or COPD. That is why our proprietary technology is so helpful to treat these serious and chronic pathologies more effectively.

Given the fragmentation and complexity of the Chinese market, what is Chiesi's commercial strategy in China working through distributors and local partners?

Given that we are a mid-sized company, we must focus on where we can excel, which is to develop and help communication for our innovative clinical solutions. To reach China's vast and fragmented market, naturally, we work with partners to support us with their complementary strengths in execution.

In the current fast-changing environment, this business model gives us the flexibility for our products to reach patients in need sooner.

What are your perspectives on the current regulatory, pricing and reimbursement environment in China, especially in terms of challenges and opportunities for companies like Chiesi?

The Chinese market for medicines is big indeed, but it is still far from maturity. In other words, it is not yet reliably meeting all current patients' needs.

Over the past ten years, China has extended access to basic healthcare to the entire population and increased its reimbursement insurance, especially for drugs already available in the market.

The current challenge is to improve the footprint for patients' access to the (newly approved) high-quality medicines, which are now available in China. We much approve of the policymakers' and regulators' work to not only broaden patients' access but also to accelerate the introduction of innovative treatments. This means that the Chinese market will gradually become much more similar to Western healthcare in terms of the wide availability of products.

In the short term, we expect to see stronger competition among off-patent products with the implementation of a reference price policy for reimbursement, which will progressively lower prices.

We look forward to the acceleration of registration processes as well as the harmonization of China's regulatory requirements with more developed and mature countries, where many of the world's most innovative medicines have been developed and are already reaching patients.

We also look forward to more frequent revisions of the National Reimbursed Drug List (NRDL) in light of the expected growth in the registrations of new innovative drugs.

As usual, the difference between challenges and opportunities will depend on everyone's perspective and especially on how policymakers and regulators will manage the equilibrium between the stronger competition between off-patent drugs and the approval timeline for better and more innovative drugs. Only the right balance of these two forces can lead the market to an equilibrium of healthy competition, which will provide Chinese patients with local access to better healthcare.

China is currently leading in the digitalization of healthcare and the use of AI in healthcare. How is Chiesi leveraging such developments here in China?

It is clear that we may expect an epochal change regarding the availability of innovative treatments in China. This country has already achieved a global standard for its development speed in many fields and healthcare will not be an exception, especially around digital technologies.

Digital healthcare and AI will bring more quality and efficiency, especially for the daily activity of healthcare professionals, whose interactions with all stakeholders, in particular with their patients,

will improve. The amount of time and attention dedicated to patients will grow because of the availability of broader and more updated databases for clinical practices, as well as innovative tools for budget control, other administrative procedures, training, and medical education. All these improved efficiencies will result in the gradual streamlining of processes for designing services and/or solutions for the patient, which will ultimately foster ‘patient-centricity’.

At Chiesi, we are also working towards this goal by supporting the creation of databases for clinical practices to help HCPs make the best choice for their patients, through sharing knowledge and expertise at conferences and medical education as well as using other tools to help us identify unmet needs and specific issues more quickly and effectively.

With your background in key markets like Brazil as well as experience at headquarters managing international commercial operations and now in China, what lessons have you learnt about forming successful long-term partnerships?

Firstly, you need to know the market and understand how to do business locally. This helps you to understand where your partner is coming from, their perspective and likely intent for the longer term. Secondly, you need to select the right partner. Their motivation for joining you is key, regardless of the nature or size of the partnership, because you need to have a partner whose future interests are, through exhaustive discussion, found to be aligned with yours. Of course, they must have the right capabilities, resources, reach and distribution network, and so on. After this, it is about fine-tuning the agreement so that it benefits both parties.

The rules are very simple. But the difficulty is in finding the right partner with such a complementary vision and purpose.

In China, as elsewhere, partnerships must be built on trust. You need to find a way to establish mutual trust, because that is the foundation of the relationship. As I have learnt, the development of trust between business partners in China is different, or at least happens differently and with a different timing, compared to my background experience in other markets. Just as an example, in other countries where I have developed new business with partners, both sides will first invest a large amount of time and energy to define the contract, because the full contract must be there to navigate any potential issues or misunderstandings, which may be foreseen to arise in the future performance of the contract. Once that contract is discussed at such lengths and finally signed, the partners will have already built a level of trust in each other’s intent and feel reassured to have already discussed possible future difficulties.

However, in China, as I have experienced it, the urgency to start is higher, and the contract may be agreed too fast without adequate exhaustive discussion on what could go wrong. Then it may become just the start of discussion when a future disagreement arises, which was not already discussed in advance and ‘aligned’ before signature in a ‘what if’ discussion. As a result of agreeing to a contract too fast, the partners’ expectations may turn out to be quite different, i.e. badly non-aligned, and this may later cause an amount of stress or anxiety for both parties.

In such cases, relationships are even more important. Having a trusting relationship with the partner makes it easier for both sides to communicate well and resolve such differences. This is why I say patience is a key skill needed in China. The best solution to any partner problem is seldom to find a new partner. Working with the same partners means that you can build an ever-stronger relationship together, to get to know each other better by working through such unforeseen issues arising, to resolve the ‘non-alignments’ not discussed in advance in the original contract, and so progress and build something together.

Finally, to begin wrapping up, what are your strategic priorities for the next few years?

Firstly, we want to further build the capacity and capabilities of our still-small organization in China. We aim to become more flexible and to be able to respond faster within China’s dynamic environment.

Secondly, we want to strengthen our leadership in Neonatology and offer more innovative treatments for premature babies.

Thirdly, we want to organize to achieve the full potential of our Respiratory portfolio and pipeline.

Fourthly, we want to expand our local R&D Hub in order to integrate China into Chiesi Group’s global clinical development programs.

Finally, we want to work on new Specialty Care areas including through pursuing opportunities for inorganic growth.

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