

# CHINA FOCUS

Issue IV / 2014

## Growing in a Healthy Market: Medical Devices

**A**s the Chinese market matures, we are observing many new opportunities in segments that were previously underdeveloped. The Medical Devices sector is a prime example: as Chinese citizens gain in purchasing power, they prioritise the importance of health. At the same time, the government is releasing increasingly stringent regulations to ensure safety and transparency. In this issue of China Focus, we bring

you a market entry special with a focus on Medical Devices. We will help you understand how the market has changed, what it looks like now, and what you need to watch out for when entering or expanding in the market.



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### The Changing Face of Healthcare

*An interview with Jürgen Steinbeck,  
Managing Director of Richard Wolf.*

**As a global business, what differences have you come across when setting up in China vs. other countries?**

When expanding your business into new regions, it is always important to consider cultural differences above all. Before we made a move into China, we had to familiarise ourselves with the processes and business practices and discuss them in great detail. We found, for example, that verbal agreements and meetings generally have a different degree of importance, meaning that start-ups without "insider" support may have difficulties overcoming the language barriers. Setting up a business or your subsidiaries in China without professional assistance is risky because it is difficult to manage these cultural differences in particular.

**How has your sales strategy changed over the years?**

Richard Wolf started selling in China decades ago. At that time, our strategy was to work with a main distributor out of Hong Kong who had his own network in Mainland China with sub-dealers within the country. When this proved successful, we established a second main distributor as a backup, also managed out of Hong Kong. This way, we had a wide reach in China while maintaining the more Western-minded Hong Kong distributors as



**core nova: Richard Wolf's integrated OP Management System**

our main point of contact.

Now, our strategy has shifted with the establishment of a branch office in Hong Kong via which we have taken over the complete dealer structure from one of our previous main distributors. By the end of this year, we will expand by taking over a second main distributor organization, managing the entire network out of our Hong Kong office. In addition to this, our Richard Wolf Service Centre based in Shanghai provides support throughout the country. This will be supplemented with a further branch office in Beijing in the coming year. We have recruited a team of Business Development Managers who proactively look after the management of the dealers and their activities.

As times change, we have adjusted our strategy and now we find it essential to have our own offices on the ground. We are able to manage our distributors better, which is

mutually beneficial, as they, too, prefer to have closer ties to the Headquarters. We can offer our expertise more readily, in addition to engaging more actively in marketing activities in China organized directly by Richard Wolf.

**How has your business model evolved since you first entered China?**

As previously mentioned, our aim was to move away from the main-distributor model. While this kind of arrangement worked well for us in the beginning, once we reached a certain sales volume, it didn't quite make sense anymore. The Greater China region has become our second most important export market after the USA! Over the past few years, the key factors for Richard Wolf as a mid-sized company were restructuring in China, centralizing the management of activities and also providing as much scope as possible to adapt the strategy to the regional differences within China.

“When people are dealing with their own health, they like to have access to the best possible products and ... medical technology that is **“Made in Germany”** is more in demand than ever before.”

### How Fiducia can help



The Fiducia team at a medical supplies factory visit in August 2014.

Fiducia can help you enter the Chinese market by supporting you in:

- ▶ Market entry strategy advisory
- ▶ Partner, distributor, and supplier search
- ▶ Import operations
- ▶ Logistics coordination
- ▶ Documentation
- ▶ Company incorporation
- ▶ Executive search
- ▶ Accounting and taxation

Email us at [contact@fiducia-china.com](mailto:contact@fiducia-china.com) for more information.

### How have you increased brand awareness in China?

After we built up our presence in China, it was much easier to implement our own marketing plan, leading to further business development within the region. Now we coordinate our own participation at all important exhibitions and workshops, as well as focus groups and meetings with Key Opinion Leaders (KOLs). Previously, these activities were arranged by our distributors but we have found that all of these channels prefer to be directly in touch with us. Through Fiducia, we were able to strategically hire Business Development Managers, who have a wide network and know where we need to be present to build our brand in China.

We work closely with KOLs in China to develop new technologies and facilitate knowledge exchange with Europe. In some cases, we will name our products after the person who has assisted in its development, so our product catalogue reflects our close work with world-renowned doctors and professors across the globe.

### What persistent challenges have you come across in China?

Overall, there were no problems that were fundamentally insurmountable. We were able to overcome all the challenges with the professional help of Fiducia. Hong Kong was undoubtedly easier than China, simply due to the lack of seemingly never-ending bureaucratic procedures, but we got through them all. Indeed, in China the hurdles presented by regulations are the biggest challenge in the area of Medical Devices. They can range from the most detailed piece of information about your product to mundane things like how many power sockets your showroom has.

In recent years, these regulations have become so inflated by the Chinese FDA that the issue for every new product, as well as existing ones, relates to whether or not a license should be sought for China. Approval times of up to 2 years are normal, which is a significant obstacle in our sector. Nonetheless, it is worth it to go through these processes to gain access to the Chinese market.

### How is the competitive landscape in China?

The medical devices market in China is effectively split into two parts: the low-end market at one end of the spectrum, occupied by mostly domestic products at a lower quality but cheaper price, and the classic

high-end market with the more familiar, mostly Western premium providers, such as Richard Wolf. Naturally, pressure comes from both sides and the boundaries are moving ever closer together. Recently, we have even seen Chinese premium providers which will undoubtedly play a very important role in the high-end segment in the future.

Hospitals tend to be divided along these lines as well. On the one hand, you have your big university clinics and premium private and public hospitals, which have access to top-quality medical equipment, while, on the other hand, the smaller hospitals tend not to have access to Western technology. Since the spectrum is so wide, competition is also spread out along these lines.

### We have seen the “In China for China” trend in many industries. How does this apply to medical equipment?

This trend undoubtedly also exists in the medical equipment industry, with certain big players adapting their products for the local market. However, at Richard Wolf, we have agreed that our focus will be on selling premium products with the same standard on a global basis. Training the people who use our equipment is essential and our products are the same in China, Germany or Brazil.

Moreover, it is important not to forget about the emotional effect here. When people are dealing with their own health, they like to have access to the best possible products and despite all the efforts of the domestic Chinese industry, medical technology that is “Made in Germany” is more in demand than ever before. This is linked to the fact that the middle class in China has undergone dramatic growth. There is a direct correlation between economic well-being and the importance people place on their health and that of their loved ones. Now, more and more people in China can afford better treatments and are willing to spend their money on this. ☺



Jürgen Steinbeck is the Managing Director of Richard Wolf, one of the leading manufacturers of high-quality products for endoscopic diagnosis and therapy in human medicine and veterinary medicine.

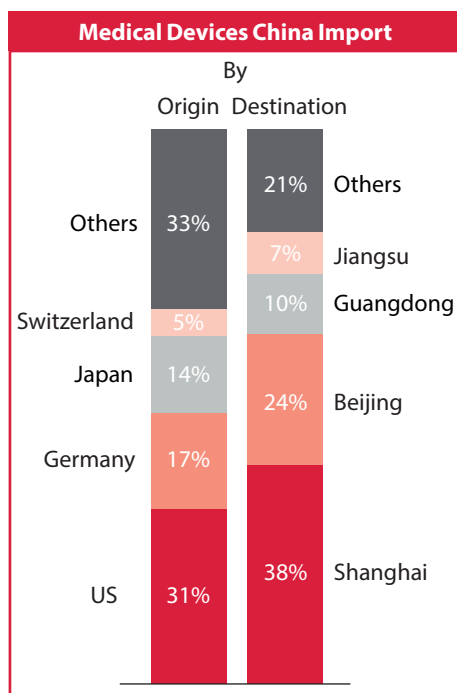
## Developments in China's Health

China is one of the world's most attractive healthcare markets, and is by far the fastest growing of all the large emerging markets. The nation's healthcare spending is projected to grow from USD 374 billion in 2013 to USD 1 trillion in 2020. China will have the largest elderly population in the world by 2016, with almost 10% of the total population over the age of 60. This, coupled with the rapid growth in wealth and disposable income, has resulted in a surge in demand for medical equipment. The Chinese government prides itself in its expanded medical insurance coverage at an official 95% of the country, though this is still widely contested by the public. Nonetheless, it shows that there is increased emphasis on the healthcare sector from not only the government, but also the people of China.

### The Current Market

The medical technology market in China is the second largest in the world after the US, totalling over RMB 21 billion in 2013 with an expected 20% annual growth over the next 3 years. While medical devices still take up the smallest share of the entire healthcare market, this segment is growing rapidly and shows high potential for the future.

The local market consists of a large number of small sized manufacturers geographically focused on the eastern and southern coastal areas. 80% market revenue is driven by the provinces of Beijing, Guangdong, Hebei, Jiangsu, and Shanghai. With a total market output of RMB 180 billion, there were just under 15,000 of these low- to mid-volume producers in 2012.



In contrast, imported products dominate the high-end market, supplying high quality and high cost products that are not available locally. In fact, the number of new imported product registrations has increased by a dramatic 49% since 2010. The value of these imports reached RMB 93 billion in 2013, with almost half originating from the US and Germany.

### Rise in Domestic Demand

The high-end segment is dominated by foreign products that are either produced abroad or locally but with a foreign design. These products typically have specialised functions as a result of more specific know-how from international experts. Targeted at large domestic premium customers, the main competition in this sector originates from top international and ASEAN companies.

The low-end market, by contrast, is made up of mostly Chinese manufactured products aimed at small-to-medium domestic customers. Concurrently, there is much room for growth in the mid-end market, which occupies 40% of total market share. For this segment, some international companies have developed special 'eco' product lines adapted to the mid-range end-customer. These products can have a local design and be locally produced along Chinese standards but originate from specialised foreign know-how.

### Product Registration

In China, medical devices are generally categorized into three classes:

- ▶ Class I: safety can be ensured through routine administration
- ▶ Class II: further control is required to ensure safety of use
- ▶ Class III: implanted into the human body, or used for life support, or pose potential risk to the human body and thus require strict safety surveillance

Depending on which class your product falls in, your application procedure will vary. The process is lengthy and very detailed (see box "Registration Procedures").

We recommend you seek out a specialist to assess for you what your market entry strategy should look like to make the process as smooth as possible. ☺

## Registration Procedure



To register your product with the CFDA (China Food and Drug Administrative), you must complete the following steps:

- ▶ Designate a legal agent and after-sales service agent
- ▶ Determine the device's classification
- ▶ Prepare all documents and translations
- ▶ Arrange for legal and technical documents
- ▶ Ready product samples for testing
- ▶ Engage in clinical trial, depending on class
- ▶ Begin technical evaluation
- ▶ Initiate evaluation by CFDA
- ▶ Obtain final approval by CFDA and certification issuance



## Taking the First Step

As with most mature markets, China is imposing increasingly rigorous regulations on medical technology, in order to provide greater protection and transparency to the public. Here we walk you through the key aspects in organising your local operations:

### Licenses

Each piece of medical equipment needs to be registered with the China Food & Drug Administration (CFDA), a lengthy process with average lead times of 12-24 months depending on the device's class. Once the product license is obtained, it has a validity of only 4 years (recently increased to 5 years to offset prolonged registration times). You are required to renew the license before expiry, a process that will take a further 6 to 9 months to complete. Moreover, each product must have Chinese language manuals and labels in order to be sold in the domestic market.

Simply due to the sheer volume of regulations in this space, it is almost impossible to tackle these without professional help from a competent partner or agent, who has a thorough understanding of not only the products, but also the regulatory requirements. A strong partner will greatly facilitate the introduction of the products to the Chinese market.

### Import

A special trading license and customs certificates are required for import and sales of medical devices in China. Some agents specialize in the import of medical devices and equipment and are familiar with the optimal tariff classification groupings of the main products, accessories and spare parts. Some international companies offer technical training to their agents so they can answer custom queries with ample knowledge. Moreover, an agent with an excellent custom enterprise classification, 'AA' being the highest obtainable rating, can greatly facilitate import of the products. If you run an exchange and repair program within China, the same agent will be able to design a solution to re-import the products at the repair value.

### Customer Service and Warehousing

Many medical technology companies have

set up showrooms and repair centres in Hong Kong or China to support their business development activities, offer product training and improve customer service. These companies can consider holding local stock of their most popular items to reduce lead times, as these can be transported to their customers more readily.

There are several alternatives for warehousing within Hong Kong, Mainland China or in a bonded zone in China. A Hong Kong warehouse offers the most flexibility as products, which are still in the process of registration, can be stocked here and used for product education before official approval. Products that are stocked in a Mainland China warehouse will have cleared customs already, therefore ensuring the shortest lead time to the customer. A repair centre and warehouse in a bonded zone can serve as the regional service hub for customers across Asia, including China.

### Working with Distributors and Dealers

For international companies, it is essential to run proper and careful due diligence on local dealerships before enrolling them and granting them any credit terms. The due diligence process should cover the distributor's or dealer's track record including general business practices, custom compliance and payment history. Some of the dealers may not have own import licenses and will use agents for import and domestic sales adding another layer to the supply chain.

The medical device industry in China is an increasingly competitive market and dealers often offer multiple brands. As many hospitals procure their instruments via a bidding process, we encourage medical technology companies to forge close partnerships with their dealers and offer them best possible local support to increase the chances of winning the bid.

With practical experience in advising and supporting medical technology companies, Fiducia can help you grow in this promising yet challenging market. Email us at [contact@fiducia-china.com](mailto:contact@fiducia-china.com) for more information. ☎

Publisher: Fiducia Management Consultants

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