Business Trends & Corporate Strategies

CHINA FOCUS

FIDUCIA 德信 Management Consultants

Issue V / 2015

Operating in China's Healthcare Market

China is one of the world's most attractive healthcare markets, and is by far the fastest growing emerging market. The medical technology segment in China is the second largest in the world after the US, totalling over RMB 250 billion in 2014 with an expected 20% annual growth over the next 3 years. Since our last China Focus issue on the topic, there have been significant changes in registration requirements, as well as advancements by local competition. In this second instalment, released to coincide with the Medica trade fair in Germany, we will address what the Chinese government has done to expand the healthcare network and what impact this has on international companies operating in China.

Stefan Kracht

In this Issue:

Tapping Into China's Mid-End Medical Devices

China is rapidly developing into the biggest medical devices market in the world. While international companies have historically entered the market with highly advanced products targeted at the top-tier segment, new opportunities are emerging in the middle range. But local players are competing for access to this same segment, moving up from the low-end and gaining more specialised know-how.

China Focus interviews Mr. Jürgen Lauterbach, former CFO of Fresenius Kabi Greater China, with over 17 years' experience in the medical device and pharmaceutical industry, on current trends and opportunities in China's medical technology market and how foreign companies can adjust their strategies to be part of this growth story.

An operating room with surgical equipment in Beijing, China

What opportunities does China hold for international medical devices manufacturers?

My general impression is that the market will continue to grow significantly, albeit not as fast as before. The Chinese government has been very successful in implementing a thorough health care policy, which has created enormous growth momentum. In the past, the highest potential for growth and opportunity for foreign companies was in the high-end segment, but this has been changing. Today, many big hospitals are already well equipped with high quality devices.

The bigger opportunity, in my view, is in the middle segment, which has increasingly become attractive because of the implemented health care reforms that aim to provide modern health care services to the entire population. The government has invested heavily in new facilities, though these are not the same top-end hospitals that you may find in China's first tier cities. The focus is rather on mid-range, good quality devices offered at affordable prices.

With increasing competition from domestic players, what can foreign companies do to defend their market share?

Local competitors are continuously moving into this mid-range space. While the top tier is dominated by international suppliers with limited local players, and vice-versa holds true for the low-end, both multinationals and local companies are now in fierce competition for the middle segment.

My advice is to focus on a well-defined, good quality, up-to-date product range with clearly defined features that address this mid-end market. If a company can offer a portfolio with a suitable technology for a competitive price and a design geared towards the medium segment, it will be able to participate successfully in this opportunity.

What changes have you witnessed in the last years?

Today, it is increasingly common for hospitals to implement the so-called Pay-Per-Use, or "Commodato" model, in which the hospital and the supplier enter into a long term contract with a supplier placing a device and the hospital purchasing the corresponding disposables for a fixed period of time. This kind of model is beneficial to both parties for several reasons: (1) hospitals with limited or no investment funds can still gain access to the newest technology, (2) instead of using generic disposables that could compromise

"China has made substantial progress in **levelling the playing field**. There is more transparency overall and the registration procedures and time lines are by and large the same."
- Jürgen Lauterbach

the effectiveness of the device, hospitals will use the products offered by the supplier and (3) there is an ongoing purchase flow for the supplier.

How does the medical technology market in China compare to the rest of the Asia Pacific region?

I wouldn't use the term "Asia Pacific" because, in reality, the region is highly diverse. There are a few clusters, for example the developed markets such as Korea, Taiwan, Singapore, and Australia, or the smaller ones in South East Asia. India is in its own category with a large number of local players and MNCs. Japan is another very important but very different opportunity.

The best chances for growth are in countries with a well-defined agenda to improve the health care infrastructure, such as China, Malaysia, Thailand and increasingly Indonesia. Out of these, China is by far the biggest in the region. The big developed markets like Japan and Australia, are primarily focus on replacement and offer substantial potential for innovative products.

Do you see a level playing field for foreign vs. domestic companies?

Yes, increasingly so. China has made substantial progress in levelling the playing field. There is more transparency overall and the registration procedures and time lines are by and large the same. However, there are still differences between imported vs. domestically produced products, which is one of the reasons why many companies decide to manufacture in China for China.

Is Intellectual Property a problem?

It is certainly still a big concern. Local players are very active in copying foreign know-how both in medical devices and disposables. Nonetheless, this should not be a reason for foreign companies to avoid the Chinese market! If the supply chain requires it and the demand is there, it absolutely makes sense to manufacture in China. It is more important to be present with the latest product generation, to be fast, and to have sales and marketing capabilities on the ground.

Speaking of which, do you need a local presence?

In today's competitive environment it is the only way. When the Chinese market first opened up, it was common practise to work with distributors because it was an easy way to gain access. But now it is not only feasible but also absolutely advisable to build up your own team if the business size and the growth potential allow it. Having your own sales and after-sales presence is essential if you want to gain a solid foothold in China. Distributors usually work with a variety of companies and therefore can only offer limited support in these areas.

What practical advice will you give to fresh entrants to the Chinese market?

Entering the medical devices market in China is challenging because it still is very fragmented. You need to identify competent local distribution partners if you do not establish your own sales organisation. There is a number of local distributors which may look good on paper but tend to be rather opportunistic in their business approach. Here it absolutely pays off to hire an advisor like Fiducia to conduct a distributor search according to your selection criteria.

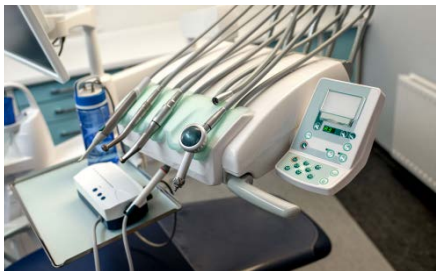
Market analysis is critical: How do you intend to position your product? In which regions and channels should you be selling? What is the demand in the different segments? What are your competitors doing? Since medical devices are so intricate and the market is very fragmented, I would highly recommend to have a thorough understanding of the dynamics before you make a move.

If you are building a team, I would also recommend to go via an executive search company with a sizeable network and knowledge of this industry. There is certainly enough talent with relevant know-how available, but they are difficult to find.

In summary, it is essential to develop a customised strategy for China. Foreign companies need to build up a product portfolio that serve the country's specific needs. As added benefit of this approach you will be able to offer a suitable portfolio as well in other emerging markets with similar characteristics.

Mr. Jürgen Lauterbach started at Fresenius Group in 1998. From 1999 to 2006 he held various management positions within Asia Pacific. After 4 years in the corporate headquarters in Germany, he returned to Hong Kong in 2010 as CFO APAC and most recently held the position of CFO Greater China Region and Executive Vice President Taiwan & Hong Kong.

How Fiducia can help



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

- Market entry strategy advisory
- Partner, distributor, and supplier search
- Tender processes & product registration
- Import operations
- Logistics coordination
- Documentation
- Company incorporation
- Executive search
- Accounting, taxation, and compliance

Email us at contact@fiducia-china.com for more information.

FIDUCIA 德信
Management Consultants

Understanding the CFDA

From October 2014, the China Food and Drug Administration (CFDA) enforced a number of new regulatory reforms regarding the registration of medical devices in China. Their reasons for doing this were three fold: for one, their aim was to create a more level playing field for domestic and foreign players, since previous to this change, all domestic Class II and III devices required clinical trials but most imported devices unfairly did not. Second, through these reforms, the CFDA was able to prioritise its workload by focusing on higher risk devices, requiring Class I products, for example, to be filed on record only, streamlining the process. Thirdly, the reforms encouraged the improvement of technical standards and increased transparency of the registration process.

Example: Class III CFDA Registration

Task	Responsibility	Time
1. Compile technical requirements	Registration Agent	1 month
2. Conduct testing	Approved testing centre	3 - 6 months depending on type
3. Translation of documents	Appointed official translator	2 - 3 months, can be done parallel to step 2
4. Conduct clinical trials, i.a.	Approved hospitals	1 year or more
5. Technical review	CFDA	150 working days for 2 cycles
6. Administrative approval	CFDA	30 working days

While in theory the regulatory reforms were a positive change, they also present a number of challenges for companies planning to bring their medical devices to China. The CFDA now requires long clinical trials for a number of products, which can draw out the registration time substantially. Moreover, the amount of mandatory documentation applicants must submit has increased significantly in complexity and amount. This, coupled with noticeably higher fees, make the decision to register a much more serious process.

Given this complex and costly exercise, it is crucial to find a suitable advisor that can help with the registration procedures. To give you some insight into what is expected, you can find the key steps below so you can prepare accordingly if you want to take the next step in bringing your medical devices to China.

The Process

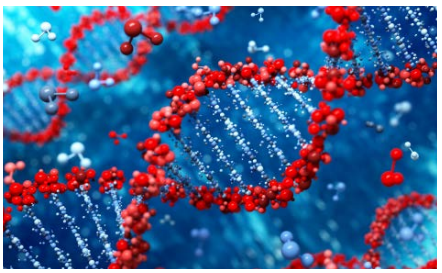
First, we recommend to begin with a thorough analysis of the registration requirements, such as the classification (Class I, II, or III), number of applications required for the portfolio, and whether or not clinical trials are needed. At this stage, it makes sense to establish a project plan with the agent. Keep in mind that several registrations per set of devices might be required, as is the case for example for dental implants. Your agent must be able to compile a list of technical requirements and testing standards for your portfolio.

Testing and clinical trials precede the CFDA registration application and can be done in one of a handful of testing centres across the country. Beware that choosing the right one with suitable facilities and available capacity is an important decision! Only a few established agents are able to directly manage the clinical trial process, while most outsource it. Additionally, distributors are often involved in the clinical trial process, as they have access to Key Opinion Leaders (KOLs), such as medical doctors and other experts. To save time, we recommend the preparation and translation of the registration documents to be done concurrently to the testing process.

More likely than not, after the technical review which takes 90 working days, the CFDA will issue a notice for supplemental information, which will take another 60 working days. If the device is highly innovative or of high risk, an expert panel review may be required, which will add another 3-6 months to the process. In addition, locally producing companies will have to undergo a Quality Management System (QMS) audit at this stage.

All in all, the registration procedure is a lengthy and costly process that can take up to several years if companies fail to submit the required information and necessary documentation in time. Working with someone who is experienced in dealing with the CFDA and is up-to-date with the current requirements is essential in increasing the chances of success.

Fiducia's Tips for Successful Registrations



- Find a competent agent with a track record in similar products, full capabilities, and a registration team in Beijing.
- Evaluate application strategies first and know the number of applications required for your product portfolio.
- Hand in a perfect package to the CFDA: you only have one chance for submitting supplemental information. The CFDA will approve or reject your application based on the submitted info.
- Budget 10% of your China sales for the registration process.
- Consider who will be the license holder.

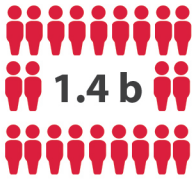
Healthy Diagnosis for China

Comparison Germany

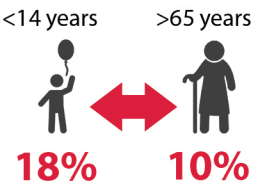
How does China compare to a mature healthcare market? Here are the facts and figures for Germany:

Population:	**81.2m**
Proportion young vs. old:	**13% vs. 21%**
Life expectancy at birth:	**80 years**
Health expenditure / head:	**RMB 31.5k (EUR 4.6k)**
Doctors per 100k residents:	**435**
Number of hospitals:	**1980**
Number of beds / 1k people:	**8.3**

THE MARKET in 2014



Population



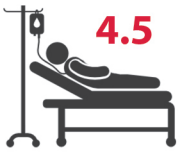
Proportion of young vs. old

Life expectancy at birth

Health expenditure per head

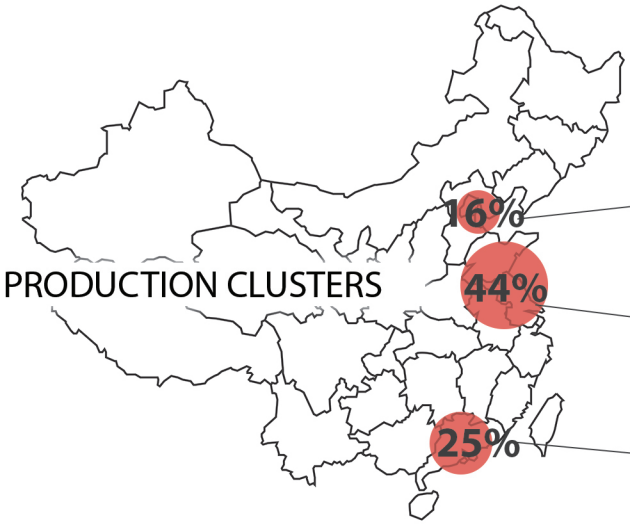
Doctors per 100k residents

Number of hospitals



Number of beds per 1k people

PRODUCTION CLUSTERS



Bohai Bay
Focus: Beijing

Yangtze River Delta
Focus: Changzhou, Shanghai

Pearl River Delta
Focus: Shenzhen

PRODUCT FOCUS

Total China Market (RMB)		Imported from Germany
3.1b	X-Ray	28%
2.5b	Orthopaedic technology	10%
2.2b	Electrodiagnostic devices	23%
1.9b	Other	25%
1.8b	Consumables	3%
400m	Therapy equipment	26%
400m	Opthalmological instruments	34%
100m	Dental instruments	25%

Sources: Fiducia Analysis, GTAI, AHK China

Publisher: Fiducia Management Consultants
Editor & contact for press and article reprints:
contact@fiducia-china.com

Please contact us for a list of sources.

Beijing
1511 Zhong Yu Plaza
A6 Gongti North Road
Beijing 100027
China
Tel: +86 21 6327 9118

Hong Kong
15/F OTB Building
160 Gloucester Road
Wanchai, Hong Kong
China
Tel: +852 2523 2171

Shanghai
2107-2110, Central Plaza
227 Huangpi North Road
Shanghai 200003
China
Tel: +86 21 6327 9118

Shenzhen
1308 Di Wang Commercial Centre
5002 Shen Nan Dong Road
Shenzhen 518008
China
Tel: +86 755 8329 2303

www.fiducia-china.com

FIDUCIA 德信
Management Consultants