The Chinese Medtech Market
2017-2020

The Reimbursement System as one of the Key Drivers

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Executive summary

The Chinese medtech market is the third largest in the world, and forecasted to be the second largest worldwide by 2020, with a steady growth in the coming years of more than 10%.

The Chinese local medtech industry has changed its product segment focus in recent years, moving from low-end to the middle portion of the market, stimulated by government initiatives, alterations in reimbursement management and tendering processes.

3 principal drivers are shaping the Chinese healthcare market:

- Demographics
- HC reforms and new policies
- Shift in the provider landscape

Particularly defining and intriguing developments are being brought about by the role of the reimbursement landscape. China has a unique and complex reimbursement system, entailing 4 main calculation factors:

- Treatment and diagnostic categorization (A, B or C)
- Type of hospital (level 1, 2 or 3)
- Type of insurance
- Location where care is received (Provincial coverage or not)

The preparatory work needed to successfully work in the Chinese medtech market, its regulation and its reimbursement scheme, shift resource use from middle/end of the cycle to early/middle of the commercial cycle. Chinese regulation also seeks to promote and protect its local industry, which presents a further hurdle to foreign manufacturers.

It is imperative to understand the system, before devising and enacting a medtech strategy within it.

- Following careful analysis, some of the most attractive HC markets in China are:
  - Private hospitals and military hospitals
  - Provincial capitals
  - Hospitals in the following regions have superior buying power and more frequently turn to innovative and sophisticated treatment and products:

To finish, we highlight the 4 crucial components needed for success in the Chinese medtech markets.
Facts and Figures

Let us look at a few facts and figures from the Chinese healthcare (HC) system.

In 2016, 5.88% of the GDP was spent on healthcare of which 3.28% came from public sources. In the coming 3 years, HC expenditures are expected to increase annually by approximately 3%.

In total, there are 8,512 acute hospitals in China, of which 1,558 are level 2 and 6,954 level 3. (Level 1 hospitals are not acute.). Together they represent 3,543,443 acute beds.

In 2016, the Chinese medtech market was estimated at almost €35m, which makes it the third largest in the world after the USA (€145m) and Japan (€41m).

As a reference, the Big 5 in Europe account for €90m, and the other BRICS countries together for €30m.

Although the growth of the Chinese medtech segment has slowed down from almost 18% to 11-13%, China remains one of the most attractive markets, and will be the second largest in the world by 2020.

<table>
<thead>
<tr>
<th>MEDTECH MARKET 2016</th>
<th>MARKET SIZE (EURO)</th>
<th>CAGR 2017-2020</th>
</tr>
</thead>
<tbody>
<tr>
<td>CHINA</td>
<td>€ 34,522,000</td>
<td>12.0 %</td>
</tr>
<tr>
<td>US</td>
<td>€ 189,584,000</td>
<td>4.5 %</td>
</tr>
<tr>
<td>JAPAN</td>
<td>€ 41,616,000</td>
<td>2.2 %</td>
</tr>
<tr>
<td>BRICS ( EXCL CN )</td>
<td>€ 30,214,000</td>
<td>3.5 %</td>
</tr>
</tbody>
</table>

Table 1: Market size medtech products worldwide
Medtech Product Segments

Imaging represents the largest product segment in the market, followed by consumables and general medical supplies.

<table>
<thead>
<tr>
<th>MEDTECH MARKET 2016</th>
<th>SHARE OF MEDTECH MARKET</th>
<th>LOCAL PROVIDERS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Imaging</td>
<td>28.0 %</td>
<td>33.0 %</td>
</tr>
<tr>
<td>Orthopedics</td>
<td>9.0 %</td>
<td>55.0 %</td>
</tr>
<tr>
<td>Surgical Equip &amp; Devices</td>
<td>8.0 %</td>
<td>20.0 %</td>
</tr>
<tr>
<td>Cardiovascular</td>
<td>7.0 %</td>
<td>40.0 %</td>
</tr>
<tr>
<td>Consumables</td>
<td>19.0 %</td>
<td>90.0 %</td>
</tr>
</tbody>
</table>

Table 2: Global market size medtech products, per application

Traditionally, Chinese companies dominated the low end of the markets. A few years ago, the government started to launch a number of initiatives, promoting innovation in the local medtech industry. The Innovative Medical Device Assessment office (part of CFDA) provides grants and loans to local companies to support R&D in segments such as diagnostic imaging, cardiovascular implants, IV-diagnostics etc.

These initiatives, together with the reforms of the reimbursement and tendering processes, have strengthened the competitive position of local companies. Today, this is reflected in an increasing share in the growing mid-portion of the market.
Market Context and Drivers

In the next few years the Chinese medtech market will be shaped by the following 3 drivers:

Demographics:

There is a single factor that is of considerable influence on the functioning and developments in China, including its healthcare, and that is sheer size.

- Effective control, far-reaching mechanisms, and Chinese government regulations for domestic and foreign business activities to create structural improvements/change, are in many aspects unique to China’s proportions.
- The consequences are most obvious on the regulatory and reimbursement aspect of the medtech market.

Additionally, there is the demographic evolution, which will change the face of HC in the coming years:

- The Chinese population is aging and chronic diseases are becoming more prevalent; 330m Chinese citizens currently have chronic diseases.
- The Chinese middleclass exceeds the population of the USA or W-Europe, and is facing more lifestyle related diseases, whilst expecting more and better healthcare.

HC reforms and new policies:

Here are some of the highlights of the reforms and changes that are taking place today:

- Basic HC insurance for all citizens through public insurance:
  The share of HC expenses covered by the government has increased from 30% in 2010 to 40 % in 2020. Nevertheless, (regional) inequalities in access to and quality of care will remain.
- Cost control through packaged pricing policy, allowing hospitals to charge a fixed amount for a specific procedure:
  This reimbursement policy results in using fewer and lower cost products.
- Tendering is gradually expanding across China and putting pressure on ASP’s:
  This creates a challenge for sales and marketing tactics, since decision criteria differ from province to province.
- Limited channel markup:
  This is aiming to limit the markup added by distributors, which will obviously affect the partner strategy for many medtech manufacturers.
- Decentralization of reimbursement-decisions and tariffs towards city, county, and province level, resulting in fragmented and complicated policies.
“Since the launch of the 2009 health reforms, China has substantially increased investment to expand health infrastructure; strengthened the primary-care system; achieved near-universal health insurance coverage in a relatively short period; reduced the share of out-of-pocket expenses—a major cause of disease-induced poverty—in total health spending; continued to promote equal access to basic public health services; deepened public hospital reform; and improved the availability, equity and affordability of health services. It has also greatly reduced child and maternal mortality and rates of infectious diseases, and improved the health and life expectancy of the Chinese people.”


**Shift in the provider landscape:**

The government wants to boost the role of local hospitals (level 1 hospitals) in low and mid-range care. They also intend to reroute part of the patient referrals from reference centers (level 3 hospitals) in tier 1 cities to level 2 and 3 hospitals in tier 2 or 3 cities.

**Different reimbursement tariffs** for the respective types of hospitals have to manage the patient streams. This will challenge the efficiency and profile of the sales and distribution resources of medtech companies.

**The private sector** is expected to play a larger role in acute care. Despite of the fact that this process is proceeding slower than expected -since no specific action plans have been put into place- the number of private hospitals and clinics is increasing rapidly. Today we see an increasing presence of (Chinese) private investors in local (level 1 and 2) hospitals that are operating in a difficult financial context, as well as an increase in military hospitals.

In the above summary, one things comes back several times: The role of the complicated reimbursement and regulatory system.

In the next chapter, we will expand on the journey medtech companies must undertake in order to obtain reimbursement and regulatory approvals in the Chinese market.
Obtaining Reimbursement-Approval for Medical Devices

This Chinese regulatory landscape presents a tricky playing field for those unfamiliar with its market mechanisms. Here are some of the basic regulatory steps and agencies needed to obtain reimbursement approval for medical devices.

The approval process

At a national level, the company must register with- and obtain approval from- the CFDA to enter the market.

Per province where the medical device aims to be sold, a maximum sales-prices must be established for the product.

There are no reimbursement lists to include all the medical devices used in the various reimbursed activities in China.

- Some products, such as certain single-patient-use implantables from a particular brand/manufacturer, could be included on a reimbursement list.
- Other medical device types, e.g. a CT scanner or a patient monitor, which are typically used multiple times, would not be listed under a particular manufacturer name on a reimbursement list.

Guidelines and extensive reimbursement sub-factors depend on the province where the care provision is given and upon the Chinese Diagnostics and Treatment Reimbursement list categorization, and will result in varying levels of funding, from 100% to 0%, dependent on numerous factors (from place of residence, to insurance scheme membership type).

The preparation efforts required for working with the Chinese administrative system, both in regards to understanding and for dealing with it, make resource deployment shift from middle/end of the cycle to early/middle of the commercial cycle.
Local manufacturers

The Chinese (medtech) regulatory and the reimbursement systems are not only to satisfy the standard requirements, but also aim to favor local manufacturers where possible and relevant.

An additional challenge

Registration and other pre-launch activities are not abnormal, but the unusually lengthy and complicated trajectory to obtain the proper reimbursement is quite China-specific. While comparable markets, such as Japan, have set up barriers at registration levels, China has an additional challenge at the level of reimbursement, embedded in a difficult tendering and bidding mechanism.

It is essential to understand the nuances of the tendering system, the dynamics of the purchasing process, and what drives these decisions. As for reimbursement, there is no national standard for tendering and bidding and there are huge differences between provinces. The recent tender system reform could create additional barriers for manufacturers.

The medtech industry, as the pharma companies did previously, will experience raised barriers for regulations, pricing, market access, and product specifications.

In order to provide more insights into the complexity of the reimbursement system and its impact on business models, competitive strategies and priority segmentation, we will expand on how to set priorities in the market and how to select business models.

Chinese healthcare regulatory agencies

It is assumed that it will take China 10 years to implement the proposed reforms and for them to reach full scale. The various regulatory agencies in charge of the policymaking, as well as the monitoring processes of the medical device industry, are

- The National Health and Family Planning Commission (NHFPC)
- The Ministry of Human Resources and Social Securities (MOHRSS)
- The National Development and Reform Commission (NDRC)
- The Chinese Food and Drug Administration (CFDA)

All of them are involved in reimbursement policies at the national level, and the first three organizations are involved in pricing matters.
Where are China’s most Attractive Hospital Segments

In this chapter, we will describe the factors and mechanisms that drive the income and buying power of hospitals in China and elaborate where medtech companies are likely to find the most attractive segments.

The financial power of a hospital in a specific province is largely based on how much they can charge the patient for their services, and influenced by the extent to which insurance covers the patient.

The following anecdote is only an illustration of the complexity of both hospital tariffs and of the reimbursement system in China.

My colleague’s mother, who is living in Ningbo, a tier 2 city in China, had to undergo a complicated dental operation. The local level 3 hospital will bill her for 6,000 RMB, of which roughly 50% will be reimbursed by her healthcare insurance. If, however, she decided to go to a top level 3 hospital in Shanghai, it would have cost her only 1,000 RMB. On the other hand, since Shanghai is in another province, her local insurance program would only have reimbursed 20% of the bill.

Financial flows in hospitals

The 3 main components of hospital costs are financially fueled by different sources:

- **Staff salaries** are mainly paid by the (local or national) government
- **Capital investments** are financed partially by individual resources coming from patient payments, and partially by (local or national) government subsidies
- **Operational costs** (including pharmaceuticals, consumables, disposables etc.) are fully covered by patient bills

Hospitals’ tariffs and billing

The hospital bills the patient for:

- Diagnostics and treatments
- Hospital-stay related expenses
- Pharmaceuticals.

In some provinces, there are maximum tariffs for specific diagnostics or treatments in line with the package pricing policy, which aims to avoid overconsumption and stimulate the usage of less expensive products or techniques. In other provinces, reference tariffs per diagnostic method and therapy are applied.
Hospital stay related costs are billed according to the length of stay (e.g. ICU days).

Finally, the hospital charges for the pharmaceuticals, nutrition products, etc. prescribed during the hospital stay.

Price levels for the billing-items mentioned above are listed by the regional DHRSS (Department of Human Resource and Social Security), often as advised by regional and national clinical experts and related administrations. These price levels are reviewed by the regional Price Bureaus.

The DHRSS will also categorize the drug, diagnosis or treatment into A, B and C specifying what percentage of the costs will be taken into account for reimbursement:

- A: Reimbursement based on the total amount spent
- B: Reimbursement based on portion of the total amount spent
- C: 100% is paid for Out-of-Pocket

Above all, the tariffs and categorizations are (sometimes very) different from one province to another.
Patients’ healthcare costs and insurance coverage

The patient always pays the full amount of the hospital cost himself or herself after receiving care. They can use their social security card; the card’s funds are financed by the card owner, the employer and the government.

The patient submits the hospital bill/forms to their medical insurance.

The insurance provider will calculate to what extent the patient is reimbursed for the care they received based on the type of coverage the program provides and on the categorization (A, B or C).

Depending on the type of hospital (tier 1-3), the reimbursement rate will vary within each of the patient’s corresponding insurance types.

The overall trend is that care provision from more specialized hospitals (i.e. tier 3) is generally reimbursed at lower rates than from tier 1 or 2 hospital.

Insurance programs cover care that is obtained within the same province where the patient resides.

Care obtained in a facility outside the patient’s province is not always entitled to reimbursement, but more and more provinces are making cross-provincial agreements and extending their coverage to include additional provinces.

There are several healthcare insurance programs in place:

- Basic medical insurance and large expenditure/severe diseases aid
  - Covers employees, residents, farmers (residents and farmers will merge – started in 2016)
  - Financed regionally (through government, households, employer)
- Social medical subsidy
  - For destitute families and people with disabilities
  - Financed regionally (civil affairs)
- Military medical insurance
  - Serving soldiers
  - Financed nationally (military) and at select hospitals
- Free medical service
  - Covers provincial organizations (Hubei, Jiangsu & Guangdong) and national organizations
  - Through regional and national financing (government)
- Retired public service managers insurance
  - For those who started working before 30 Sept. 1949
  - Through regional and national financing (government)
Also within this context, the HC insurance landscape differs from province to province. Depending on the region, there are a different number of insurance types available. These can vary between 3-10 different insurance types/plans.

Overall, a patient in the Chinese healthcare reimbursement/insurance system can expect to pay around 50% of their tier 2-3 medical care Out-of-Pocket. Consequently, people who can afford it will subscribe to private insurance policies. We estimate that 10% of patients currently have private healthcare insurance.

Finally, each year around 75,000 Chinese patients go abroad for medical treatment, e.g. for oncology (Japan), IVF (Thailand), plastic surgery (S. Korea), etc.

**Priority segments**

- Private hospitals and military hospitals:
  Private hospitals that are part of the national healthcare system and that have been accepted by the HC insurance programs, are often more profitable than general (public) hospitals. The main reason is that they tend to concentrate on less expensive pathologies and treatments. For the same reason, military hospitals are financially stronger and invest into more modern equipment and techniques.

- Provincial capitals:
  The highest quality care and medical resources are typically found in the capital cities of a given province.

Based on the hospital services tariffs, categorization and insurers’ policies, hospitals in the following regions have superior buying power and more frequently turn to innovative and sophisticated treatment and products:

- Beijing
- Shanghai
- Sichuan
- Guangdong
- Zhejiang
- Hunan
- Shandong
- Jiangsu
What business models to apply?

Four crucial components for being successful in the Chinese medtech markets are centered around:

**Preparation:** China requires a different preparation and form of operation; something that companies should not be finding out whilst already in the middle of the process.

**Real partnership:** Find local partner and/or staff whom you trust, and who trust you.

**Understand:** Grasp the complexity of the differences in reimbursement, tendering and bidding, buying power, local competition etc., in the different segments.

**Set priorities:** It requires a much more rigorous prioritization of resources and a specific, dedicated, new and improved sales process.
TforG’s Chinese expertise

Founded in 1991, TforG Group provides business intelligence and decision support to international MedTech businesses worldwide. Its unique focus is the medical devices and medical technology markets within a hospital context. Our customers operate worldwide and face very different challenges in mature markets and high growth countries.

We have over 400 hospitals located in China in our database, providing us with direct access to senior managers and heads of department. Our approach is to establish a partnership with these managers, involving them in our research. They also serve as a great reference, allowing us to expand our research scope to tier 1, 2 and 3:

- **Tier 3**: Acute hospitals with typically more than 500 beds, acting on a national level, having a high level of educational and research responsibilities.
- **Tier 2**: Acute hospitals having anywhere between 100 and 500 beds, serving more than 1 community.
- **Tier 1**: Typically no larger than 100 beds, serving only 1 community.

Another interesting profile in our database is the experts and Key Opinion Leaders, covering all major pathologies (consisting of 3-5 experts/KOLs per pathology).

Furthermore, our database provides a number of VIP contacts, such as policy makers and the Ministry of Health (which we visit face-to-face every 3-4 months). These contacts are working closely together with our Chinese field research team, to design patient flows/care tracks for 150 to 160 different diseases.

In China, TforG does not outsource any interviews with market specialists, on the grounds that we have our Shanghai-based Greater China regional headquarter.
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