THE CHINESE MEDICAL DEVICE MARKET:
RIDING THE DRAGON

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BY MICHAEL ALPER IN COOPERATION WITH
MEDICAL DEVICE MANUFACTURERS ASSOCIATION

mnaiper@neuvomedica.com

MDMA
MEDICAL DEVICE MANUFACTURERS ASSOCIATION

NeuvoMedica
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Introduction

The goal of this paper is to assist small and medium sized medical device companies with entering and succeeding in the Chinese market. The paper provides a framework for these companies to follow and refer to when formulating and executing their China market entry strategy. The paper will specifically focus on companies whose products’ final manufacturing location is outside of China though companies who are manufacturing in China should find value as well.

The paper will start with a brief background on China as it relates to the medical device industry, including socio-economic trends, government policy including healthcare reform, the healthcare system, medical insurance, medical device market size information, market trends, etc. This will help the readers understand the attractiveness of the Chinese market as well as some of the challenges.

The next portion of the paper will focus on market entry and market development. We see market entry into China as a four phased approach: Market Evaluation, Regulatory Approval, Market Launch and Market Expansion and Growth.

In terms of Market Evaluation, first we will look at evaluating market potential for medical device products in China to help readers determine whether they should enter the Chinese market and how much priority they should assign to such an endeavor. We will go over many general factors that affect market potential for a medical device product (i.e. clinical evidence, substitute products, etc.) as well as talk about the specifics of the Chinese market which may be different (provider support needs, incidence/prevalence, healthcare economics, etc.). Next, we will go over the information needed to be obtained in the market to help with evaluation and planning. We will also go over how they should enter the market (i.e. choosing a distribution partner, setting up a subsidiary, etc.) and what factors they should consider. Distribution in China will also be addressed here in depth.

As for Regulatory Approval, the process will be reviewed in detail including the testing process, dossier prep & submission, expert panel reviews, and clinical trials (if necessary). The nature of the regulatory approval certificate, associated agents (legal, after sales and registration) and their rights and responsibilities and renewal requirements will also be discussed. Finally, we will talk about avoiding common pitfalls that manufacturers often face.

For Market Launch and Market Expansion and Development, we will first discuss about the launch itself and everything that is necessary for preparation including pricing, messaging, KOL/Speaker Development, customer service preparation, etc. We will also go over the logistics of the launch event and how to maximize the effectiveness of the event with limited resources. We will then go into all the aspects of market development including KOL Development, Physician Education, Reimbursement, guidelines, etc.

Finally, we will touch on typical concerns, such as local competition and Intellectual Property issues, and then wrap up and summarize.
China background

With the rise of China on the global economic stage, small and medium sized US medical device manufacturers can no longer ignore this very important market both for its current and future potential.

Before we can discuss how the US and other international medical device manufacturers can be successful in China, we first need to ensure that the reader has a basic understanding of China as it is today.

Economics

As it stands now, China has the second largest national economy in the world both in purchase power parity and real terms\(^1\). This is the culmination of over 20 years of GDP growth which averaged over 9% per year starting with economic liberalizations that began in the late 70’s. At the current rate of growth, China should overtake the US by 2020 as the world largest economy.\(^2\) This economic growth has brought about significant changes in the lifestyles and diet of many Chinese. Specifically there have been huge increases in the per capita consumption of such things as meat, milk and oils leading to increasing obesity and other related problems.

Demographics

With a population of over 1.3 billion people, China is the largest country in the world. Of this large population a little less than half (47%) lives in the cities while the rest lives in the rural countryside. Since the Chinese government instituted its one child policy, the average age has been continuously growing. The median age in China is about 35.5 while about 8.9% of the population is above 65. This is expected to grow to 23% by 2050.\(^1\)

With the growing population, and increased prosperity, the prevalence of “lifestyle” diseases such as diabetes and heart disease has greatly increased. For instance, the diabetes prevalence increased almost 20 times since 1980 and with it all of the associated complications including heart disease have also dramatically increased.
**Geography**

China is roughly 9.5 million square kilometers which depending on how measured is either slightly bigger or slightly smaller than the US. From an administrative perspective, China is divided into 33 provincial administrative divisions of which include 22 provinces, 4 municipalities, 5 autonomous regions and 2 special administrative regions.


Provinces
1. Hebei
2. Shanxi
3. Liaoning
4. Jilin
5. Heilongjiang
6. Jiangsu
7. Zhejiang
8. Anhui
9. Fujian
10. Jiangxi
11. Shandong
12. Henan
13. Hubei
14. Hunan
15. Guangdong
16. Hainan
17. Sichuan
18. Guizhou
19. Yunnan
20. Shaanxi
21. Gansu
22. Qinghai

Municipalities
1. Beijing
2. Shanghai
3. Tianjin
4. Chongqing

Autonomous regions
1. Inner Mongolia
2. Guangxi
3. Tibet
4. Ningxia
5. Xinjiang

Special Administrative Regions
1. Hong Kong
2. Macau
From an economic perspective, China’s coastal areas tend to be the most developed with the highest GDP per capita and concentration of wealth.

City Tiers

When mentioning China, one often hears the terms Tier 1, 2 and 3 when referring to cities. These generally refer to cities’ level of economic development and size. However, there is no generally accepted definition for such terms. Generally, Tier 1 cities refer to Beijing, Shanghai, Guangzhou and Shenzhen. For Tier 2 and 3 there is much less consensus however Tier 2 tends to be the next rung of cities that are relatively high in per capita income with large GDPs and populations followed by Tier 3 cities which are smaller and poorer. Some consulting companies such as McKinsey, tend to further break down these Tiers into 2a, 2b, 3a, etc. to further differentiate the city segments of China.
Traditionally, multi-nationals when entering the Chinese market start in the Tier 1 cities and as their business matures move out into the smaller “Tier 2” and “Tier 3” cities.

**Healthcare System**

**Hospitals and Clinics**
There are almost 21,000 hospitals of which about 14,000 hospitals are public and the rest are private. However, on average the private hospitals are smaller as only 11% of all hospital beds are in private hospitals.

In addition there are over 900,000 centers and clinics providing basic healthcare including about 650,000 rural clinics, 175,000 urban and township clinics, and other specialty health centers.

<table>
<thead>
<tr>
<th>Institutions</th>
<th>Beds</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Total Institutions</strong></td>
<td><strong>936,927</strong></td>
</tr>
<tr>
<td><strong>Hospitals</strong></td>
<td></td>
</tr>
<tr>
<td>Public</td>
<td>20,918</td>
</tr>
<tr>
<td>Private</td>
<td>7,068</td>
</tr>
<tr>
<td><strong>Community Medical Institutions</strong></td>
<td><strong>901,709</strong></td>
</tr>
<tr>
<td>Community Health Service Center - Gov't Run</td>
<td>32,739</td>
</tr>
<tr>
<td>Township Hospitals - Gov't Run</td>
<td>37,836</td>
</tr>
<tr>
<td>Village Clinics</td>
<td>37,217</td>
</tr>
<tr>
<td>Clinics (Infirmaries)</td>
<td>648,424</td>
</tr>
<tr>
<td><strong>Specialized Public Health Institution</strong></td>
<td><strong>11,835</strong></td>
</tr>
<tr>
<td>Local centers for disease control</td>
<td>3,513</td>
</tr>
<tr>
<td>Specialized Disease Prevention and Treatment Institutions</td>
<td>1,274</td>
</tr>
<tr>
<td>Maternity and childcare institutions</td>
<td>3,025</td>
</tr>
<tr>
<td>Health Inspection Institution</td>
<td>2,992</td>
</tr>
<tr>
<td><strong>Other institutions</strong></td>
<td><strong>2,465</strong></td>
</tr>
</tbody>
</table>


For hospitals, the Ministry of Health has a classification system determined by several factors including hospital size, number of doctors, number of beds, utilizations rates, etc. which divides the hospitals into three classes: Class 3, Class 2, and Class 1. Class 3 hospitals are the largest while Class 1 are the smallest. The hospitals are further broken down for each class with designations of A, B, and C, with 3A being the best quality hospital. C hospitals theoretically exist but one does not often see them in the market. To get a classification, hospitals must apply and be approved by their local Ministry of Health officials.
Currently large urban hospitals are severely overutilized due to the perception that the quality of physicians and care is better in these institutions. Oftentimes, these institutions are the first line for many patients leading to long queues and crowded conditions. The Chinese government is working to alleviate this problem by its investment into “grassroots” institutions.

### Physicians

The typical Chinese physician in an urban hospital is extremely busy and compared to the US spends much less face to face time per patient. China currently has about 2.4 million active physicians of which 90 are trained in Western medicine as opposed to Chinese traditional medicine. This equates to about 1.79 physicians per 1000 people. The US in comparison has about 2.67 physicians per 1000 people. Compounded by this, is that there are significantly less nurses and other support staff (1.52 nurses per 1000 people in China compared to 9.82 in the US). Furthermore, patients tend to prefer the class 3 hospitals due to the perception that the level of quality and physician skill is higher at these hospitals. Thus, class 3 hospitals tend to be extremely busy with very long queues.

For the most part, Chinese physicians are trained as specialists and there are very few general practitioners (GPs) in China. When patients arrive at the hospital they are triaged by a nurse who directs them to the appropriate department.

The level of training varies quite widely among the country. Oftentimes, many physicians only receive a three-year post-secondary school certification program, though five-year programs are most common in the major cities. Only two universities offer eight-year MD training programs comparable to the US.

**Insurance**

Currently most of the population of China is covered by one of the three major insurance programs offered in China: Urban Employee Basic Medical Insurance (UEBMI), Urban Resident Basic Medical Insurance (URBMI) and New Rural Cooperative Medical System (NRCMS). The most mature health insurance scheme is UEBMI which currently covers over 220 million employees of state-owned or private enterprises. This scheme has the most coverage and is most relevant to US medical device companies entering China. However, coverage varies widely across the country as many coverage items are determined at the provincial level.

<table>
<thead>
<tr>
<th>Insurance</th>
<th>Description</th>
<th>Covered Population (Millions)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Urban Employee Basic Medical Insurance (UEBMI)</td>
<td>• Mandatory for urban employees of state-owned and private enterprises&lt;br&gt;• Contributions from both employer and employee</td>
<td>25 160 220</td>
</tr>
<tr>
<td>Urban Resident Basic Medical Insurance (URBMI)</td>
<td>• Optional plan for those not covered by UEBMI (children, students, unemployed, etc.)</td>
<td>n/a 10 181</td>
</tr>
<tr>
<td>New Rural Cooperative Medical System (NRCMS)</td>
<td>• Voluntary coverage for rural residents&lt;br&gt;• Very low coverage</td>
<td>n/a 410 833</td>
</tr>
<tr>
<td><strong>Total Coverage</strong></td>
<td></td>
<td>25 million 580 million 1.23 billion</td>
</tr>
</tbody>
</table>

In terms of reimbursement, with the exception of very basic pacemakers and stents, most implantables are not covered at all by UEBMI and must be paid by patients 100% out of pocket. Also, “home use”
reimbursement of external medical devices such as insulin pumps is specifically excluded by the insurance code. However, varied reimbursement does exist for procedure and consumable fees for certain medical devices and equipment.

**Healthcare Reform**

In April, 2009 the Chinese announced that it would invest 850 billion RMB (approximately $1.3 billion USD) over a three year period to improve the healthcare system in China. This is the first step in a long term plan issued by the Chinese government that sets the direction, provides the framework and sets the long term goals for the Chinese health care reform.\(^vi\)

This reform initially sets five reform priorities:

1. **Accelerate the Construction of the Basic Medical Insurance System** – the goal at the time of the announcement was to increase coverage of rural and urban residents to 90% by 2011 as well as increase the level of insurance via increased subsidy.

2. **Preliminarily establish national essential drug system** – A new National Essential Drug List was created which is a list of drugs that all Chinese should be able to access and afford. These drugs would be produced and distributed under government control and supervision and covered by medical insurance.

3. **Improve grassroots level medical and health care service system** – The idea behind this is create smaller healthcare institutions as a way to provide general healthcare for the masses. These institutions will serve a General Practitioner role leaving the bigger hospitals for more specialized issues. To do this China is undergoing the construction of tens of thousands of small hospitals.

4. **Steadily promote universal access to basic public health services** – This priority is related to ensuring basic services such as preventative care, immunizations, prenatal and postnatal care, and disease prevention education are readily available to both urban and rural populations.

5. **Advance public hospital pilot reform** – The government wishes to improve the management of hospitals and in addition to reforming public hospitals in terms of management and compensation schemes it is also encouraging the development of non-profit and for-profit private healthcare institutions.

Overall, this healthcare reform will drive a large increase in the market growth for medical devices due to the increased investment in lower level medical institutions.

**China Med Device Market**

Since 2001 the Chinese medical device market grew at a CAGR of 26.5%. It is now estimated to be valued over $8 billion US dollars in terms of prices to the dealers. This makes it approximately the sixth largest market in the world for medical devices and is around the size of UK or Italy. It is also estimated that the Chinese medical device market is growing between \(13\%\) and \(25\%\) per year.
The largest portion in terms of value of the Chinese medical device market comes from diagnostic imaging (MRI, X-Ray) at 37%, followed by consumables (catheters, syringes) at 21%, and orthopedics & implantables (pacemakers, joints, stents) at 13%.

Overall, due to its size and projected growth, China is an extremely attractive market for medical devices and will only become more attractive over time.
Entering the Chinese Market

Now that the reader has some background on China, its healthcare system and the Chinese medical device market, we will look at what is necessary for a foreign medical device manufacturer to enter China. For the scope of this paper, we will focus only on medical device companies whose products final manufacturing location is outside of China.

Market Entry into China for medical devices can be thought of as a phased approach.

The first thing that needs to be done is a Market Evaluation to determine how attractive the Chinese market is for your product. If the attractiveness of the Chinese market is very apparent, the time of this phase should be kept at a minimum as the typical regulatory process takes anywhere from 1.5 to 2.5 years but can be as long as 3.5 years for certain Class III devices.

Once it is determined that the Chinese Market is sufficiently attractive for your product, the next stage would be getting China SFDA (State Food and Drug Administration) approval.

Next, would be preparing for and executing the market launch as well as follow-up. Typically preparation should start 3-6 months before the expected SFDA approval for your product.

Once the product has been launched, the next phase would be to focus on developing the market to help it grow and expand.

**Market Evaluation**

When evaluating the attractiveness of the Chinese market there are several factors you should take into account:

1. **Product Completion** - Since any major change in the product would require a new regulatory approval (including many changes which would not require a new FDA approval), it is best to have the product complete before you approach the Chinese market.
2. **Regulatory Approvals** (FDA/CE) - China has a country of origin approval requirement. That is an imported product must be approved in the country of the manufacturer which is applying for SFDA approval before it can be approved in China.

3. **Clinical Evidence** - The stronger the clinical evidence, the easier it is to get Chinese physician buy-in. Also, good clinical studies can help avoid the SFDA requiring local clinical trials.

4. **Foreign Medical Community Acceptance** - Since new products are most often launched in US & Europe before China, Chinese physicians tend to be early followers, not early adopters. When evaluating products they look to see how they are used in US and Europe.

5. **Incidence/Prevalence** – Certain disease states have higher or lower incidence/prevalence rates than their European and American counterparts. For instance, Type I Diabetes has extremely low prevalence and incidence rates in China while Osteoporosis tends to have higher incidence and prevalence rates than in Western countries.

6. **Physician Education Required** – If significant amount of physician education is required you will need to have tighter control of your sales channel to avoid physicians not properly educated on your product to use it. This creates a bottleneck to your growth and acceptance in China which can be overcome with higher investment.

7. **Provider Support Required** – Products which require significant amount of support by the hospital provider especially nurse support will have additional challenges to overcome. As noted previously there are much less nurses per capita in China then in more developed countries. Also, nurses tend to have much more of an assistant role then their Western counterparts and their responsibilities (and what they are allowed to do by law and practice) are much more limited.

8. **Patient Education Required** – Products requiring significant amount of patient education will also have additional challenges due in a large part to the lack of provider support as mentioned above.

9. **Perception of being State of the Art** – Products which are perceived as state of the art can have an advantage as hospitals will see the ownership of such products as a competitive advantage and something they can use to advertise their hospitals.

10. **Positive Hospital Economics** – As hospital presidents and ward heads are more and more being held for the overall profitability of their domain, products that can help generate revenue have a significant advantage.

11. **Commodity Product** – Products which are perceived as commodities (lower end and consumable products) will have challenges in that hospitals will look to local cheaper alternatives. Differentiation and branding will be the keys to overcome this challenge.

12. **Total cost of product versus substitute** – One needs to consider the cost of substitutes. Some substitutes might be cheaper in China then in the West especially when involving things that are labor intensive.

13. **Effectiveness of product/therapy versus substitute** – However if the effectiveness of the product is significantly better than the substitute, this can more than make up for the price difference.
In addition to these factors, you should gain a thorough understanding of the market for your product in China. Specifically you should focus on the following areas:

1. Market Potential Evolution
   a. Similar products and their market evolution
   b. Major centers and emerging centers of excellence that possess or can develop programs to fully utilize your product
   c. KOLs and/or evangelists who can have future potential impact on product acceptance
   d. Competitive/substitute activities past and present

2. Drivers and Limitations of Market Growth
   a. Physician level of satisfaction with currently available therapy
   b. Physician receptivity to your product
   c. Patient access to advanced therapies in your disease area
   d. Healthcare economics issues – trends in insurance coverage, pricing levels, economics of currently available therapy options

3. Company Readiness
   a. Resources that can be used to support entry

Once the evaluation is complete and you have decided that you wish to enter the Chinese market, it is best to get the regulatory approval process started as soon as possible to as much as possible avoid opportunity costs due to lost revenue and market position.

Depending on your company’s resources and strategy, you might decide to fund the regulatory approval process yourself and defer the decision as to how you will enter the Chinese market (distributor versus subsidiary) for a later time or decide to go with a national distributor and have them pay for the regulatory costs.

In terms of whether to go in alone (subsidiary) or to leverage a distribution partner, each option has advantages and disadvantages as summarized below:

<table>
<thead>
<tr>
<th></th>
<th>Distributor</th>
<th>Subsidiary</th>
</tr>
</thead>
<tbody>
<tr>
<td>Resources Required</td>
<td>Low</td>
<td>High</td>
</tr>
<tr>
<td>Affect on Main Business Focus</td>
<td>Low</td>
<td>High</td>
</tr>
<tr>
<td>Timing</td>
<td>Immediate</td>
<td>Longer</td>
</tr>
<tr>
<td>Control</td>
<td>Low</td>
<td>High</td>
</tr>
<tr>
<td>Market Understanding</td>
<td>Low</td>
<td>High</td>
</tr>
<tr>
<td>Ability to build brand and develop market</td>
<td>Low</td>
<td>High</td>
</tr>
</tbody>
</table>
In addition to the two options listed here there are two other options which we will mention here for you to consider:

1. Joint Venture – A joint venture with a local Chinese company in theory can be a good way to align a Chinese and foreign partner. In practice however, joint ventures due to many different factors including differences in culture and motivation are very difficult to manage. Though there are some examples of success, many joint ventures in China either fail or have very limited success.

2. Logistical Partner – There are niche players that will actually provide all administrative and logistical services and even hire a team which report directly to the manufacturer. In essence this is almost like having a subsidiary with outsourced administrative functions. One other advantage is that the company does not have to go through the administrative burden of setting up and providing registered capital to set up their own WOFEs (Wholly Owned Foreign Entity). However, the cost and investment can be as much or more than that of setting up a WOFE.

If you decide that you wish to utilize a distributor and have them pay for the regulatory process, you will also need to evaluate distribution partners at this time. See the distribution section for a more in depth discussion of distribution and how to evaluate distribution partners.

**Regulatory Approval**

After you have done your market evaluation and determined that you wish to enter the Chinese market and decide how regulatory approval will be funded, you need to start this process.

This process can take anywhere from one year (for a Class I product) to three years if a clinical trial is required.

Regulatory approval of medical devices is governed by the State Food and Drug Administration and must be received before a medical device can be legally sold in China.

China has its own classification for medical devices similar to that of the US and Europe. Officially they are defined as follows:

- “Class I Medical Devices are those for which safety and effectiveness can be ensured through routine administration;
- Class II Medical Devices are those for which further control is required to ensure their safety and effectiveness.
- Class III Medical Devices are those which are implanted into the human body, or used for life support or sustenance, or pose potential risk to the human body and thus must be strictly controlled in respect to safety and effectiveness.

As with many regulations in China, these definitions are vague and open to interpretation. Typically, the definition for Class in China when referring to a medical device is more conservative than that in other countries. For instance, a surgical mask would be considered Class II in China, whereas in most other countries it would be considered Class I.

If the product already has a similar product that has been registered in China before, its category will be listed in the Medical Device Category Catalog. This catalog is available online and can help you determine how the product will be classified (Chinese only). This is the best indicator of how the new product would be classified in China. One good test for class III is if the product penetrates the skin and touches blood. So for instance an infusion set which would be Class II in the US would be Class III in China. However an intubation tube which penetrates the throat is Class II in China. Furthermore, certain types of products considered risky due to various concerns by the government are also considered Class III (certain RF products for the skin).

Current SFDA regulations stipulate that imported medical devices must have approval in country of origin. This refers to the country of the manufacturer which is applying for SFDA approval. Thus, for US medical device makers, the product must have FDA approval in order to be approved in China. For medical device manufacturers based in the European Union, CE approval is sufficient.

**Product Testing**
For Class II and Class III products, the regulatory process starts with product testing. This is a four to six month process. Testing can actually occur before the country of origin approval is received but test results are only good for one year.

Product standards must be compiled by the applicant. The applicant has the choice to use Chinese national or professional standards when available for the particular kind of product or compile a Registration Product Standard which must be at least as stringent as the Chinese or professional standard. The Chinese national professional standards are typically the same or almost the same as their international counterparts (ISO and IEC).

The testing process occurs in one of the ten accredited national testing centers where type testing is conducted based on the standards mentioned above. The manufacturer must supply samples for these tests.

**Dossier Process**
After the testing process is complete, the dossier can be submitted. The dossier includes several documents including the manufacturer’s business license (incorporation documents), proof of marketing approval in country of origin (copy of 510K or CE certificate), product standards (pre-shipment quality
standards), product operation manual, type test report from the testing center, and a few other documents issued by the manufacturer.

After the initial application is accepted, the SFDA reviewers could require additional information and documentation which they then review as an addendum to the dossier. They can also request clinical data, and can accept foreign clinical data. Sometimes they require a local clinical trial (typically for Class III products). Before they do so, the SFDA typically organizes an expert panel to review the product and make the final decision.

After the addendum is submitted, the dossier is reviewed again. The entire review process including time waiting for the dossier to be accepted is on average about one year (assuming no clinical trial is required).

**Expert Panel Review**

The expert panel is organized by the SFDA when faced with a high-risk or new innovative product. Typically the panel will include high-level physicians from the department relevant to the product, high-level procurement (equipment department) and statisticians. The company will not know who the experts are till the actual panel meeting.

The company will be allowed to bring its own experts to present before the panel and then will be asked detailed questions about the product, clinical data, etc., focusing on the safety and efficacy of the product being reviewed. For such a meeting it is best to be appropriately prepared by bringing people who are experts in the design of the product and in the clinical data supporting the product.

**Clinical Trial**

For certain high risk devices, a local clinical trial is required to gain regulatory approval. It is expected that a new regulation will likely be passed in the near future that will require all Class III products to perform a local clinical trial.

If one is certain that a clinical trial will be required, it is best to start the clinical trial at the beginning of the regulatory process to save time. Otherwise, one can submit the dossier, try to convince the SFDA that a clinical trial is not required and if one fails, finally carry out the clinical trial.

The clinical trial needs to be conducted in at least two SFDA appointed medical institutions. It is best to strategically consider which medical institutions to carry out the clinical trial as this can be an opportunity to engage the KOLs and publish clinical articles which can be used to support your market launch and other marketing efforts.

**Associated Agent Items on SFDA certificate**

The SFDA certificate is written in the name of the manufacturer. There are three items associated with the SFDA certificate that represent organizations with certain rights and responsibilities related to the product in China. Changing these items typically require the cooperation of the companies in which the items are named. Thus it is recommended that none of these items are in the name of your distributor in order to avoid complications. If the foreign manufacturer has a legal entity in China (a Wholly Owned
Foreign Entity or Representative Office) it is best that these items are all in the name of the manufacturer’s legal entity to avoid potential future complications. Otherwise, a trusted third party can be used as well.

1. Registration Agent – The registration agent represents the manufacturer when registering the product in China.
2. After Sales Service Organization – Responsible for technical training, consultation and other related after sales service.
3. Legal Representative – Acts as the administrative body for the manufacturer in China (if the manufacturer has no legal entity in China) and is responsible for post market adverse event reporting and recalls

**Distribution**

China’s distribution is very regional, fragmented and localized. Relationships are the key to distribution in the medical device market due to the nature of the healthcare system in China. There are tens of thousands of distributors and their direct coverage is usually very limited to one or two departments of a hospital in the city or provincial level, sometimes even as small as a few hospitals. Distributors often partner with other distributors to increase their coverage splitting margin along the chain.

Distributors tend to be very local in their makeup and business practices. They tend to be small and non-professionally managed. Western business ideas of honesty, integrity and honoring agreements are not thought of in the same way as in the West. In fact, among Chinese professionals who manage distributors it is commonly understood that distributors will do anything imaginable (and sometimes unimaginable) to gain benefit (with great focus on the short term) and that this must be taken into account in any business dealings with them.

The following discussion details how distribution works in China at the time of the publication of this paper (February 2012). However, there are discussions about setting limitations on the margins of distributors, which depending on if and how implemented, might lead to significant changes in the way distribution is done in China. Please see the discussion below on “Markup Limitations and the Future of Distribution” below for more information.

**National Distributors**

Many distributors that act as national distributors are often very similar in nature to the aforementioned distributors in terms of business practices and mentality. However, there are a few national distributors who are more used to dealing with Western business practices or are themselves Western or Western trained. Thus if the medical device company decides to enter the market using a national distributor it is very important that they choose very carefully and carry out appropriate due diligence on the distribution company, its management and its reputation.

As distribution is so relationship based, many national distributors (even ones that have reputations of being more Westernized in their practices or Western owned) are focused on just leveraging their
existing relationships and channels and are not interested or sometimes even able to help build the market for the manufacturer’s product. Such a strategy might work for certain products but for many new and innovative products, with such a strategy one can expect sales to flatten out after one or two years. Thus depending on the product, the manufacturer might wish to find a national distributor willing and able to focus on market development for the product in question.

**Distributor Value Add**

Aside from managing distribution, national distributors are often willing and sometimes expected to take care of several other aspects of the business in China including:

- Getting regulatory approval and carrying out necessary clinical trials for regulatory approval.
- Providing local customer and technical support (at the national level)
- Developing and providing local sales and marketing collateral
- Taking care of import and customs procedures
- Some level of national level marketing (national conference support, etc.)
- Manages National Distribution Network with 2nd and 3rd level distributors

Second level distributors (those that national distributors are selling to) and 3rd level distributors (those that Second level distributors sell to) main roles are as follows:

- **Hospital Channels** – Adding to the distribution coverage by providing hospitals channels that the distributor has strong relationships with
- **Cash Flow** – Typical payment cycles for hospitals (from delivery of goods to payment) is about 3 months in the more developed coastal regions of China (Beijing, Shanghai, Suzhou, Guangzhou, etc). In the developing regions (North, Yunnan, Sichuan, Xinjiang) the cycle can be from 6 months to 2 years. Distributors will often pay for product in advance and carry the cash burden. Distributors’ relationship can also help decrease the payment cycle time with the hospital.
- **Local Government Relationship** – This is very important for getting pricing and reimbursement as well as winning government tenders.
- **Loading Product Stock** – Many multinational listed companies load their dealers (incentivize them to buy more product) to help meet short term financial expectations

**Using one national distributor or multiple regional distributors to cover China**

Due to the fact that distribution is so regional some medical device companies entering the Chinese market feel they should have several non-exclusive distributors in China for different regions.

This only makes sense if the medical device company has a local presence in China. This is for two main reasons.

First of all, if there are multiple distributors in the market that are not actively managed, it is almost impossible to maintain a standard level of pricing across the market. Even if there is no overlap in the regions of the different distributors in China, product from one region will end up being sold in different regions and there will be price competition among the different distributors. This can have significant
long term consequences for the market for your products in China. A national distributor on the other hand will have an incentive and ability to appropriately manage and supervise the distributors better than if the company is trying to manage several distributors from its home office outside of China.

Secondly, there is no incentive for non-exclusive distributors to support any kind of national marketing. For developing the market and brand for a new medical device, there needs to be investment in marketing at the national level. Since non-exclusive distributors only get part of the benefit of such investment, they would not be willing to make such an investment. A national distributor would have at least some incentive.

**Distribution Strategy: Choosing 2\textsuperscript{nd} Level Distributors**

2\textsuperscript{nd} Level Distributors refer to those distributors that the national level distribution contact sells to. This can be the national distributor that the foreign manufacturer assigns or it could be the local Chinese subsidiary of the manufacturer.

Assuming that you will establish your own presence and will be managing the 2\textsuperscript{nd} level distributors you and your team will need to build and establish your distribution network. Your distribution strategy needs to be closely tied in with your marketing strategy. Typically, marketing focus starts in key cities and regions in the more developed coast areas starting with Beijing, Shanghai and Guangzhou building up physician buy-in and then slowly moving in to the less developed regions. Thus your distribution focus will usually be the same.

One good practice is to split the provinces (provincial administrative regions) into two exclusive zones and then using one distributor for each zone. This creates a level of competition between the distributors, gives you better visibility into what is going on, and makes it easier if you ever need to transition to a new distributor.

When choosing 2\textsuperscript{nd} Level Distributors, it is important to understand how your product will be sold as this will affect the type of distributors that are most suitable for you.

- **Big Equipment** (>\$100K) – For larger hospitals, typically the department head (head of cardiology, orthopedics, endocrinology, neurology, etc.), purchasing department and hospital president are involved in the purchase. For smaller hospitals, these products are usually sold through government tender process.

- **Small Equipment** – Depending on the hospital, the department head can be the final decision maker.

- **Implantables/Consumables** – The products that are available to be implanted or used are typically decided by the department head. Department head also provides guidance on when to use the products. However, whether or not to implant and what product to use among the available product is usually left to the attending physician.

- **Aesthetics** – Public hospitals make up about 50% of the medical aesthetic market, specialty clinics and private hospitals make up the other 50%. This is very different from other products
which 90+% of the market is public hospitals. Also, some aesthetic products are sold to the salon market which can be important for your product.

- **OTC Medical Devices** – Devices such as glucose meters and other OTC medical devices are sold through hospitals, pharmacies and even retail.

**Negotiating Distribution Agreement**

When negotiating the distribution agreement there are many items to consider.

- **Regulatory** – Who pays for the regulatory costs (samples, clinical trial, etc.)
- **Exclusivity** – Best have exclusivity with clear regional definitions to avoid competition among dealers
- **Region** – China, China +HK, regional, provincial, etc.
- **Term Length** – For 2nd level usually only one year, for national usually # of years after regulatory approval
- **Annual Sales Goals**
- **Initial Order**
- **Pricing/Margins** – Price to distributors range from 15% to 50% of final (hospital) sales price
- **Payment Terms**
- **Change of control** – If one of the parties gets acquired...
- **Customer Information** - Ensure you are able to keep this info in case you wish to switch distributors

**Markup Limitations and the Future of Distribution**

For a long time there have been many discussions at several layers of the government about limiting distributor markup of drugs and medical devices. In order for such change to occur there would need to be significant structural and political changes from an economics perspective in the Chinese healthcare system before such caps could be put into place.

Recently, Zhu Chen, the Minister of Health, provided for the first time a timeline for changing the hospital financing system starting with a pilot program in 2012 starting with 300 counties and expanding to all counties by 2013 and all public hospitals by 2015. Such changes in hospital financing can be a precursor to the issuance of formal mark-up guidance to regulate drug (and medical device) prices. In fact there are some concerns that the NDRC (National Development and Reform Commission) will issue formal mark-up guidance to regulate drug prices (and medical devices) as they did issue draft guidelines in mid-2010.\(^{11}\)

If formal mark-up guidance or regulations are put in place to impose such regulations, actual enforcement will determine what kind of impact this will have on distribution of medical devices in China. Although generally speaking, we do not see the implementation of such regulations in any foreseeable future, we hesitate to predict when and how these changes will occur. China is a dynamic market from the perspective of its laws and regulations. We recommend that the reader be vigilant to such potential future changes.
**Market Launch**

Market Launches are the best opportunity to introduce and gain traction for a new product in the market. The Market Launch will typically be carried out by either the national distributor or the manufacturer’s local subsidiary. Coordination with the headquarters for international KOL support and ideas can also be very helpful. The Market Launch gives you a chance to give exposure to and educate a large group of physicians about your product very quickly. The preparation for such an event also gives you a chance to interact with KOLs and sets the stage for your future product sales. Even if the product is only an incremental upgrade over an existing product, a market launch can help grow the market and gain market share. Thus it is very important that the appropriate attention, preparation and investment are given to this important event.

**Preparing for the Launch**

There are many things that need to be coordinated and prepared in order to ensure a successful launch. Ideally all of these things should be completed around the time of regulatory approval culminating in a major launch. This event should occur at a major academic congress meeting associated with your product. The time during the registration period is an ideal time to carry out these preparations.

**Sales/Marketing Tools**

Local market messaging and product positioning should be developed while the product is being registered. Based on the messaging and marketing, all detailing aids, brochures, etc. should be complete. Clinical research reprints, etc. should also be ready.

**KOL/Speaker Development**

If a local clinical trial is necessary for your product approval, the clinical trial itself is a good opportunity to build up relationship with KOLs (Key Opinion Leaders) who can also support you in marketing events (including the launch event) by speaking about your product and presenting their research.

Even if a clinical trial is not necessary, small clinical evaluations or studies can be completed at a couple of key hospitals to gain KOL buy-in into your product and help the KOL publish some sort of article which he or she can talk about in the future.

International KOLs speaking at a market launch or other event about the product can also be very impactful.

**Logistics**

All logistic and supply chain systems need to be in place so that you can quickly get the product to the customer. This includes import procedures, freight forwarding, insurance, labeling, etc.

**Distribution**

Prior to the launch event, all 2nd level distributors need to be contracted, trained up and aligned on product and market messaging. Also, they should have sufficient product stock for the expected sales after the market launch event.
**Customer Support**

Ensure customer support infrastructure team is trained and in place. Customer/Technical support team needs to be set up appropriate for the load of support issues you expect to have to deal with.

**Pricing**

Pricing, including suggested retail price, and prices to the 2nd level distributor need to be determined based on appropriate analysis of the market with sufficient margin to cover the various distribution costs and give sufficient profit to the 2nd level distributor. Standard pricing to your 2nd level distributors throughout is very important to maintain the integrity of pricing in the Chinese market.

**Launch Event**

The Market Launch event is best made to coincide with a major Academic Society event such as an annual conference. Depending on your budget, you can get a booth, one or more lectures (presenting your product and related clinical evidence), a luncheon and various types of advertising. For the lectures, you can use the KOLs you developed during the registration of the product, international KOLs who are well versed on your product or a mixture of two. International KOLs though expensive, tend to create more excitement and attract more people to the lecture.

Ensuring your distributors are well attended is also important, as they can help bring traffic to your booth and encourage participants to attend your lecture series.

It is also important that after the market launch event, you and/or your 2nd level distributors carry out follow-up events in various regions throughout China to help increase recognition and knowledge of your product and keep up the momentum generated by the launch of your new product.

**Expansion and Growth**

In order to expand and grow the market for your products, Market Development is key. This is identifying and addressing the key barriers to adoption of your product in China. The typical areas where you will find market barriers are as follows:

**Clinical Evidence/Value Proposition**

In addition to the clinical evidence that you should have from studies published in the US and Europe, local clinical studies can be (depending on your product) very helpful, important and even necessary to help with adoption of your product in China. Sometimes there are questions of product efficacy on Chinese patients and/or in a Chinese environment. Oftentimes, there are questions as to whether the product is worth its premium over alternative therapies. To overcome these barriers the use of clinical and other evidence can be very helpful. Though economic studies are still not often used in China, they can be a useful tool. Sponsoring clinical activities has an added benefit of helping improve relationships with KOLs.

**KOL Support and Advocacy**
KOL (Key Opinion Leader) support can be a key driver of your products’ acceptance and growth in the Chinese market, while the lack thereof can be a major barrier. A KOL’s influence can be at the national level or only limited to a regional or provincial area. KOLs can help speak about your product, publish papers, help get pricing and reimbursement, help set government policy, etc.

Aside from educating KOLs on the clinical benefit of the product, it is important to build a relationship with the KOLs through programs that help support the KOLs and their initiatives. It is best to find initiatives that help both KOLs and support your marketing goals. Initiatives that tend to work well are as follows:

**Academic Society Events (Annual Conferences)**
In any medical field in China, there are at least one or more academic societies. Each academic society will have an annual conference. Academic conferences are good for building up a relationship with the head of the academic society who can in turn help build relationships with other KOLs. In addition to KOL development, Academic Society annual conferences are good places to showcase your product.

Sponsorship of an academic society annual conference will allow you to (depending on the amount of your sponsorship) have a booth to showcase your product, provide a symposium, or advertise your product. If you plan to sponsor an academic society, it is best to decide the amount you wish to invest and sign up quickly as symposium times and the best booth locations get taken quickly.

If you plan a product launch to take place at an annual conference, it is best to invest heavier and communicate this to the responsible KOL. Academic societies usually expect at least the same sponsorship if not more from previous years. Carefully communicating that you are investing more due to a launch will make it easier to sponsor less in following years if you decide to do so.

**Clinical Trials**
As KOLs are always looking to publish, sponsoring the KOL to lead a clinical trial related to your product could help you with your clinical evidence as well as your KOL relationship. However, clinical trials can be risky so make sure to weigh the benefits of the trial versus the trial’s costs and risk of failure and only support such a trial if there is significant market value to be gained which more than compensates for that risk. Also ensure your company’s clinical person/team is involved in the trial design to help ensure a positive outcome.

**Sponsoring attendance of international conferences**
One other customary thing that Med Device and Pharma companies do to help with KOL relationships is to sponsor KOLs and/or their underling physicians to attend international academic conferences. Due to the costs involved, KOLs for such trips should be chosen very carefully. If after careful evaluation of the costs and benefits involved, you decide to sponsor such a program, having a side-trip to your company’s HQ can be extremely mutually benefitting to your company and the KOLs.

If you decide to go down this route, it is best to decide early and invite early. This is because the top KOLs get invited by multiple companies and it can be competitive to attract the KOLs you want. Asking earlier will help you get the KOLs to commit earlier and block out the competition.
Also, when inviting multiple physicians it is very important to worry about group dynamics. Like most countries, there exists a lot of politics among different KOLs. Be aware of the politics and avoid any potential confrontations which can hurt your relationships with the KOLs you are trying to build.

It is important to make sure that the trip is educational and entertaining to keep the KOLs interested and help facilitate relationship building. So ensure that there is sufficient time for the physicians you are sponsoring to rest, shop, and do a little sightseeing. A good rule of thumb is to give the physicians one day on each end of the trip to relax for the long flights and get over jet lag and have each of the remaining days to have at least one educational activity (international conference, hospital visit, seminar, etc.).

Setting expectations with the physicians you are sponsoring is very important as well. Some companies in the industry have turned these trips into pure entertainment or rewards for the physicians. Choosing this route carries a significant amount of risk and is not recommended. Thus you should ensure the physicians’ expectations are appropriate for the contents of your trip so that they are happy with the actual content.

**Clinical Education Programs**
Clinical education programs related to your product for the KOL and his/her department would also be a good idea. This gives you and your team a chance to develop deeper relationships while educating more people on the use of your product.

**Advisory Boards**
Advisory boards are another way to get help build relationships with a group of KOLs and get product and market feedback. Deep market insights can be gained from such a forum however, relationships and politics need to be appropriately managed.

**Hospital Economics (Pricing & Coding and Reimbursement)**
Hospital Economics can be a barrier or driver to adoption of your medical device. Department heads and hospital presidents are directly responsible for the finances of their hospital or ward. If the use of a medical device or equipment represents a major cost to the hospital it can be a deterrent. If on the other hand, profit can be delivered from the use of a medical device or equipment it can be an incentive.

To create positive hospital economics, the first step is to obtain coding (Medical service item and medical device) and pricing for your device. This can include procedure fees for the use of equipment as well as consumable and implantable device prices. It is important to get pricing sufficiently high to make sure it is worthwhile for the hospital to use your device or equipment. This means that the pricing should at least cover costs and give the hospital some profit. Ideally the profit to the hospital would at least equal to if not greater than the substitute or competing therapies/modalities.

With pricing and coding in place, the hospital can charge for a procedure, consumable and or device. However with only pricing and coding in place, only those who can afford the full cost will be able to use
the therapy. Thus after pricing and coding is established, one needs to work on obtaining reimbursement.

Pricing, coding and reimbursement is managed at both the national and provincial level. However, in general when medical device and equipment products are first introduced to the Chinese market, pricing, coding and reimbursement must be applied for at the provincial level. It is possible to apply and get approved at the national level without going through the provincial level first, but is very unlikely.

Building up from the provincial level to ultimately get listed in the National Reimbursement/Procedure Coverage catalog is certainly a goal. But like in the US, avenues exist at the provincial level to do a pretty healthy business especially for smaller companies with limited resources and reach.

Since it is very hard to predict how long each provinces'/provincial administrative regions’ process will take, the typical strategy is to work on a few key provincial regions in parallel and then use these successes to drive pricing and reimbursement in other regions. This would have to be in line with your overall marketing and business strategy.

At the time of the publication of this paper, the majority of reimbursement in most of China is based on a FFS (Fee for Service) system. In the past few years, DRG (Diagnosis Related Groups) systems have been implemented experimentally in a few hospitals in China. It is possible that with reforms in hospital financing over the next few years, DRG systems might become more prevalent and the coding/pricing and reimbursement process might change from what is described below.

**Local Coding/Pricing**

The process to obtain coding and pricing in different provincial administrative regions is pretty much the same. First a code for the medical service item and medical device must be established. The application for the code must be submitted by the hospital. Typically this is a Class 3A hospital and the more prestigious the hospital the better. To get the hospital to submit this application on behalf of the manufacturer involves working closely with the head (director) of the department of the hospital that works with your product. This person would start the internal hospital evaluation process to submit this application. Typically this would be a KOL that you previously developed a strong relationship with.

Once the hospital decides to apply for coding and pricing, it first submits the coding application to the Local Health Bureau. Once the Local Health Bureau approves the coding, the hospital then works together with the Local Health Bureau to apply for pricing from the Local Price Bureau. Once pricing is approved, it is entered into a catalogue of pricing items called the Local Green Book.

**Local Reimbursement**

After pricing and coding are approved, the manufacturer then needs to get the hospital (can be a different hospital used for coding/pricing with similar characteristics) to then submit an application to the Local Medical Insurance Administration Center. The Local Medical Insurance Administration Center then puts the question before and group of experts for evaluation. Once approved, the item is entered into the Local Reimbursement Catalogue. However, it remains rather challenging in the Chinese market for high-end procedures to get reimbursed.
**Expansion to National**

Once a significant number or provincial regions have approved pricing and reimbursement, it is possible to extend the pricing and reimbursement to the national level. The National Green Book and National Reimbursement Catalogue are updated once every two years. At this point the supplier has the chance to work with a top hospital in Beijing to apply for entry into the National Green Book and National Reimbursement Catalogue. The more Local Green Books and Local Reimbursement Catalogues that have items that cover your product, the higher likelihood that the application will be successful.

Once items are added to the National Green Book and National Reimbursement Catalogue, the manufacturer still needs to work to get reimbursement in all of the provincial regions; however, the National Green Book and Reimbursement Catalogue significantly influence and help the process.

**Physician Behavior**

Physician Behavior can be a key barrier to the wide acceptance of your product in China. Barriers related to physician behavior basically come in two forms:

1. **Using or recommending your product over the substitute/competitive product** - Assuming that a physician has access to your product, he or she will only use or recommend it if he/she knows about the product and believes in the benefit of the product over the substitute or competitive products that exist. Typically this comes from exposure from other physicians, seminars, academic conferences and sales people/distributors.

2. **How well physicians use the product and its effect on the outcomes associated with the product** – Physicians decision to use a product as mentioned above is directly affected by their belief in the benefit of the product to their patient. This is in turn is influenced by the physician’s previous success with the product or other physicians’ success with the product. For many medical device products, how well the physician uses the product has a direct effect on the patients’ clinical outcomes and thus the physicians’ success. For instance, the implantation of a procedure if done incorrectly can make a medical device ineffective. Diagnostic equipment if used incorrectly can lead to inaccurate results. Unfortunately in this case, the product will be blamed.

The main approach to overcome the barrier of physician behavior is physician education. This includes both educating physicians on the benefits of your product as well as usage.

If the usage of your product is particularly complex with many details, you need to be especially careful both during product launch and expansion. A few negative experiences with your product due to physician carelessness early on can significantly negatively affect your ability to grow in the Chinese market. Focusing on developing a few key centers first and then spreading out in a focused and deliberate fashion as well as providing strong support in developing an educational infrastructure are key. This is especially important in China where the quality of the physicians in terms of capability, education and attention to detail is not as high as those in more developed countries.
Typical education channels include academic conferences, education forums, and symposiums, where KOLs very familiar with your product can lecture on and educate other physicians. Using forums as a platform to share best practices on product usage is another good way to help physicians improve their usage of your product.

Supporting the establishment of Chinese guidelines around your products can be a good way to help with physician education. Guidelines require getting many KOLs to work together to come to a consensus and could be a good way to help with your KOL development as well. Once the guidelines are established, you can leverage the KOLs who helped draft the guidelines to disseminate the information throughout the market. This can have a significant impact on the market.

**Provider Capacity including hospital, physician and support staff**

As mentioned previously in this document the per capita number of clinicians (especially nurses) is much less than that of developed countries such as the US. This can be a very difficult barrier to overcome if the use of your product relies significantly on hospital support staff. On the other hand this can be a very important driver if your product helps reduce provider capacity (ie by reducing procedure times, or automating manual tasks, etc.).

If your product requires significant provider support, for instance physicians to answer patient questions, long procedure times (for implantables), nurses to provide patient education or support, then you will need to come up with creative ways to help reduce the provider staff burden.

**Patient related barriers (patient flow)**

Sometimes issues related to the patients can be a barrier to your product becoming pervasive in China. One of the major patient related issues is patient flow. The physicians who are seeing the patients most appropriate for your diagnostic or therapy might not be the same physicians who actually administer the therapy or diagnostic.

As patient flow can be very different in China as opposed to other countries, this barrier might exist in China but not elsewhere. One key factor about the Chinese healthcare system is the lack of GPs which might in other countries funnel the patients to the appropriate patients. Oftentimes, physicians do not wish to refer their patients to other specialists as they are afraid of losing these patients.

These barriers need to be identified and appropriate programs need to be carried out to address them.
Other Concerns and Issues

**Competition**

Depending on what sector your medical device/equipment is competing in, the competitive landscape can be very different. High end products tend to be dominated by foreign players while the low end of the market tends to be dominated by local players. Foreign and local players tend to act in different ways, focus on different segments of the market and provide different benefits to the customers.

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<td><strong>Price</strong></td>
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<td><strong>Margin to Distributors as % of retail price</strong></td>
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<td><strong>Market Investment</strong></td>
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<td><strong>Brand Perception</strong></td>
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<td><strong>Target Hospitals</strong></td>
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The general trend is that the quality and technological capability of local companies is improving and in certain sectors, particularly strong local players have emerged. Drug Eluting Stents, trauma products, and X-Ray/CT Equipment are all examples where local players dominate in terms of volume. Foreign players still command a premium price and image.

In response to this market phenomenon, large foreign players such as Medtronic and J&J are moving towards local production and partnerships so that they can provide “value” segment offerings. That is products that are of good quality but offer pricing in line with local competitors.

When considering China market entry, it is important to understand how this market dynamic affects your product and what is the most appropriate strategy for you.

**IP Protection**
IP Protection is one major concern that business people from many industries need to face when dealing with the Chinese market.

The good news is that China does have extensive laws on IP Protection including various types of patents on inventions, designs, etc. The bad news is that enforcement can sometimes be problematic. Court cases can drag out for years and even if the company whose rights are infringed wins the case, their compensation might not be in line with the damages it received. However, this has been improving in recent years. One major driving force for this is innovative domestic companies who need to protect the IP that they create from their own competitors. In fact since 2002, PRC entities have made more patent applications than foreign entities and this trend has continued. Furthermore, domestic IP cases (cases not involving foreign entities) made up over 75% of cases from 2001-2006.

One important way for a company to protect themselves is to register their patents in China. It is best to do this at the same time or soon after the patent is registered in the home country. Waiting for more than one year risks losing the ability to register the patent. Registering the patent will give the company some measure of protection and a leg to stand if there is some sort of IP infringement. Also, since patents in China last 10 (utility model and design model) to 20 years (invention model), getting it now can protect the company when it eventually enters the Chinese market when the enforcement will likely be better.

Even if it is too late for patent registration for the company’s product, this does not mean the company should not enter the Chinese market. In fact one might reason that it is best to enter as quickly as possible to get an early mover advantage and carve out as much of the market share as possible competing on quality, premium image and service. The worst one thing one can do is to not register the patent in China and delay entering the Chinese market. This risks losing the market entirely to local copycats or having to do significant catch up to gain a decent market position. It is generally naive to think that by avoiding entering the Chinese market, manufacturers can avoid Chinese copycats.
Summary

The Market for Medical Devices in China is very attractive both due to its current size, growth and potential. However it is not equally attractive for all products and one must evaluate the market for each product on a case by case before determining whether it is the right time to consider market entry.

Once the decision has been made to enter the Chinese Market, careful thought and planning are required in order to overcome the challenges both unique and common to other markets in order to be successful.
About the author and sponsors

**Michael Alper**

Michael is the co-founder and Managing Director of NeuvoMedica, a company which provides distribution and consulting services for the Medical Device Market in Greater China.

Before co-founding NeuvoMedica, Michael spent several years working at Medtronic in a number of business development and marketing roles in the Asia Pacific region including China and Japan. In his last role at Medtronic, he led the Marketing team for the Medtronic Diabetes business in Greater China. Michael also previously worked at Accenture doing consulting work related to US health insurance and spent several years in a number of sales and business development roles in the software/IT industry. Michael speaks fluent Chinese and Japanese, has an MBA from the Wharton Business School, an MA in international studies from University of Pennsylvania and a Bachelor's from Harvard College in Computer Science.

Michael is happy to answer any questions related to this paper and can be reached via email at mnalper@neuvomedica.com.

**MDMA**

The Medical Device Manufacturers Association (MDMA) is a national trade association based in Washington, DC providing educational and advocacy assistance to innovative and entrepreneurial medical technology companies. Since 1992, MDMA has been the voice for smaller companies, playing a proactive role in helping to shape policies that impact the medical device innovator. This is accomplished by maintaining relationships with key Members of Congress, senior staff at FDA and CMS, and through the grassroots support of our members.

MDMA's mission is to promote public health and improve patient care through the advocacy of innovative, research-driven medical device technology.

MDMA plays a proactive role in helping to shape policy that impacts the medical device innovator. To achieve these goals, MDMA represents its members' collective interests before the United States Congress, the Food and Drug Administration (FDA), the Centers for Medicare and Medicaid Services (CMS), and other federal agencies that develop or implement policies that affect the medical device industry. MDMA encourages its members to actively engage in the advocacy process through MDMA Working Group participation and grassroots mobilization.

For more information see [http://www.medicaldevices.org](http://www.medicaldevices.org).

**NeuvoMedica**
NeuvoMedica provides Marketing, Distribution, Regulatory and Technical Service solutions, acting as a one stop shop for biomedical device & equipment companies doing business in Asia Pacific (with focus on Greater China).

NeuvoMedica combines Western management techniques along with a deep understanding of the business and culture of China to provide a professional, transparent and disciplined approach to sales and distribution in China and the rest of Asia Pacific.

NeuvoMedica was co-founded by individuals with many years of experience in the medical device and equipment industry in the US and Asia. The team has come from such companies as Medtronic, J&J and Microport (a Chinese drug eluting stent company).

Having spent significant time building successful and profitable international businesses in areas including cardiology, cardiac electrophysiology, neurosurgery, orthopedics, and endocrinology, NeuvoMedica brings significant knowledge and expertise that are directly relevant to the mission.

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