



China – The Opportunity and The Risks

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■ Why China? Why Now? - Macro

- Growing domestic economy.
- Increasing expenditures on healthcare - \$125 Billion.
- Increasing desire for/ utilization of advanced technologies.
- Increasing availability of healthcare insurance – universal coverage by 2011.
- Increasing establishment of private hospitals and clinics.

■ Why China? Why Now? - Micro

- Foreign investment in life sciences encouraged – subsidies for foreign investments.
- R&D, pre-clinical, clinical costs are significantly lower than in other countries.
- An increasing population of educated scientists at lower costs.
- The SFDA has implemented straightforward drug and medical device approval processes.
- Improving IP protection.

■ Considerations for Marketing and Distributing in China

- SFDA.
- Reimbursement Issues.
- Distribution Network.
- Local Representative.
- Protecting IP in China.

■ SFDA – State Food and Drug Administration

- SFDA regulates medical devices, pharmaceuticals and health food products.
- Approvals required for:
 - The product
 - The distributor
 - The manufacturer
- FDA/EMEA approvals not sufficient.
- Clinical trials must be conducted in China by SFDA testing centers.

■ Medical Devices by Class

- Medical devices are classified according to safety criteria:
 - Class I – Medical devices the safety and effectiveness of which can be ensured through routine administration;
 - Class II – Medical devices for which further control is required to ensure their safety and effectiveness;
 - Class III – Medical devices that 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.

■ Medical Devices by Class Cont'

- Clinical trials must generally be conducted for Class II and Class III medical devices.
- Regulatory authority, approval process and complexity vary from class to class.
- Governmental Authorities range from those at the municipal level, to the provincial level and up to the central government.

■ Medical Devices by Class Cont'

- Timeline:
 - Class I – approximately 7 months.
 - Class II – approximately 10 months (not including clinical trials).
 - Class III – approximately 24 months (not including clinical trials).
- Incomplete information or inconsistencies – back to the beginning.

■ Reimbursement Issues in China

- Reimbursement strategy critical.
- China's reimbursement system has not kept up with the increasingly advanced technologies and products available.
- Chinese reimbursement system is fragmented. Guidelines and policy come from the Central Government but are managed by local government agencies.

■ Reimbursement Issues in China Cont'

- Local governments are responsible for setting pricing based on factors such as local economic condition, income levels, population and distribution.
- Many new products and treatments are not defined or associated with appropriate reimbursement rates - hospitals decide what to charge patients.
- In China, retail prices are generally set by distributors.

■ Medical Device Industry – How to Distribute in China?

■ Distributors

- Hospitals in China purchase through distributors.
- Medical device distribution highly specialized and localized in China.
- Difficult to cover entire country – focus generally on Eastern coastal cities.
- Different provinces have different medical and insurance practices, purchasing policies and regulatory requirements.
- Ability to leverage local contacts and knowledge is vital to creating an effective distribution network in China.

■ Medical Device Industry – How to Distribute in China? Cont'

- Tenders – published by hospitals.
 - Constant communication is necessary to obtain information regarding tenders.
 - New policy - centralizing purchasing efforts among provinces.
 - Documentation – integral part of process.

■ Local Representative in China

- Generally granted exclusivity status by way of a POA.
- Address for regulatory process.
- Address for warranty purposes and technical support.
- Connections to industry - “Guanxi”.
- Legal liability.

■ IP Protection

- Inventive Patent; Utility Model; Design Patent.
- Software copyright.
- Trademark/trade name protection.
- Unfair competition.
- Proper contractual protection.