Set up steps for biotech businesses in China

Geeske In 't Velt & Robbert Görris

China has witnessed a biotech boom over the past decade. Where previously the market was dominated by generics of variable quality and an opaque and highly bureaucratic regulatory system, recent government reforms, together with massive domestic and foreign investment, have transformed China into the world's second-largest biopharmaceutical market, with ever increasing demand for more innovative drugs to improve treatment outcomes that can match China's growing economy.

Step 1: Investigate before you invest

You will need to research if there is a market for your product and clearly define that market. You must gather data and then verify it with reliable professionals.

- The Chinese market changes rapidly and innovates fast. Do you know the current state of play? Have you been in touch with potential business partners, clients, suppliers, distributors or competitors?
- Price is an important factor. Is your product likely to be competitive?
- What is your USP in the Chinese market? How will your product be distinguished from competitors?
- Choose the right moment to enter the market. Chinese embrace innovative products and technologies but also look for a track record of success. Is your product already successful in the EU/US markets?
- What is the best location for your business – close to market, close to suppliers or are you looking to take advantage of tax incentives in specific regions.

Step 2: Legal and fiscal checks

You will need to draw up a comprehensive business model, which will depend on market factors, legal requirements and your strategic choices. This model will set out the best structure and location for your business, the amount of investment required and the projected growth with clearly defined targets.

- After selecting the most suitable corporate structure, you will need to form and register your local company in China.
- Is your product/activity on the latest edition of the Chinese government's Special Administrative Measures on Access to Foreign Investment ('National Negative List')? This list is updated every year. It is currently prohibited, for example, to invest in the development and application of human stem cells and gene diagnosis and treatment technologies. It these sectors it will not be possible to set up a Wholly Foreign Owned Enterprise (WFOE) but you can enter a partnership with a Chinese company (JV) or, in some specific cases, it may be possible to take advantage of the special pathway for drugs and devices to enter China through the Bo Ao Lecheng International Medical Tourism Pilot Zone in Hainan Province.
- Protect your IP – If you plan to do business in China, it is essential to know how to use, guard and enforce the rights you have over your intellectual property (IP). The most important way to avoid problems when defending IP rights in China is to be prepared.

Step 3: Plot your regulatory pathway

Pharmaceutical and medical technology companies must identify the correct regulatory pathway for a specific product with the National Medical Products Administration (NMPA), the Chinese agency for regulating drugs and medical devices. A part of the State Administration for Market Regulation (SAMR), the NMPA's responsibilities include drafting laws and regulations for drugs, medical devices and cosmetics, as well as establishing medical device standards and classification systems.

- First, check for any special regulations for specific products in Free Trade Zones, like the Hainan Free Zone pathway for drugs and devices. These may permit your business to enter the Chinese market with a European or US-registered product and start sales directly.
- Chinese Contract Research Organisations (CROs) provide a wide array of services to clients ranging from drug discovery to clinical trials. The demand from subsidiaries of foreign companies in China has increased since China joined the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use in 2017, which has allowed clinical data generated from trials in China to be accepted for drug approval applications in other countries on the council.

- Choosing a CRO is a crucial and complex process and should be evaluated cautiously. Developers need to look for partners who deliver reliable outcomes with comprehensive data and add support to their research. Before you choose a CRO, you should ask the following questions:
    - Can the CRO offer exactly the services that my business needs?
    - Does the CRO have related experience and a good track record of similar projects?
    - Is the CRO financially stable?
    - Does the CRO have an experienced team to deliver qualified results?
    - Does the CRO have the required infrastructure for a trial?
    - Does the CRO have a robust quality assurance system?

Step 4: Set up your corporate structure

In Step 2, analysis was undertaken to identify the most appropriate corporate structure for your business model, financing and regulatory category. Now is the time to establish this structure and there are a number of decisions that will have to be made.

- If a Joint Venture (JV) is the only legitimate structure available for your specific product or service, or if a JV is considered to be commercially preferable, then rigorous research and due diligence will need to be undertaken to find a suitable partner.
- A JV is essentially a limited liability company that is created via a partnership between a foreign-invested enterprise (FIE) and Chinese investor(s), who will share the management, expenses and profits of the JV.
- Once a qualified and reliable partner has been identified, attention must be paid to the JV contract and Articles of Association, which will set out govern the specific obligations and rights of the JV parties, the principles of the organisation and methods of operation, and will serve as the 'real' shareholders' agreement between the parties.
- Both documents need to be in written forms and must be signed by all partners. Sufficient time and resources, including legal counsel, will be needed to ensure that both the contract and Articles are effective and robust. You should never rely on legal opinions provided by the other parties.
- If a WFOE is the preferred structure, then the establishment process will vary depending on the chosen activity – service WFOE, manufacturing WFOE or trading WFOE – and its associated business scope.
- In 2014, China's Company Law was amended to do away with the fixed minimum capital requirement for WFOE registration. However, a sufficient amount of registered capital is key to running a successful business in China and the

Ministry of Commerce (MOFCOM) and the Administration for Industry and Commerce (AIC) will review the proposed capital level of a WFOE.

- A company's registered capital can be in the form of cash, land, plant and equipment, intellectual property, or any such asset up to 20%, and does not have to be injected in a single transaction. The amount of registered capital should be based on the funds that a WFOE will actually need before it is cashflow positive in China, which will be different for every WFOE.
- The best practice to choose the right level of capital investment is to draw up a comprehensive business plan. Accurate financial projections will assist in calculating how much capital the business will need for its operations in China.
- Keep the timing in mind. We often see that the establishment process can take six months or longer. This is not necessarily due to the government procedures but because so many decisions have to be made. This takes time, so you must be realistic.
- For more information on the set up considerations, read our article (XXXXXX [link]

Step 5: Hiring local staff and/or appointing foreign personnel

WFOEs and JVs are able to hire both local employees and foreigners to work in China. Any business seeking to build a strong base in China will inevitably confront the question of how 'local' an approach to adopt, particularly when it comes to management. Foreign firms implement a wide variety of strategies, from flying in supervisors from head office for a transition period to train up local staff, to instituting a permanent expatriate management layer.

The diversity of the workforce can be a challenge for businesses. Language barriers, cultural nuances and value divergence can easily lead to unintended misunderstandings and low efficiency. Cross-cultural communication serves as a lubricant to mitigate frictions, resolve conflicts and improve overall efficiency.

Step 6: Implementing Quality Management

Leadership is one of the key principles of quality management (QM), the effectiveness and efficiency of the system is dependent on the leaders communicating the purpose and aims of QM within the company. You will need to stay in touch continuously. Some useful practices for doing business in China would include:

- Verifying documents – always checking the authenticity of any documents, such as business licence or certificate of incorporation, that are provided by partners, suppliers or customers;

- Visiting companies – it is strongly advisable to visit a partner's factory in China to check if it has the required capacities and quality assurance measures, and to strengthen co-operation;
- Sales agreement – these should include detailed information on quality and compliance requirements and should be in Chinese language and signed by legal representatives from both parties to ensure legal enforceability;
- Effective communication is essential to avoid conflict or misunderstandings with staff, partners, suppliers or customers;
- Test before shipment – you should always check goods before the shipment, especially when they are shipped overseas;
- Translator – you should always have a fluent Chinese speaker with you at negotiations, contracts, visits or audit to prevent loss of information or misunderstandings.

Business Support Services China

Sovereign China has been accelerating the ability of its clients to understand and operate in the China market for almost two decades. We provide a suite of services that is designed to lead foreign investors through the market entry process and stay with them to develop long-term success. From helping clients to understand the market and developing their market entry strategy, through to establishing operations and providing back-office support, we are there from planning to execution. Our services in this area include:

- Due Diligence
- Trademark Registration
- Market Understanding
- Legal Entity Structuring
- HR and Corporate Services
- Accounting and Tax Compliance

https://www.sovereigngroup.com/china/

Robbert Gorris | Director Northern Europe / Senior BD, Sovereign China
Robbert works with client companies to provide them with the market entry experience and strategy that they will need to set up in China successfully. He possesses a comprehensive knowledge of Chinese commerce that has been gained from over 10 years of working closely with SME's that are seeking to enter the China market.

rgorris@sovereigngroup.com
Mobile: +32 456338629
www.SovereignGroup.com
Sovereign (China) Limited

3EACON provides strategic consultancy, operational support and business development in the pharmaceutical, medical device and biotech industries between East-Asia and Europe. We offer these services both to Chinese companies entering the European market and vice versa.
We are based in Europe, with local presence in Beijing - China and in Tokyo - Japan, having a long-term expertise in the pharma, biotech and medical device industries, 3EACON helps medium and small enterprises to navigate the complex landscape of R&D and business development and overcome language barriers and the hurdles of local business cultures
www.3eacon.com
Advice needed?
Please contact us directly if you have any questions:

Geeske In ’t Velt 海思柯| Partner / Director China Desk
Geeske has over 15 years of experience in advising Chinese and Dutch SME’s and knowledge institutes. She has an impressive track record in business development and project management, and has been instrumental in establishing numerous local affiliates in China for European companies. She is fluent in Chinese and trained in international management. She brings a strong network in the Chinese life sciences and high-tech industries.

gi@3eacon.com
Mobile: +31 6 282 58912
3eacon.com

On 14-15 October the hybrid event (online & offline) Access Biotech China (ABC) will take place. ABC will provide European biotech companies with valuable insights in the Chinese Life Sciences & Health sector. It will bring best practises to the stage, inspire you to explore the opportunities and help you to avoid the pitfalls made by others. It will connect Chinese and European companies, investors and experts who are interested in entering or expanding into the Chinese market. Sovereign and 3EACON have joined the event as Sponsor and Programme Partner and look forward to share their experiences with you at ABC.
More information on Programme and Registration for Access Biotech China: https://www.hyphenprojects.nl/abc/