Procedures and Licensing for the Establishment of Life Sciences Company in China

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McDermott Will & Emery has a strategic alliance with MWE China Law Offices, a separate law firm based in Shanghai. This On the Subject was authored by MWE China Law Offices lawyers Henry Chen, John Huang and Kevin Qian, and U.S. lawyer Christopher Donovan.

Intricate rules and regulations govern the procedures and licensing of life sciences companies in China. However, with careful due diligence and a thorough evaluation of the regulatory requirements, foreign life sciences investors can capitalize on the opportunity to enter and successfully operate within China's vibrant life sciences industry.

2011 marks the inaugural year of China's Twelfth Five-Year Plan, which continues the country's goal of modernizing its health care sector to provide its roughly 1.3 billion inhabitants universal access to health care by 2020. To achieve this ambitious goal within a decade, China's burgeoning life sciences industry requires an influx of "know-how" and resources to drastically increase its capacity, quality and innovation. Consequently, enormous opportunities exist for foreign life sciences companies and investors.

Foreign pharmaceutical and biotech companies looking to participate in the booming Chinese market should however tread carefully, as the requirements imposed by China's complicated and amorphous regulatory regime prove too often to be a trap for the unwary. One way in which some pharmaceutical and biotech companies have chosen to test the waters and mitigate their risks is by entering into partnership with a Chinese counterpart. Regardless of the corporate vehicle eventually chosen by the partnership, thorough due diligence of the Chinese counterpart is crucial to its success and should cover a number of issues, such as:

Licenses and approvals: Does the Chinese counterpart have the appropriate licenses and approvals to conduct the relevant work (in accordance with local regulations and restrictions)?

Background checks: Are the Chinese party (and owners) who they claim to be? If so, what is their reputation? Do their financial statements give a true and accurate picture of their assets and liabilities?

Compliance record: What is the compliance record of the Chinese party (and its owners)? Are there potential or existing Foreign Corrupt Practices Act (FCPA) issues (*i.e.*, are there any State shareholders of the potential partner or relationships with State entities that trigger FCPA jurisdiction)? Are sufficient internal control policies implemented?

The difficulties to successful market participation are thus present, but not insurmountable with careful due diligence and evaluation of local regulatory conditions. This newsletter therefore aims to shed some light on the various requirements, procedures and licensing required of a foreign invested life sciences company in China.

Establishment of a Research and Development Enterprise

The initial point of entry by a foreign biotech or pharmaceutical company may be via a research and development (R&D) institution, which are highly encouraged by the central government. According to the Circular Concerning the Establishment of Foreign-funded Research and Development Center (Circular on R&D Establishment), issued by the Ministry of Commerce (MOFCOM), R&D institutions or centers are defined as those engaged in the research, development and experimentation (including intermediate experimentation) in natural sciences and related scientific and technological fields.

The scope of their research and development may cover basic or fundamental research and research on the application and development of products, but they cannot engage in projects prohibited under the Foreign Investment Industries Guidance Catalogue or in any other technological trade not associated with their own R&D achievements and production activities. In addition, the R&D center may transfer the fruits of its technological research and development. It may also conduct cooperative research and development with Chinese research institutions either under a management or a cooperation contract.

According to the Circular on R&D Establishment, conditions for the establishment of a foreign invested R&D center include having:

- A clearly defined R&D area and specific R&D projects
- A fixed business location, machinery and equipment, as well as other conditions necessary for R&D
- R&D funding of no less than US$2 million
- Professional, managerial and technical personnel, of which at least 80 percent should be technical staff with an undergraduate degree or above that is directly related to R&D activities

To establish any type of enterprise in China, the first step is the name pre-registration with the State Administration of Industry and Commerce (SAIC). Thereafter, approval must be obtained from the relevant government authorities. For the establishment of an R&D enterprise, the approval process is delegated to the relevant authorities at the provincial level in accordance with the provisions of the Circular on R&D Establishment. Investors must submit their applications and related documents for examination and approval by the relevant administrative bodies. For example, in Shanghai, applications are submitted to the provincial Foreign Investment Commission (the local MOFCOM counterpart).

Apart from the application documents (which address issues related to the conditions for establishment such as location, research plan and staff), certain other related documents and approvals may also need to be obtained, details of which may differ depending on the relevant approval authority for the R&D center. Again using Shanghai as an example, a feasibility study report must be submitted to the provincial Foreign Investment Commission in order to receive project approval.

The appropriate application and related approved documents are then submitted to the provincial Foreign Investment Commission for issuance of a Foreign Investment Enterprise Approval Certificate. Within 30 days after obtaining the certificate, the applicant must register with the local SAIC for a business license. Once the business license is issued, the enterprise is formally and legally established in China.

Lastly, other licenses may be obtained in order to facilitate the research activities of the R&D center. For instance, animal testing requires animal testing permits or an operating license from the Shanghai Science and Technology Commission. Other certificates that may be considered in future stages of an R&D center's operation include the Good Laboratory Practice Certificate and Hi-tech Enterprise Certificate. In a greenfield project, other local rules and regulations regarding environmental, health and safety must also be carefully investigated.

Vehicles for Expansion

As R&D projects mature, the need to manufacture and distribute drugs would likely occur. The foreign investor may choose to:

- Establish a new company through a joint venture (JV) or a wholly foreign-owned enterprise (WFOE)
- Establish a JV or WFOE through use of an existing Chinese company
- Simply conduct activities through co-development agreements

Various pros and cons are attached to the different forms. As discussed above, foreign investors may be able to mitigate their risks by entering into a JV with a Chinese counterpart. However, if a new company is established through a JV with a Chinese party, new licenses would need to be obtained, and the resulting time and costs expended may detract from the benefits of a partnership with a Chinese company. If a WFOE is established through the acquisition of an existing Chinese company, time and costs may be saved as an already operational business is being acquired. However, certain other issues such as FCPA liability may be inherited. A simple cooperative relationship may be developed through co-development agreements in which one party may provide the research and methodology and the other party provides the facilities and relevant licensing necessary to conduct the work. This arrangement however, has its own predicaments such as less cohesiveness in working on a long-term project or goal as both parties are unrelated with only a contractual agreement between them.

Establishment of a Drug Manufacturing or Drug Distribution Company

Establishment of a drug manufacturing or drug distribution company may be considered in the future development of the foreign invested life sciences enterprise. However, the establishment of a foreign invested drug manufacturing company is limited or restricted in the following ways. Foreign invested drug manufacturing companies are restricted in manufacturing specially regulated drugs, certain vitamin products, vaccines, anaesthetics, blood products and syringes. They are also prohibited from carrying out activities related to wild herbs and rare and endangered plants, as well as traditional Chinese medicines with secret recipes.

Licensing authority for drug manufacture is vested in the State Food and Drug Administration (SFDA). Numerous procedures and licensing must be followed. First, the drug manufacturing company must obtain a Pharmaceutical Manufacturing License from the provincial level SFDA. A Good Manufacturing Practice Certificate may be obtained from the provincial pharmaceutical bureau within 30 days of obtaining the Pharmaceutical Manufacturing License. For a new drug to be clinically tested on humans, a Clinical Test Certificate must be obtained from the SFDA. A New Drug Certificate may be obtained if it can be demonstrated to the SFDA that the new drug successfully passed laboratory and clinical tests. Finally, a Production Permit Number must be obtained from the SFDA before a new drug can be produced.

For drug distribution companies, there are detailed rules regarding issues such as logistics, supply, purchase, inspection, storage, warehousing and delivery, which are discussed by the SFDA in Opinions on Strengthening Supervision of Pharmaceuticals and Promoting the Development of a Modern Logistics for Pharmaceuticals.

Conclusion

Many intricate rules and regulations govern the procedures and licensing of life sciences companies in China. However, with careful legal due diligence and evaluation of the requirements, it is an exciting time for foreign life sciences investors to enter and successfully operate in China's vibrant life sciences industry.

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in academic medical research centers, universities, investment banking, private equity and venture capital firms.