Medical Devices: An Introduction to the Regulatory Regime in China and Options for Foreign Investors in the Medical Device Sector

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With the fast-growing medical device market in China, an increasing number of foreign investors are watching this industry. In this *White Paper*, we introduce the current regulatory environment, investment vehicles and other relevant aspects for manufacturing, trading and importing medical devices in China.

The People's Republic of China has probably already surpassed Japan to become the second largest medical device market in the world after the United States. It is estimated that the market for medical devices in China will shortly (if not already) account for more than 5 per cent of the world market for medical devices.

As the world's most populous country and the fastest growing economy, China offers vast opportunities for investors in a medical device market that has shown strong growth in recent years. This note provides a general introduction to the legal environment and foreign investment process in China's medical device industry.

1. Medical device regime in china—a short introduction

1.1 SUPERVISION AND ADMINISTRATIVE AUTHORITIES

In China, the State Food and Drug Administration (SFDA) supervises the medical device sector at the national level. In practice, the SFDA delegates a lot of administrative powers to its local branches. The food and drug administrations of the provinces, autonomous regions and municipalities directly under the central government (Local FDAs) are authorised to issue specific licenses and product registration certificates to medical device companies. One of the characteristics of the China market is that different local FDAs may have their own specific examination and approval requirements that go beyond national requirements.

1.2 CLASSIFICATION OF MEDICAL DEVICES

According to the definition provided in China's medical device law, a medical device is a tool, apparatus, material or other good, including but not limited to software, that is independently or jointly used on the human body. In order to effectively supervise and manage the medical device market, the SFDA classifies various medical devices into three classes (*i.e.*, Class I, Class II and Class III).

The classes were determined according to their properties, uses and other aspects, essentially based on the risk to the user. Depending on the classification into which the device falls, before the medical device can be placed on the market, different procedures and requirements apply in order to obtain relevant licenses and/or certificates.

Specifically, Class I medical devices refer to those under routine administration for their safety and efficacy, such as rehabilitation techniques, disinfecting devices and apparatus. Class II medical devices include those that must be controlled for their safety and efficacy, such as weak laser in-vitro treatment instruments, blood assay devices and apparatus. Class III medical devices are those implanted into the human body, or used for life support or sustenance, and pose potential risk to human life, such as implanted artificial internal organs and infant care devices. Class III medical devices are those subject to the strictest controls for safety and efficacy.

2. Certification of Medical Devices in China

2.1 GENERAL REQUIREMENTS

Generally, any business entity engaged in medical device manufacturing or trading (distribution and/or sale) must obtain specific licenses in addition to the normal business licenses. Application for a manufacturing or trading license is made with certain competent authorities. In addition, the medical device must be registered with the SFDA. In practice, Class I medical devices are subject to record-filing procedures approved by an authorised Local FDA. Class II devices are registered at the provincial level FDA. Class III medical devices are subject to a more stringent approach, that includes going through a prior examination process and then approval from the central SFDA. Completion of the required steps, if approval is forthcoming, results in registration of the device as a medical device.

Because the registration process for each Class and with each provincial FDA is somewhat different, a high level overview of the critical steps for Class II and Class III medical device registration is described below (Class I registration is not described due to its relative simplicity in comparison with Class II and Class III registrations).

1) Formulate and submit formal standards for medical device

According to Article 14 of the Medical Device Standards Administration Method (the Method), the applicant must formulate and submit standards for the to-be- registered products when registering a medical device. According to Article 15 of the Method, standards formulated by the applicant must be ratified, approved by seal and recorded by the provincial FDA.

2) File for medical device testing approval

The applicant must have a nationally "designated organization" test the product according to the standards formulated above. There are 10 SFDA designated testing centres and formal written approval from one of these centres is required.

3) CCC testing for specialized medical devices

In China, certain medical devices must be certified with China Compulsory Certification (CCC). There are seven medical devices that require CCC: electrocardiographs, haemodialysis equipment, extracorporeal blood circuits for blood purification equipment, hollow fibre dialyzers, implantable cardiac pacemakers, medical x-ray diagnostic equipment and artificial heart/lung machines.

In practice, the CCC process is supervised by the State General Administration of Quality and Supervision (AQSIQ), which oversees the inspection and quarantine of goods and establishes the technical standards for their inspection. The (current) seven above-mentioned medical devices must successfully complete the CCC procedure with AQSIQ before obtaining product registration as a medical device.

4) Apply for clinical trials approval

Under China's medical device regime, new medical devices falling within Class II and III require clinical trials before the submission of a product registration to SFDA or Local FDAs. The results of the clinical trials must demonstrate the safety and efficacy of the medical device. "New" medical devices are those that have not yet entered China's market or whose safety, efficacy and performance have not been recognized within the territory of China.

The entities qualified to conduct clinical trials for medical devices, are only those medical institutions jointly designated by the SFDA and the State Ministry of Health (MOH).

5) Apply for medical device manufacturing quality control evaluation report

The applicant must also apply for SFDA, or provincial FDA, approval for a medical device quality control evaluation report. In the application, the applicant must clearly specify its manufacturing process along with a blueprint of its manufacturing site. The plan must be detailed and identify clear critical quality control points. Testing for quality at these points must be done according to statistical requirements and be carefully recorded. In addition, the manufacturer of the raw materials used in the production of the medical device must often present a formal quality guarantee document.

The approval process requires an on-site visit by the SFDA or provincial FDA in which they evaluate numerous criteria. This approval must be in writing and provided under seal of the relevant authorities.

3. Establishment and Licensing of a Medical Device Company in China

3.1 MEDICAL DEVICE MANUFACTURING

3.1.1 General Requirements

As a general rule, all enterprises engaged in production of a medical device must meet certain conditions, including in particular:

1) Having professional technicians, a production site and physical conditions, as well as production equipment, that is suitable for the production of the medical device

2) Having a department or personnel in place, along with inspection equipment to conduct quality inspections of the medical device produced by the enterprise

3.1.2 Manufacturing Licenses

As mentioned in section 2.1, an enterprise engaged in the manufacture of Class I medical devices must complete the record-filing procedure with the local FDAs at provincial, autonomous regional or municipal level. The regulatory approval procedures for Class II and Class III medical device manufacturers are more onerous. Instead of record-filing, the manufacturer of Class II and III medical devices must go through the process of examination and approval by the SFDA or authorised local FDAs for obtaining the medical device manufacturing license. Without such a manufacturing license, the enterprise will not be permitted to obtain a business license for operation and hence will not be able to conduct any business. A manufacturing license is normally valid for five years and must be renewed before it expires.

The manufacturer of a Class II medical device must, amongst other requirements, satisfy the following during the examination process before being licensed:

1) Appropriate qualifications of the individuals in charge of production, quality and technology

2) Suitable proportion of technicians amongst the total number of employees

3) Suitability of the production facilities, production and warehousing locations, and overall physical conditions

4) Suitable quality inspection department and quality inspection capabilities

5) Records of all relevant regulations and technical standards such as the Medical Devices Production Measures

Regarding the licensing of Class III medical device, the manufacturer is required to apply with the central SFDA and is subject to additional criteria, including:

1) Having at least two internal examiners who meet quality management system requirements

2) Having at least two full-time technicians at mid-level positions or above with an associate college degree (or higher) in relevant subjects

It might be noted that properly approved medical device manufacturers can distribute their self-produced and previously licensed devices without applying for a trading license.

3.2 MEDICAL DEVICE TRADING—DISTRIBUTION, SALE AND IMPORTS

3.2.1 General Requirements

Generally speaking, enterprises engaged in medical devices trading (*i.e.*, selling or distributing products manufactured by a third party, including its affiliates) are supervised under a different set of criteria and licensing requirements. The requirements include:

1) Having a business site and physical conditions, as well as quality inspection personnel, that are suitable for its medical device trading operations

2) Having capabilities for providing technical training, maintenance and after-sales services

3.2.2 Trading Licenses

Similar to the approval process for medical device manufacturing enterprises, a Class I medical device trading company only needs to carry out record-filing with the local FDAs. Class II and III distributors/traders are required to go through examination and approval procedures with the competent SFDA and authorised local FDAs, and obtain the medical device trading license. Without the medical device trading license, a business license will not be issued to the medical device trading company for it to start business in China. A medical device trading license is generally valid for five years and needs to be renewed before it expires.

Below are listed some of the requirements for obtaining a trading license:

1) Suitably qualified management and staff with relevant educational qualifications

2) Suitable business location in relation to its business scale and scope

3) Suitable storage facilities and conditions

4) Sound product quality management systems (such as purchase and inspection systems as well as warehousing)

5) Suitable technical training and after-sales service capabilities

3.2.3 Requirements for Import

Typically, a medical device trading enterprise wishes to import medical devices and sell them to the domestic market in China. Under such circumstances, the enterprise must ensure the overseas manufacturer of such medical device has applied for and obtained a product registration certificate in the overseas manufacturer's name.

As indicated above, all medical devices must have a product registration certificate in China including imported medical devices, even if it has already been officially registered and certified in the device's country of origin. For the most part, registration of an imported medical device follows the critical procedures described in 2.1 above with the following additions or exceptions:

1) All imported medical devices must be registered with the central SFDA

2) The supplier must appoint a legal agent and after-sales agent located in China who will coordinate and control SFDA device registrations

3) The applicant may not use the clinical trials/medical device testing approval from its home country, and so must undergo China-based clinical trials and medical device testing approval

4) Although a manufacturing quality control evaluation report (see 2.1 (5) above) is not necessary, the applicant must supply the notarized proof of compliance with certain international or other (equivalent) acceptable national quality system standards

4. Financing of Medical Devices

4.1 REIMBURSEMENT THROUGH STATE HEALTH INSURANCE

China's 12th Five-Year Plan has the ambitious goal of universal health care for its immense population by 2020. This Plan also calls for quantity, quality and innovation. Achieving these goals will involve a dramatic upgrade in China's health industry, including in the medical device sector. Further, China's health care reform also envisages increased

funding and harmonization of the health insurance system that will increase the amount of money available for reimbursement of medical device use.

In China, reimbursable devices are set out in a medical device insurance list released by the provincial social security bureau. Currently, the majority of domestic medical devices can be reimbursed via the national health care insurance system, such as locally made Chinese disposables including syringes, infusion sets and blood bags.

In contrast, imported medical devices are generally not reimbursed via the national health care insurance system and almost always require some level of self-payment by the user. That is, the insurance will pay some of the cost and the patient will pay the remainder. Examples include orthopaedic surgical products like plates and screws, cardiac pacemakers, vascular stents and catheters, and artificial organs, such as heart valves.

While China is more than capable of meeting local demand for low-end medical devices such as dressings, sponges, drapes and gowns, some reports suggest that more than 80 per cent of high-end medical devices, *i.e.*, durable goods, equipment, implants and drug-eluding stents, are imported. It seems then, that China still has a long way to go before its State health insurance system will provide significant reimbursements for the use of imported medical devices.

4.2 PAYMENTS TO HOSPITALS AND MEDICAL PROFESSIONALS—BRIBERY RISK?

In China, the health industry has long been included on the list of high-risk industries for possible commercial bribery as an issue for manufacturers and suppliers. In order to increase the sales volume of the medical devices, some manufacturers or distributors have been known to develop relationships with certain medical service providers (e.g., doctors) in hospitals by offering incentives, such as cash, entertainment and rebates paid to personal accounts.

The Chinese government has long been trying to control bribery in the health and other sectors. In addition to the enforcement of penalties under administrative law and other sanctions under criminal law for flagrant cases of bribery, other measures have been taken to improve the market environment.

As part of the effort to curb bribery, China's central and local governments are establishing online centralized procurement systems. With the implementation of these centralized procurement systems, all not-for-profit medical institutions must participate while the for-profit medical institutions are encouraged to join. By doing so the sourcing of medical devices can be centralized with the objective of preventing abuses.

The MOH has also issued rules regarding the maintenance of commercial bribery records in medical sales. Each health department at provincial level must maintain and publish a bribery blacklist of manufacturers or traders of health care products who have been found to have engaged in bribery. Medical institutions cannot purchase any medical products from blacklisted companies for two years. Companies are added to the blacklist if they:

1) Provide financial or other benefits to medical institutions or their representatives

2) Were convicted of bribery as a criminal offence

3) Were investigated and punished for bribery by the disciplinary supervision authorities

4) Received administrative punishment for bribery from the relevant authorities

It is expected that as these measures are implemented over the next few years, medical device manufacturers who export to China, as well as foreign-invested entities in China, will ultimately benefit from such efforts.

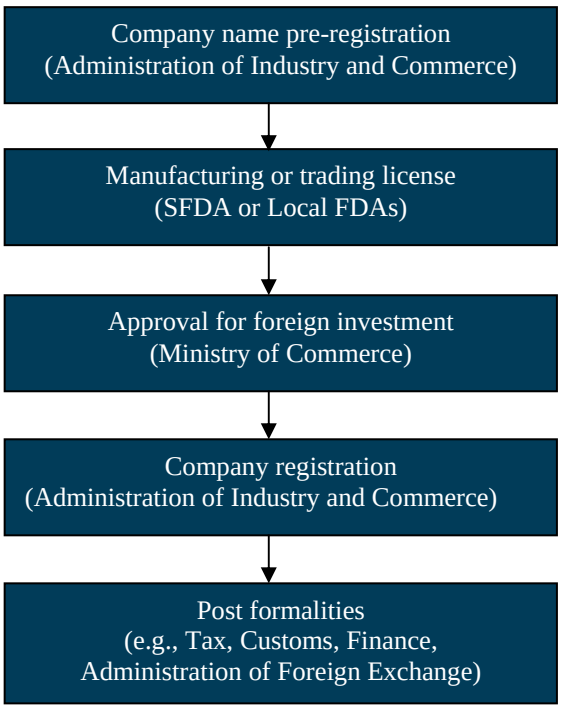
5. Foreign Investment in China's Medical Device Industry

5.1 NEW ENTITY

In order to set up a business engaged in medical device manufacturing or trading in China, a foreign investor must have a legal presence in China, either as a wholly foreign-owned enterprise or as part of a joint venture.

In China, all foreign investments are classified into one of three categories according to the Guidance Catalogue for Foreign Investment Industries (2007). These categories are encouraged, restricted and prohibited business. Except for the production of non-self-destructive disposable syringes, infusion instruments, blood transfusion instruments or blood bags (such production is within the restricted category), the production and distribution of all other medical devices are currently classified within the encouraged categories for foreign investment.

The flow chart below illustrates the general establishment process for a medical device manufacturing or trading company.



5.2 MERGERS & ACQUISITIONS (M&A)

Another way to enter the China market for medical devices is through a merger or acquisition. There are two options under the M&A model, namely equity acquisition and asset acquisition. Either approach has its pros and cons.

Apart from its intellectual property rights, probably the most vital assets of a medical device company are its medical device manufacturing or trading licenses and relevant registration certificates. Under Chinese law, such assets are non-transferable and remain personal to the company that applied for such licenses and certificates. Therefore, in conducting an asset acquisition of a medical device company, all but the most vital assets of the target company can be purchased and transferred, making the intended acquisition of the target company's business much less attractive. Meanwhile, under an equity acquisition, such licenses and certificates remain with the acquired target company and the purchaser can take advantage of the licenses and certificates through its control over the target company.

Of course, other issues need to be carefully considered before opting to set up a new entity in China or to acquire or merge with an entity already doing business in China. These issues would normally include tax, governmental procedures and permits (other than those specific to the medical device sector) and inheritance of legal liability.

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Given the highly regulated nature of the medical device industry in China, foreign investors looking to access the market or step up their presence need to weigh the legal, supervisory and commercial risks against the benefits of setting up in China. When deciding on investment structures or distribution/licensing arrangements, the solution is not "one size fits all". The specific circumstances and objectives of the investor together with the regulatory constraints applicable will

determine the best approach to be taken. This will include the scope of the relationship with distributors and/or the type of medical device entity to be established in China that is best adapted to the investor's needs.

MWE China Law Offices, based in Shanghai, has a strategic alliance with McDermott, Will & Emery, and extensive practical experience advising international clients on regulatory and other legal issues with respect to the medical device industry in China, as well as in relation to setting up the most appropriate investment vehicle. We consider both the local China issues as well as the cross-border issues that will impact the establishment, expansion and ongoing business operations of a medical device producer and/or distributor in China.

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