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EXECUTIVE SUMMARY

INTERNATIONAL HEALTHCARE AFFINITY GROUP *OF THE* BUSINESS LAW AND GOVERNANCE PRACTICE GROUP

Overview of Legal Issues in China's Medical Device Sector

Daniel F. Roules, Esquire*
Chen Changshun (Ryan)
Squire Sanders & Dempsey LLP
Shanghai, China

This Executive Summary explores the legal issues involved in foreign investment in the medical device sector of the People's Republic of China (PRC or China). The first section will identify and analyze key issues with respect to effective due diligence for the purpose of forming a joint venture in China. This type of investment could occur either through a "greenfield" investment[1] with a China-based partner or through investment in an existing PRC domestic company. The analysis set forth below will cover both general issues commonly present in foreign-invested projects in China, regardless of the sector or industry, as well as specific issues related to the medical device industry. The second section will then discuss incentives and restrictions on foreign investment in the medical device industry in particular.

Due Diligence Investigation

General Issues

Business License and Operational Approvals/Certificates

All companies formed under PRC law must have a business license issued by the PRC Administration of Industry and Commerce or its local counterpart. The business license will identify the company's "vital statistics," including the identity of its shareholder(s), the amount of registered capital, business scope, term of business operation (unlike U.S. corporations, Chinese companies do not have perpetual

[1] A greenfield investment refers to—as opposed to an acquisition—a foreign investor's formation of a foreign-invested enterprise in China, primarily including a wholly foreign owned enterprise, an equity joint venture, and a cooperative joint venture.

existence), legal responsible person,[2] and the company's registered address. The business license will also indicate whether the company passed the annual examination of government agencies, which indicates to some extent whether the company is in good standing. Accordingly, obtaining a copy of the current business license of the target company is imperative in any due diligence investigation. In addition, other government-issued certificates such as the legal entity code certificate[3] and tax registration certificate[4] are also important indicators of the target's legal standing.

Apart from the regulation of corporate entities generally, depending on the industry in which the company is engaged in business, there may be additional industry-specific regulatory requirements. Specific approvals/licenses for a medical device company will be discussed under the headline "Classification and Registration of a Medical Device," below.

Real Estate

The rights to land in China possess some distinctive characteristics because almost all land is owned by the state except for certain rural land areas owned by rural collectives.[5] While land generally cannot be "owned," rights of use may be. Generally, the state grants land use rights (LUR) with the obligation to pay a grant fee. In some limited exceptions, the state can allocate LUR free of charge, but those situations are not generally applicable to foreign-invested companies. At the time that the state grants LUR with respect to a parcel of land, the holder must sign a LUR grant agreement with the state specifying the area, term, and usage of the land, as well as the amount of the LUR grant fee and the annual land use fee, and the restrictions in terms of floor area ratio, construction density, and green area coverage. Subsequently, the LUR holder can transfer, lease, or assign them much as a real estate owner may do in the United States (there are some exceptions to this general rule, of course).

[2] Such person serves a role that combines the functions of a registered agent and a corporate secretary in a U.S. corporation.
[3] The legal entity code certificate records a code unique to a given entity registered in China, which helps to confirm whether such entity is duly registered.
[4] After registering with local tax authorities, an entity registered in China will receive a tax registration certificate.
[5] The rural collective economic organizations refer to villagers committees.

In a due diligence investigation, regardless of whether the target leases or owns its facility, the potential foreign investor needs to confirm that the target has valid rights in the real property. Whether the site is leased or owned, the focus is on confirming the rights available under the lease and verifying that the landlord has valid title (and thus, the ability to grant the rights set forth in the lease). It is also advisable to confirm whether there is any special restriction stipulated in the LUR grant agreement that might affect the proposed transaction, whether the LUR holder has paid the LUR grant fee and land use fee in accordance with the LUR grant agreement. Regardless of whether the target holds lease rights or ownership rights, whether the LUR has been mortgaged to secure bank or other loans should be confirmed.

Intellectual Property Rights

Many Chinese companies do not pay sufficient attention to intellectual property (IP) protection and may be using a third party's IP rights inadvertently or intentionally. It is therefore imperative to ensure that all IP rights are appropriately registered or in the application process,[6] that the company is free from violation of others' IP rights,[7] and where needed, that valid IP license agreements are properly concluded.

Material Agreements

Business in China is typically conducted in a less document-intensive way than is common in the United States. Some Chinese companies may use very simple forms of agreement that would be viewed as inadequate according to U.S. legal standards. An interview with key executives of a Chinese partner/target company about underlying factual matters may, however, reveal more substantial information about the deal concerned. Accordingly, it is advisable to use both forms of conducting diligence and then consolidate such information into the representations and warranties in the joint venture contract or equity transfer agreement.

Accounting and Tax

One of the pitfalls of doing business with a Chinese company is that some companies have two or more sets of accounting books. Although it is not lawful,

[6] The intellectual property (IP) registration in China can be quite time consuming. For example, a trademark registration will typically take three years to complete.

[7] It is possible that some companies are not aware of its violation of others' IP rights. As an example, some may use others' product photocopy in its marketing brochure.

many PRC companies maintain one set of books for internal reference, stating the company's true financial position, and another set for government agencies that may show lower taxable revenues. Even in the case of a company with a single set of books, a foreign investor may still feel confused with its accounting system because the accounting standards used might deviate significantly from U.S. Generally Accepted Accounting Principles. Therefore, it is often recommended to involve a capable accounting firm to assist with the accounting/financial due diligence, and to place the records in a context that a U.S. investor can understand

Employment

PRC labor laws, being basically employee-friendly, require that an employer sign an employment contract with each of its employees. Employers are allowed to terminate their employees only in limited circumstances, and, typically, severance is required upon termination. Where a transaction will require a layoff of employees, a foreign investor may want to require the Chinese target to conduct the termination prior to the closing.

In addition, it is also critical to ascertain whether the Chinese company has made mandatory contributions to statutorily required social insurance funds in its employees' respect. In the case of an equity acquisition, if the PRC company has been underpaying such funds, the potential liability will remain with the target company, and thus the foreign investor may discover undisclosed liabilities after closing.

Specific Issues for Medical Device Industry

Classification and Registration of Medical Device

At the outset, it is worth noting that China does not recognize a drug and medical device combination product. This is probably because registrations of drugs and medical devices are governed by separate departments under the State Food and Drug Administration of the People's Republic of China (SFDA), the regulatory body in charge of the administration of medical devices in China. Consequently, in the case of a combination product with medical device primary mode of action, the

SFDA will deem it as a medical device and vice versa.[8] If needed, a manufacturer or importer may request that the SFDA confirm whether a product should be deemed a drug device or a medical device.

- Classification of Medical Device

Under PRC laws, medical devices—whether imported or manufactured for sale in China—are classified into three main categories:[9]

> ***Class I*** *Medical devices shall refer to those devices whose safety and effectiveness can be ensured through routine administration.*
>
> ***Class II*** *Medical devices shall refer to those devices whose safety and effectiveness should be controlled.*
>
> ***Class III*** *Medical devices shall refer to those devices that are implanted into the human body, or used for life support or sustenance, that may pose potential risk to the human body, and the safety and effectiveness of which must be strictly controlled.*

The SFDA has issued the Guidelines for Classification of Medical Devices to introduce methodology for determining the relevant class for any given medical device.[10] The classification of medical devices is determined by an assessment based on three main aspects of the device: (1) structural characteristics (active or passive);[11] (2) form of operation;[12] and (3) conditions for use.[13] Based on such

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[8] *See* Article 1 of the Circular Concerning the Registration and Administration of Drug and Medical Device Combination Products, issued by the State Food and Drug Administration on April 5, 2004, and effective as of August 1, 2004.

[9] *See* Article 5 of the Provisions for Medical Device Administration and Supervision, issued by the State Council on January 4, 2000, and effective as of April 1, 2000.

[10] *See* Article 5 of the Provisions for Medical Device Classification, issued by the State Drug Administration (now SFDA) on April 5, 2000, and effective as of April 10, 2000.

[11] The structural characteristics refer to whether a medical device is "active" or "passive." An active device is a device that operates on electric power or other forms of energy excluding those directly generated by human body or gravity. Consequently, any medical devices other than active devices are passive devices. *See* Article 5 and 8 of the Provisions for Medical Device Classification, issued by the State Drug Administration (now SFDA) on April 5, 2000, and effective as of April 10, 2000.

[12] The form of operation actually refers to various usages of medical devices. In terms of passive devices, the form of operation includes surgery devices, implant devices, disinfection devices, nursing devices, etc. In terms of active devices, the form of operation includes energetic therapy devices, diagnosis and monitoring devices, ionization and radioactive devices, etc. *See* Article 5 of the Provisions for Medical Device Classification, issued by the State Drug Administration (now SFDA) on April 5, 2000, and effective as of April 10, 2000.

[13] The condition for use refers to whether or not the device makes contact or is inserted into the body. *See* Article 5 of the Provisions for Medical Device Classification, issued by the State Drug Administration (now SFDA) on April 5, 2000, and effective as of April 10, 2000.

methodology, the SFDA then issued the Classification Catalogue of Medical Device (Classification Catalogue). A medical device manufacturer or importer should carefully study the Classification Catalogue to assess an appropriate classification of any given medical device that it contemplates manufacturing or distributing in China because such classification will have a material impact on the registration of such device as further discussed in the paragraphs immediately below.

- Registration of Medical Device

Any medical devices either imported or manufactured for sale in China must be registered with the SFDA or its local branch, as the case may be. In terms of a device manufactured in China (Domestic Product), the applicant for such registration must be a medical device manufacturer with an appropriate manufacturing license.[14] In terms of a device manufactured outside of China and imported into China for sale (Foreign Product), the applicant must be a China-based entity designated by a foreign medical device manufacturer with an appropriate manufacturing license issued by the competent authority in its origin country.[15] In other words, only specially approved companies are allowed to manufacture or distribute overseas medical devices.

The registration application for a Class I Domestic Product must be submitted to the SFDA branch of the city/district where the applicant is located.[16] The SFDA branch at the provincial level will be responsible for the registration of Class II Domestic Products, and the SFDA at the national level will be responsible for the registration of Class III Domestic Products and all Foreign Products.[17]

The registration of a Class I medical device, regardless of whether it is a Domestic Product or a Foreign Product, is somewhat less complicated because it does not require registration testing or clinical trial in China, which is required in the case of

[14] *See* Article 6 of the Regulation on Administration of Medical Device Registration, issued by the State Food and Drug Administration on August 9, 2004 and effective as of August 9, 2004. The requirement for medical device manufacturer will be further explored in the "License of Medical Device Manufacturing/Distribution," below.
[15] *See* Article 6 of the Regulation on Administration of Medical Device Registration and its Appendix 6 to 9, issued by the State Food and Drug Administration on August 9, 2004, and effective as of August 9, 2004.
[16] *See* Article 4 of the Regulation on Administration of Medical Device Registration, issued by the State Food and Drug Administration on August 9, 2004, and effective as of August 9, 2004.
[17] *See* Article 4 of the Regulation on Administration of Medical Device Registration, issued by the State Food and Drug Administration on August 9, 2004, and effective as of August 9, 2004.

the registration of a Class II or Class III medical device, with certain exceptions.[18] Notwithstanding the aforementioned, a Class II or Class III device might be exempted from clinical trial in China under certain circumstances such as (1) for a Class II Domestic Product, the applicant's other products of the same category as the device concerned have been approved for more than two years by the SFDA to be used in China market; or (2) for a Class II or Class III Foreign Product except those to be implanted into the human body, the device concerned has received approval to be sold in its country of origin.[19] Likewise, an applicant may apply for the exemption from registration testing if all statutory conditions are satisfied.[20]

If granted, the medical device registration would be valid for four years and may be renewed within six months prior to its expiration. Non-manufacturing of the concerned product for two years automatically invalidates a registration.[21]

In light of the aforementioned, a foreign investor that contemplates acquiring a China-based medical device manufacturer needs to determine whether the target has received an appropriate medical device registration certificate in China. On the other hand, in the case of a greenfield investment, any newly established device manufacturer should perform such registration for each of the products to be manufactured and distributed in China in accordance with PRC laws. The ability to effect such registration is clearly an important consideration in any such proposed transaction.

License of Medical Device Manufacturing/Distribution

Entities seeking to manufacture medical devices for sale in China must obtain approval to do so. The type of approval needed will depend on the Class of device

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[18] *See* Articles 9 and 16 of the Regulation on Administration of Medical Device Registration, issued by the State Food and Drug Administration on August 9, 2004, and effective as of August 9, 2004.
[19] *See* Appendix 12 of the Regulation on Administration of Medical Device Registration, issued by the State Food and Drug Administration on August 9, 2004, and effective as of August 9, 2004.
[20] *See* Article 13 of the Regulation on Administration of Medical Device Registration, issued by the State Food and Drug Administration on August 9, 2004, and effective as of August 9, 2004. Such conditions include: (1) the manufacturer (applicant) has passed the medical device quality system certification in China; (2) the primary functions, structure, materials, and usage of the device is within the same category as the applicant's other medical device products that have been registered in China; (3) no serious adverse impact has been discovered on the applicant's registered medical device products of the same category; (4) no quality failure of the applicant's registered medical device products of the same category occurs within one-year period; and (5) for a Foreign Product, such product has received marketing approval in its country of origin.
[21] *See* Article 14 of the Provisions for Medical Device Administration and Supervision, issued by the State Council on January 4, 2000, and effective as of April 1, 2000.

that will be manufactured. An enterprise that engages in the manufacture of Class I medical devices only is required to perform a simple registration with the provincial-level SFDA at its locality within thirty days from the receipt of its business license.[22] If the enterprise contemplates manufacturing Class II or Class III medical devices, it must apply to the SFDA for a medical device manufacturer license (Manufacturer License)[23] before applying for its business license.[24] The SFDA has established certain general conditions for the application for a Manufacturer License, including the capabilities of an applicant's chief quality controller, the composition of technical personnel, and requiring that the manufacturing facility, equipment, and the quality-testing system conform to the devices proposed to be manufactured.[25] An applicant is also required to state and record on its Manufacturer License the scope and category of the devices it expects to manufacture.[26] Where a licensed manufacturer intends to expand its business scope beyond the approved range of products in its Manufacturer License, such manufacturer must apply for an update of its Manufacturer License at least thirty days prior to such expansion.[27] Therefore, in an acquisition scenario, it is advisable that a foreign investor check whether the target company's Manufacturer License covers all the medical devices that are being produced.

After obtaining the Manufacturer License, a manufacturer may apply to register the medical devices that it will manufacture. Similar to the registration/license requirements for a medical device manufacturer, an entity seeking to distribute Class I medical devices throughout China must register with the competent SFDA branch.

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[22] *See* Article 6 of the Measures on the Administration and Supervision of Medical Device Manufacturing, issued by the State Food and Drug Administration on July 20, 2004, and effective as of July 20, 2004.
[23] *See* Article 9 of the Measures on the Administration and Supervision of Medical Device Manufacturing, issued by the State Food and Drug Administration on July 20, 2004, and effective as of July 20, 2004.
[24] *See* Article 20 of the Provisions for Medical Device Administration and Supervision, issued by the State Council on January 4, 2000, and effective as of April 1, 2000.
[25] *See* Article 7 and 8 of the Measures on the Administration and Supervision of Medical Device Manufacturing, issued by the State Food and Drug Administration on July 20, 2004, and effective as of July 20, 2004.
[26] *See* Article 16 of the Measures on the Administration and Supervision of Medical Device Manufacturing, issued by the State Food and Drug Administration on July 20, 2004, and effective as of July 20, 2004.
[27] *See* Article 18 of the Measures on the Administration and Supervision of Medical Device Manufacturing, issued by the State Food and Drug Administration on July 20, 2004, and effective as of July 20, 2004.

By contrast, an entity seeking to distribute Class II or Class III devices[28] must obtain a medical device dealer license (Dealer License).[29] Notwithstanding the foregoing, a licensed medical device manufacturer may sell its products to a licensed dealer or a hospital without separately becoming a licensed dealer itself.[30]

The Manufacturer License and the Dealer License are each valid for five years.

Medical Device GMP

Early in 2006, the SFDA took a significant step toward implementing of Good Manufacturing Practices (GMP) on medical device products nationwide. The adoption of GMP raised the standards for medical device manufacturing to international levels, not only benefitting the health of China's general public but also increasing the competitiveness of China-based medical device manufacturers in the global market. However, there was no general GMP rule applicable to all medical devices until December 2009, when SFDA promulgated a package of regulations specifying GMP for medical devices. These included the Regulation on Medical Device GMP[31] (GMP Rules) and the Regulation on Examination of Medical Device GMP[32] (GMP Exam Rules). Both the GMP Rules and the GMP Exam Rules will become effective as of January 1, 2011.

Under the GMP Rules, it is critical for a manufacturer to create and maintain documentation that evidences the manufacturer's compliance with GMP. The following requirements deserve particularly close attention: [33]

- A manufacturer is required to create a package of quality management rules, including quality standard, product specification, standards for product manufacturing, testing, examination, installation, and after-sales services.

[28] Distribution of certain specified Class II medical devices does not require a medical device dealer license. Such Class II devices include thermometer, manometer, medical masks, medical gauze, and wheel chair.
[29] *See* Article 24 of the Provisions for Medical Device Administration and Supervision, issued by the State Council on January 4, 2000, and effective as of April 1, 2000.
[30] *See* Article 26 of the Provisions for Medical Device Administration and Supervision, issued by the State Council on January 4, 2000, and effective as of April 1, 2000.
[31] The Regulation on Medical Device GMP, issued by the State Food and Drug Administration on December 16, 2009, and effective as of January 1, 2011.
[32] The Regulation on Examination of Medical Device GMP, issued by the State Food and Drug Administration on December 16, 2009, and effective as of January 1, 2011.
[33] *See* Articles 10, 11, 17, 26, 34, 38, 41, and 57 of the Regulation on Medical Device GMP, issued by the State Food and Drug Administration on December 16, 2009, and effective as of January 1, 2011.

- At an early design stage, a manufacturer must well-document, after internal review and confirmation, the anticipated function, usage, and performance of its products, and the associated safety issues and risk-control arrangements.
- With respect to the sourcing process, the standards for evaluating and selecting suppliers must be established by the manufacturer, with the evaluation process and results appropriately recorded.
- With regard to the production process, the manufacturer must create and maintain manufacturing records for each set of products, and such records should specify the output and offer the product's traceability.
- The manufacturer must adopt written procedures for product monitoring and measurement. The monitoring and measuring devices must be regularly calibrated and the calibration records appropriately maintained. If any monitoring or measuring device malfunctions, the reliability of the data previously collected from such device must be re-evaluated and the re-evaluation result must be recorded.
- The manufacturer must designate a department to receive, investigate, evaluate, and handle customer complaints, and maintain a record of all such complaints. If a manufacturer decides not to take any corrective or preventive action after receiving a complaint, such decision must be given internal approval and supported by reasons specified in writing.

The GMP Rules also require a manufacturer to adopt document control procedures. The issuance of document and any amendments thereto must be internally approved, and all amendments must be identified to ensure that the applicable version is available on the work site.[34] For product repair and product liability determinations, any repealed document must be appropriately labeled and preserved for a specified period.[35] Unless otherwise stipulated in other laws or regulations, a manufacturer must maintain its documents for the life cycle of the relevant medical device product, or two years from the date when the product was released, whichever is longer.[36]

[34] *See* Article 12 of the Regulation on Medical Device GMP, issued by the State Food and Drug Administration on December 16, 2009, and effective as of January 1, 2011.
[35] *See* Article 13 of the Regulation on Medical Device GMP, issued by the State Food and Drug Administration on December 16, 2009, and effective as of January 1, 2011.
[36] *See* Article 14 of the Regulation on Medical Device GMP, issued by the State Food and Drug Administration on December 16, 2009, and effective as of January 1, 2011.

According to the GMP Exam Rules, a manufacturer of Class II or Class III medical devices must apply for a GMP examination after its establishment of the necessary quality management system in accordance with the GMP Rules, whereas a manufacturer of Class I medical devices is exempted from the GMP exam.[37]

As a portion of the GMP exam, the SFDA or its local branches will conduct on-site investigations within thirty business days of a manufacturer submitting all required application materials. A manufacturer will be given an exam notice five business days in advance. SFDA will then select at least two inspectors to form an investigation committee that will notify the manufacturer of the investigation's scope and agenda. The on-site investigation will be conducted in accordance with the standards applicable to the medical device concerned. At the end of 2009, SFDA issued examination standards for sterilized devices and implantable devices.

A manufacturer that passes the exam will receive a pass notice that should be valid for four years. Given that the GMP rules will not become effective until January 2011, an investor in the medical device sector in the PRC should check whether the target company has begun the process of upgrading its quality management system to conform to the GMP standards, as it is likely that the registration of any Class II or Class III medical device in the PRC will require a manufacturer to pass the GMP examination.

OEM Model

The term Original Equipment Manufacturer (OEM) typically refers to an outsourcing arrangement whereby a company contracts with a secondary company that carries out all or part of the production processes based on contractual arrangements. Under PRC law, the use of such an OEM arrangement is referred to as "Consignment Manufacturing," with the company that "hires" the secondary company termed the "Consigner" and the secondary company termed the "Consignee."[38]

To adopt Consignment Manufacturing for medical devices, both the Consigner and the Consignee must be medical device manufacturers, each holding a valid license or registration (In the case of Class II or Class III devices, this would be a

[37] *See* Article 4 of the Regulation on Examination of Medical Device GMP, issued by the State Food and Drug Administration on December 16, 2009, and effective as of January 1, 2011.
[38] *See* Chapter 4 of the Measures on the Administration and Supervision of Medical Device Manufacturing, issued by the State Food and Drug Administration on July 20, 2004, and effective as of July 20, 2004.

Manufacture License; in the case of Class I devices, it would be a manufacturer registration certificate).[39] The Consignor must have obtained the medical device registration certificate for the devices to be manufactured by the Consignee based on the contractual arrangement.[40] Such devices must also be within the Consignee's[41] business scope, as evidenced by its Manufacturer License.[42] The Consigner must be responsible for the quality of the medical device manufactured by its Consignee under the Consignment Manufacturing.[43]

In addition, a Consigner must register such Consignment Manufacturing with the provincial-level SFDA branch at its locality within thirty days of the execution of the consignment manufacturing agreement with its Consignee.

It is noteworthy that the SFDA does not allow the use of Consignment Manufacturing on certain specified medical devices, including artificial heart valves, drug-loaded stents, and traditional blood bags.[44] The SFDA may prohibit more medical devices from Consignment Manufacturing if such devices meet the following conditions: (1) the devices contain high risk and their quality failure may cause substantial damage to the human body; (2) there is a large demand for the devices, which might be used by a wide range of people; (3) the manufacturing process and procedures for the devices should be subject to strict control; and (4) a number of suspect adverse impacts could arise from the use of the devices.[45]

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[39] *See* Articles 26 and 27 of the Measures on the Administration and Supervision of Medical Device Manufacturing, issued by the State Food and Drug Administration on July 20, 2004, and effective as of July 20, 2004.
[40] *See* Article 26 of the Measures on the Administration and Supervision of Medical Device Manufacturing, issued by the State Food and Drug Administration on July 20, 2004, and effective as of July 20, 2004.
[41] *See* Article 27 of the Measures on the Administration and Supervision of Medical Device Manufacturing, issued by the State Food and Drug Administration on July 20, 2004, and effective as of July 20, 2004.
[42] If the product to be manufactured by the Consignee is a component, part, or material of a medical device that itself is not deemed as a medical device, such consignment manufacturing will not be subject to the restrictions discussed in this Executive Summary. *See* Article 34 of the Measures on the Administration and Supervision of Medical Device Manufacturing, issued by the State Food and Drug Administration on July 20, 2004, and effective as of July 20, 2004.
[43] *See* Article 28 of the Measures on the Administration and Supervision of Medical Device Manufacturing, issued by the State Food and Drug Administration on July 20, 2004, and effective as of July 20, 2004.
[44] *See* Article 2 of the Notice for Issuance of The First Batch of Medical Devices Prohibited from Consignment Manufacturing, issued by the State Food and Drug Administration on April 22, 2005, and effective as of April 22, 2005.
[45] *See* Article 1 of the Notice for Issuance of The First Batch of Medical Devices Prohibited from Consignment Manufacturing, issued by the State Food and Drug Administration on April 22, 2005, and effective as of April 22, 2005.

Incentives and Restrictions for Foreign Investment in Medical Device Industry

Incentives

Encouraged Industries

China classifies all industries into categories for foreign investment purposes. The PRC Guidance Catalogue of Industries with Foreign Investment (Investment Catalogue)[46] and other relevant regulations classify industries with foreign investment into four categories, namely encouraged industries, permitted industries, restricted industries, and prohibited industries.[47] Certain medical-device-related industries, including the manufacturing of electronic endoscopes, medical transducers (3D), hemodialysis machines, automatic enzyme immunoassay equipments, new types of drug quality-control equipment, and key components of medical imaging equipment[48] are in the "encouraged" category. This has significance in various ways, as explained below.

Unless otherwise stipulated by applicable PRC law, any foreign-invested project in an encouraged industry is entitled to exemption from import duties and import value-added tax for any equipment imported for self-use and the ancillary technology, components, and spare parts.[49] In addition, compared with a foreign-invested project in a restricted industry, foreign investment in an encouraged or permitted industry might be subject to examination and approval by government agencies at lower levels, which generally will require less time and involve less scrutiny (i.e., the presumption will tend to be that the investment should be allowed absent some major problem). To illustrate, a foreign-invested project in a restricted industry with a total investment of no less than $50 million is subject to approval by the Ministry of Commerce (MOFCOM)—i.e., the national level agency responsible for oversight over all foreign investment into China—which will typically take three months. In

[46] Guidance Catalogue of Industries with Foreign Investment, jointly issued by Ministry of Commerce and National Development and Reform Commission on October 31, 2007, and effective as of December 1, 2007.
[47] The Investment Category lists the encouraged industries, restricted industries, and prohibited industries. The industries beyond the Investment Category should be in the permitted industries, jointly issued by Ministry of Commerce and National Development and Reform Commission on October 31, 2007 and effective as of December 1, 2007.
[48] *See* Item 45 to 54, Section 18 of Encouraged Industries of the Investment Category, jointly issued by Ministry of Commerce and National Development and Reform Commission on October 31, 2007, and effective as of December 1, 2007.
[49] *See* Article 1 of Notice of the General Administration of Customs Order 67 of 2007, issued by the General Administration of Customs on November 26, 2007, and effective as of December 1, 2007.

contrast, any foreign-invested projects in an encouraged industry except those requiring national overall balance[50] will be subject to approval by a MOFCOM local branch at the provincial or even lower level, depending on the size of the total investment, and such approval will typically take one to two months.

China has also adopted some geographically focused initiatives to encourage investment. As a part of China's middle and western area development campaign, any foreign investment in designated industries located in the middle and western portions of the country may enjoy the same preferential treatment available to encouraged industries of the Investment Catalogue. Such designated industries include the development and manufacturing of (1) digital medical devices and their key components in Liaoning and Sichuan Provinces; (2) digital medical devices or devices with biological materials in Jiangxi Province; (3) laser medical devices in Hubei Province; and (4) new types of medical devices in Chongqing Municipality.[51]

High-and-New Technology Designation

If the products or services of a company, whether foreign-invested or purely domestic, fall within the scope of the High-and-New Technology Industries Supported by the State (Hi-Tech Industries), such an enterprise may apply for designation as a High-and-New Technology Enterprise (Hi-Tech Enterprise) provided that other stipulated conditions in terms of the ownership or possession of intellectual property, the composition of science and technology personnel, the allocation of development and research budget, and the revenue of such product or service within the scope of Hi-Tech Industries are all satisfied.[52] An approved Hi-Tech Enterprise is entitled to enjoying a preferential enterprise income tax rate of 15%,[53] instead of the 25% rate otherwise applicable to non-Hi-Tech enterprises.

Certain medical device-related industries are included in the Hi-Tech Industries, including new types of minimally invasive surgical devices, emergency-use devices,

[50] There is however no clear definition of "projects requiring national overall balance," which leaves MOFCOM with huge discretion.
[51] *See* the Catalogue of Advantageous Industries for Foreign Investment in Middle and Western Area, jointly issued by the National Development and Reform Commission and the Ministry of Commerce on December 23, 2008, and effective as of January 1, 2009.
[52] *See* Article 10 of the Administration Measures for Designation of High and New Technology Enterprise, jointly issued by the Ministry of Science and Technology, the Ministry of Finance, and the State Administration of Taxation on April 14, 2008, and effective as of January 1, 2008.
[53] *See* Article 28 of the Enterprise Income Tax Law of the People's Republic of China, adopted at the fifth Session of the tenth National People's Congress of the People's Republic of China on March 16, 2007, and effective as of January 1, 2008.

medical laser equipment, digital electrophysiological testing and monitoring devices, automated and so-called informationized biochemical testers, and analyzers.[54]

Special Incentives in Certain Provinces/Industrial Parks

- Jiangsu Province

Jiangsu Province in eastern China has established a fund to encourage the commercialization of science and technology in specified industries such as biological technology that covers medical devices. Any Jiangsu-based enterprise with strong science and technology innovation capabilities and sound credit performance may apply for such funding. Jiangsu government uses the fund as a government subsidy to compensate for research and development expenses or interest on bank loans for qualified enterprises. It is reported that a Jiangsu-based company received a government subsidy of more than $1.47 million in 2009 for its development and industrialization of a certain high-definition, digital X-ray apparatus.[55]

- Wuhan Donghu New Technology Development Zone

An enterprise engaged in biological industries including medical device and located in the designated area of Wuhan Donghu New Technology Development Zone of Hubei Province may enjoy the following incentives:[56] (1) a lump-sum bonus up to $440,000, available to a research and development entity, marketing, and sales center or manufacturing base established by a Fortune 500 company or a listed company; (2) a refund of the local portion of enterprise income taxes paid within three years from the commencement of operations, available to a project with its total investment amount not less than $2.9 million; (3) a lump-sum bonus of $2.9 million, available to a foreign-invested company whose principal business revenue reaches $14.7 million; and (4) a lump-sum subsidy of up to $140,000 for each medical device registered with the SFDA.

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[54] *See* the Appendix of the Administration Measures for Designation of High and New Technology Enterprise, issued by the Ministry of Science and Technology, the Ministry of Finance, and the State Administration of Taxation on April 14, 2008, and effective as of January 1, 2008.
[55] *See* Yuyue Medical Receives Government Funding for Commercialization of Substantial Science and Technology, *available at* www.yuyue.com.cn/shownews.asp?id=452 , last visited on October 28, 2009.
[56] *See* Article 2, 4, 5, 6, and 10 of the Implementation Rules of Encouraging the Development of Biological Industries in Wuhan Donghu New Technology Development Zone, *available at* www.biolake.gov.cn/show.asp?id=1341, last visited on March 11, 2010.

- Shanghai Upper Bio-Tech Business, Research, and Manufacturing Center

A Hi-Tech Enterprise located in the Shanghai Upper Bio-Tech Business, Research, and Manufacturing Center may enjoy a full refund of business tax and enterprise income tax retained by the local government within two years from its designation as a Hi-Tech Enterprise, and a 50% refund of enterprise income tax retained by the local government from the third year to the fifth year.[57] In addition, a start-up company with its own intellectual property and development potential may apply for subsidies to compensate for 30% of its annual research and development expenses for up to two years.

Restrictions

Restricted Industries

According to the Investment Catalogue, the manufacturing of non-self-destructing disposable syringes, infusion apparatuses, and blood bags are restricted industries.[58] Though not expressly stipulated, foreign investment in such industry will likely be subject to more cautious examination by government agencies.

User Direction, Packaging, Labeling, and Advertisement

In addition to the registration/license requirements described in the "Restricted Industries" section above, there are strict regulatory requirements with respect to user directions, packaging, labels, and advertisement of medical device products. User directions, packaging, and labels for a medical device must specify certain stipulated information such as the name, registered manufacturer address, place of manufacturing, and the registration number of the medical device registration certificate.[59] In particular, user directions and the packaging and label of a medical device produced using a Consignment Manufacturing arrangement must indicate the company name of both the Consigner and the Consignee. A manufacturer is not allowed to state comparisons between its products and the products of other manufacturers in terms of the functions or the safety of the products, or to use any

[57] *See* Preferential Policies in Upper Bio-Tech Business, Research, and Manufacturing Center, *available at* www.uppercenter.com/info/ShowInfo.asp?ID=7, last visited on October 28, 2009.
[58] *See* Item 6, Section 7 of Restricted Industries of the Investment Category, jointly issued by Ministry of Commerce and National Development and Reform Commission on October 31, 2007, and effective as of December 1, 2007.
[59] *See* Articles 7 and 8 of the Regulation on Administration of User Direction, Packaging and Labeling of Medical Device, issued by the State Food and Drug Administration of July 8, 2004, and effective as of July 8, 2004.

language with absolute assertion such as “best effect,” “completely no adverse impact,” “100% cure,” or other misleading language.[60]

To advertise a medical device product,[61] a manufacturer or distributor must obtain approval of the advertisement from the competent provincial-level SFDA.[62] Such advertisement must specify the name of the medical device that will be advertised and the manufacturer, registration number of the medical device registration certificate, and the number of the advertisement approval.[63] The advertisement may not contain any absolute assertion, exaggerated or misleading language, or use the image of a doctor, expert, patient, or hospital.[64]

This concludes the Executive Summary of the key aspects for evaluating the potential formation of or investment in a medical device manufacturing operation in China. As indicated, there are myriad factors that will drive the feasibility and attractiveness of such an investment, and careful consideration of these issues is vital for a good outcome for the foreign investor.

**Access Daniel F. Roules' biography at www.ssd.com/droules/life_sciences and Chen Changshun's (Ryan) biography at www.ssd.com/crchen/.*

[60] *See* Article 9 of the Regulation on Administration of User Direction, Packaging and Labeling of Medical Device, issued by the State Food and Drug Administration of July 8, 2004, and effective as of July 8, 2004.
[61] If an advertisement indicates the name of a medical device only, the advertisement approval is not needed. *See* Article 2 of the Measures for Examination of Medical Device Advertisement.
[62] *See* Article 2 of the Measures for Examination of Medical Device Advertisement, jointly issued by the Ministry of Health, the State Administration for Industry and Commerce, and the State Food and Drug Administration on April 7, 2009, and effective as of May 20, 2009.
[63] *See* Article 6 of the Standards for Publication of Medical Device Advertisement, jointly issued by the Ministry of Health, the State Administration for Industry and Commerce, and the State Food and Drug Administration on April 28, 2009, and effective as of May 20, 2009.
[64] *See* Article 10, 11, 12 of the Standards for Publication of Medical Device Advertisement, jointly issued by the Ministry of Health, the State Administration for Industry and Commerce, and the State Food and Drug Administration on April 28, 2009 and effective as of May 20, 2009.