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 **NORTON ROSE FULBRIGHT**

# Tapping into China's medical devices industry

Top ten things to know



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## Top ten things to know

### 01 | Why enter into the China Market?

China has become the world's second largest medical device market with an average growth of 20 per cent year-on-year. However, this rapid growth has not kept up with strong demand driven by an increasingly aging population and a growth in the number of affluent consumers who seek better quality medical services. Currently, there is a lack of resources and underdevelopment in relation to medical devices in rural areas and it is anticipated that the demand for medical devices will also increase from second and third tier cities and villages in the coming five to ten years.

China's first comprehensive five-year blueprint for the healthcare sector, the National Planning Guideline for the Healthcare Service System (2015–2020), sets out clear targets for 2020 including (i) one clinic and one medical service centre for each community with a population of over 30,000; and (ii) 1.2 hospital beds for every 1,000 residents within the community. Li Beiguang, Deputy Director of the Planning Department of the Ministry of Industry and Information Technology, who was in charge of drafting the national plan 'Made in China (2025)' recently stated that at least 70 per cent of the medical devices used by county level hospitals and clinics in China must be domestically manufactured in China by 2025. This signals potential for development of China's medical device market which may offer opportunities for multinational corporations as well as for SME manufacturers.

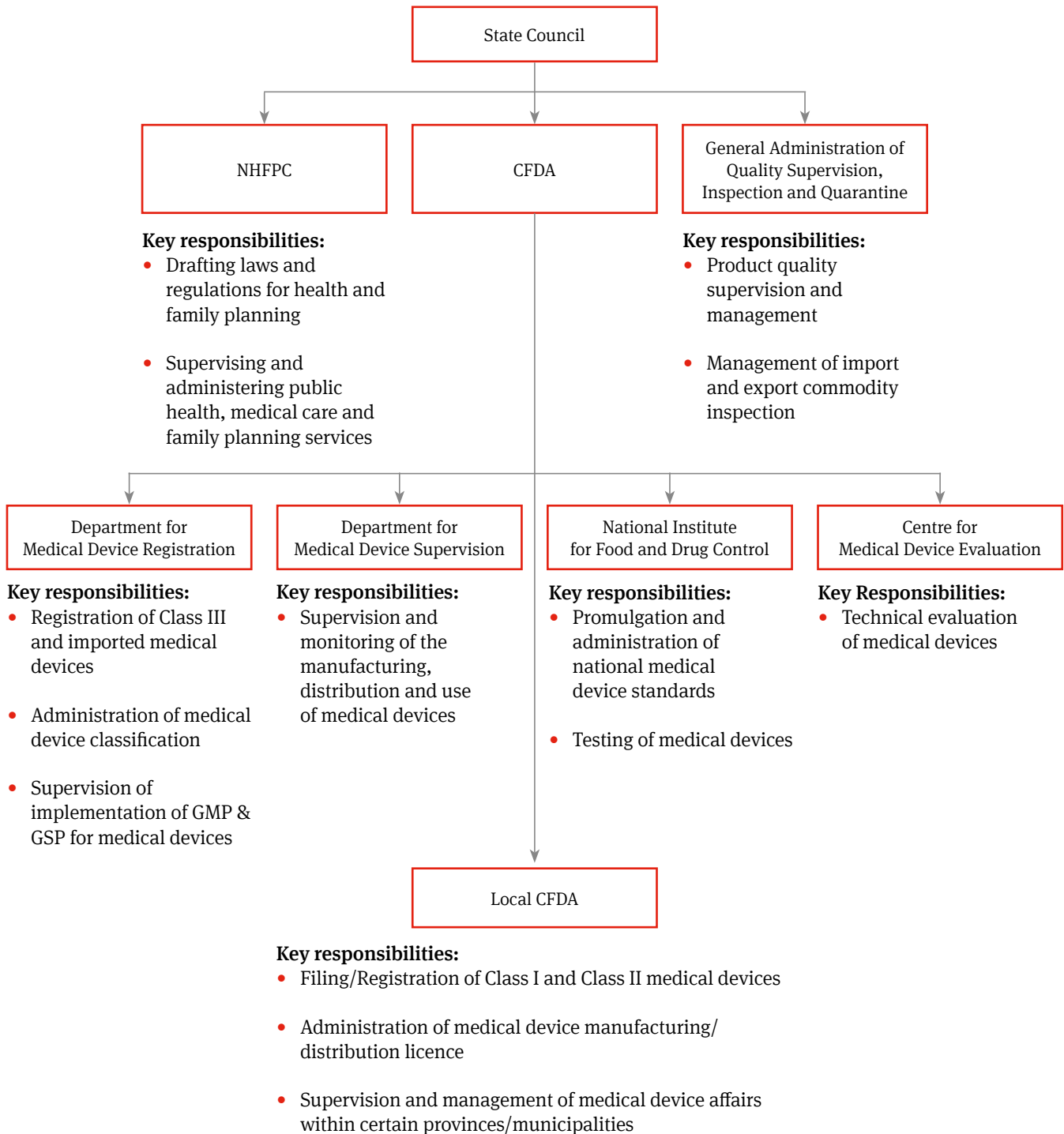
### 02 | Do I have to move my manufacturing to China?

Yes. There are over 16,000 hospitals in China, 85 per cent of which are publicly owned and which spend more than RMB200 billion every year purchasing low to mid-end medical devices from domestic manufacturers and import mid to high-end products from foreign manufacturers. Procurement is conducted through a centralised tender process.

Public hospitals are not prevented from importing medical devices; however, in practice, public hospitals are encouraged to purchase domestically manufactured and domestically branded products. The National Health and Family Planning Commission (NHFPC) is in the process of establishing an incentive scheme to encourage the use of domestically produced medical devices and it is creating a series of lists of qualified products. In light of this incentive scheme, a number of foreign companies are moving or considering moving their production to China so that their products can meet the qualifications under the incentive scheme in order to remain competitive in the Chinese market.

### 03 | What is the key legislation and what is the key regulatory body?

In 2014, China's State Council promulgated the revised Regulation for the Supervision and Administration of Medical Devices, following which a number of implementation regulations have been issued by the China Food and Drug Administration (CFDA), the key regulator of China's pharmaceutical and healthcare industry. These include the Provisions for Supervision and Administration of Medical Device Manufacturing, the Provisions for Supervision and Administration on Medical Device Distribution and the Provisions for Administration of Medical Device Registration.



**04 | Is foreign investment in medical device manufacturing encouraged?**

Foreign investment in the manufacturing and distribution of medical devices is generally encouraged. Foreign investors may establish wholly owned subsidiaries (WFOE) in China or form joint ventures with Chinese partners.

However, the foreign investment regime in China is still not entirely open. A foreign investment project is still subject to the approval of the Ministry of Commerce or its delegated local branch (MOFCOM), although the central government has been trying to delegate authority to local level authorities to a greater extent as part of its attempt to simplify the procedure and to shorten the timeline for approval. Once the MOFCOM approval is received, business registration with the competent Administration for Industry and Commerce (AIC) needs to be completed within one month and the foreign investment enterprise (FIE) is deemed to be established from the day its business licence is issued.

Please see the flowchart at the end of this article for an overview of the procedure for a foreign medical device manufacturer setting up its own business in China.

**05 | How does the risk-based classification system make product filing/registration easier?**

Unlike most other FIEs which can commence business as soon as they receive their business licence, a medical device manufacturing/distribution FIE can only go into operation after the product to be manufactured/sold in China has been recorded or registered with the CFDA and the FIE itself has obtained the manufacturing and/or distribution licence.

Medical devices are classified into three categories in China based on the level of risks in connection with the use of the devices. Class I devices are deemed safest and Class III devices are deemed most risky. Different classes of devices are subject to different filing and registration requirements with different levels of the CFDA. Class I devices are not subject to a clinical test while Class II and III devices are, with the exception of a few prescribed cases.

The time period for registering a medical device varies from three months to eighteen months, depending on the complexity of the device. Given that a foreign manufacturer is not required to set up its FIE first before registering its product, it is advisable that a foreign manufacturer starts the registration process as soon as it plans to set up a manufacturing facility in China.

Medical Device Registration Certificates are valid for five years from the date of issuance and can be renewed.

**06 | Have CFDA licensing requirements relaxed?**

Compared to the foreign investment approval process, obtaining CFDA licences for the manufacturing and distribution of medical devices is more complex and can be unpredictable. Manufacturing and distribution of different classes of products are subject to different requirements. The table below summarises the licensing and registration requirements for each class of product.

	Product Registration/Filing	Production Licence	Distribution Licence
Class I products	<ul style="list-style-type: none"> <li>Filing with municipal level CFDA</li> </ul>	<ul style="list-style-type: none"> <li>Filing with municipal level CFDA</li> </ul>	<ul style="list-style-type: none"> <li>No filing required</li> </ul>
Class II products	<ul style="list-style-type: none"> <li>Registration with provincial level CFDA</li> <li>Registration Certificate required for each product</li> </ul>	<ul style="list-style-type: none"> <li>Registration at provincial level CFDA</li> <li>Medical Device Production Licence required</li> </ul>	<ul style="list-style-type: none"> <li>Filing with municipal level CFDA</li> </ul>
Class III products	<ul style="list-style-type: none"> <li>Registration with CFDA</li> <li>Registration Certificate required for each product</li> </ul>		<ul style="list-style-type: none"> <li>Registration with municipal level CFDA</li> <li>Medical Device Production Licence required</li> </ul>

In summary, local level filings or applications for Class I and II medical devices are relatively easy and quick compared to the registration of Class III products which must be submitted to the central CFDA.

Each Medical Device Production Licence and Medical Device Distribution Licence is valid for five years from the date of issuance and can be renewed.

#### 07 | Will an expedited procedure be available for innovative medical devices?

Innovative medical devices are eligible for an expedited registration procedure. Medical devices registered and patented in China and other devices which satisfy prescribed technical requirements can be innovative medical devices. However, the CFDA can take up to two months to decide whether a device qualifies as an innovative medical device. Once the CFDA determines that a device qualifies, such device will be given priority in the registration process and an official from the local CFDA will be designated to guide and assist the applicant manufacturer with registration. As a result of this arrangement, the registration procedure and the obtaining of the Medical Device Registration Certificate is likely to be accelerated.

#### 08 | Does the strengthened on-going surveillance help quality control?

The regulatory regime is currently undergoing an overhaul which has seen some barriers removed but a tightening of regulation in some areas. As part of the CFDA's attempt to strengthen its ongoing surveillance and implementation of good practices and following the issuance of the 'Good Manufacturing Practice' and 'Good Sale Practice', manufacturers and suppliers may be subject to regular spot checks and unannounced on-site inspections. The CFDA is also building up a database which will rank medical device registrants, manufacturers and distributors based on the track record of their compliance with regulatory requirements. The database will allow for increased scrutiny from the CFDA, particularly for products which are ranked low in the database.

The CFDA has also introduced more severe penalties for violations. For example, failure to meet the statutory standards or technical specifications will result in a fine of up to ten times the value of the relevant products. In more serious cases, violations could result in the revocation of the Medical Device Registration Certificate and the Production/Distribution Licence which could lead to a product recall for disqualified products.

#### 09 | How can I advertise my products?

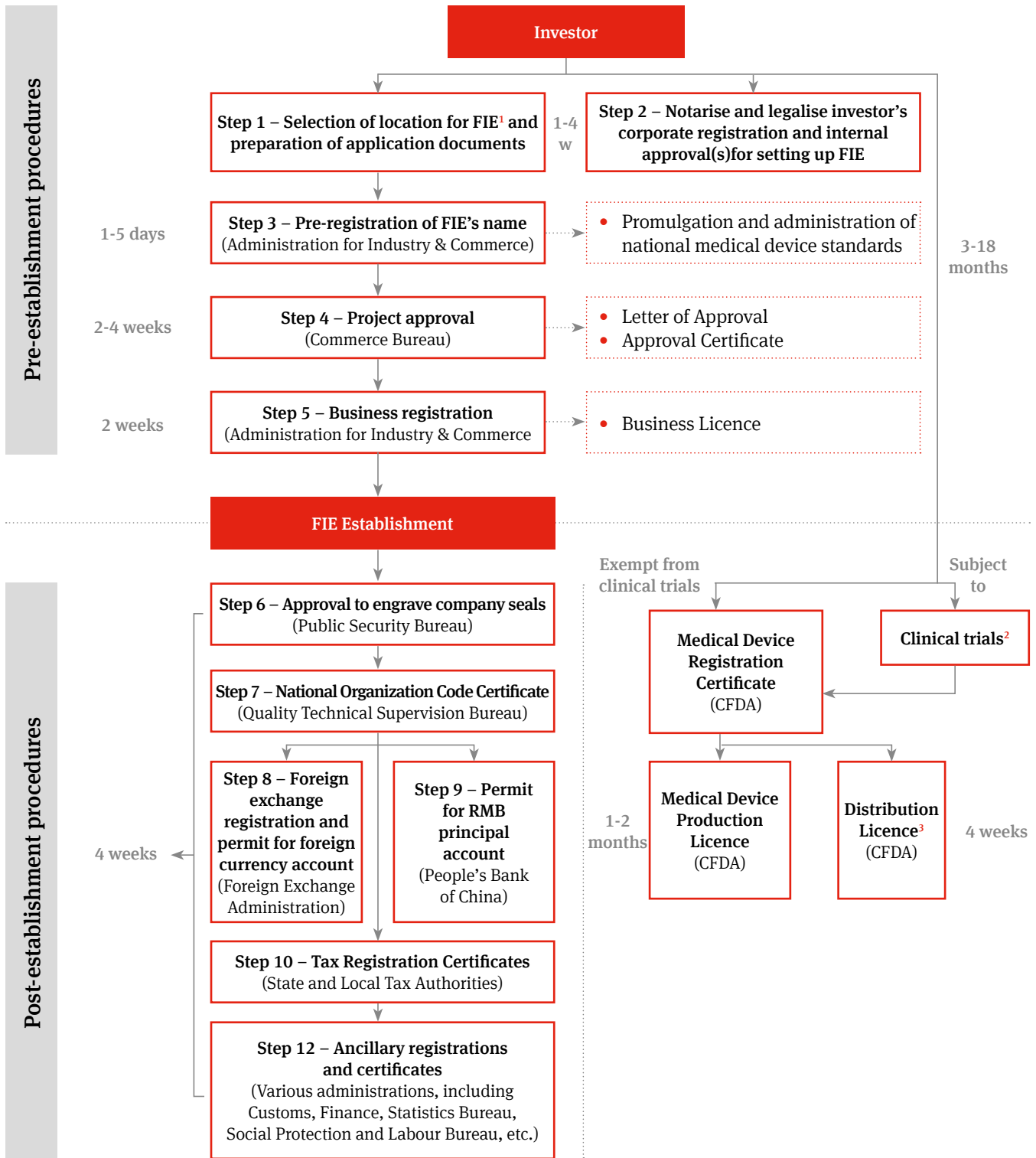
Before advertising a medical device, an advertisement approval code is required and the proposed content of the advertisement must be approved. Only the manufacturer or the licensed distributors of a medical device can apply for the advertisement approval code for such product. The approval authority will either be the provincial or the central CFDA, depending on the intended geographic reach of the advertisement.

#### 10 | Why compliance is key?

As part of China's anti-graft campaign, the pharmaceutical and health care industry has been highlighted as a target sector. Over the years, loopholes in the public procurement mechanism and over-reliance on intermediaries have inadvertently created bad practices and resulted in bribery activity in the sector.

In response, China has now established an anti-bribery legislative system and the government has been proactive in investigating pharmaceutical companies, public hospitals, officials of regulators and individual doctors in connection with potential bribery offences. Any manufacturers found in compliance will be banned from selling their products in China and their names will be added to a blacklist maintained by the CFDA. The scope of the anti-bribery regime is extensive as it includes public officials. The definition of 'public officials' is wide and includes certain doctors from public hospitals and medical institutions. As China adopts a more stringent approach to bribery, foreign manufacturers will need to ensure they have a robust compliance program locally to ensure their operations in China meet all the relevant requirements.

In addition, doctors from Chinese public hospitals and medical institutions may also qualify as 'foreign officials' under the Foreign and Corrupt Practices Act, and thus be subject to the scrutiny of the US government.



**Note:**

- 1 Depending on the FIE's location, the approval and registration procedures may vary.
- 2 There is no prescribed time period for a clinical trial which varies by different types of products. Class I products are not subject to a clinical trial, but Class II and III products are unless exempted by the CFDA.
- 3 Class II products are subject to a simple recording and filing process for obtaining an operational licence, but for Class III products, a more sophisticated and time-consuming approval process will apply.

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