Guideline on Market Access for Medical Device in China

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1. Introduction

China has one of the largest medical device markets in the world. In the end of 2018, there are nearly 1.4 billion people in the mainland of China. In the meantime, the aging population of China is accelerating. The population of the country's population aged 60 and over was 240.9 million, accounting for 17.3% of the total population, of which 158.31 million were 65 years of age and older, accounting for 11.4% of the total population. Thus, the demand of medical devices, especially for the aged, is increasing rapidly and global medical device companies will acquire huge benefits after entering Chinese markets.

However, the regulations of medical device in China are accelerated to be optimized and improved. If an overseas medical device company plans to export its medical devices to China, it will takes a long time to learn and understand Chinese regulations, including the priority it can apply for. The purpose of this guideline is to list all key points overseas companies may consider and practical information for each points. Hope the guideline could help all overseas medical device companies enter Chinese market successfully and conveniently.

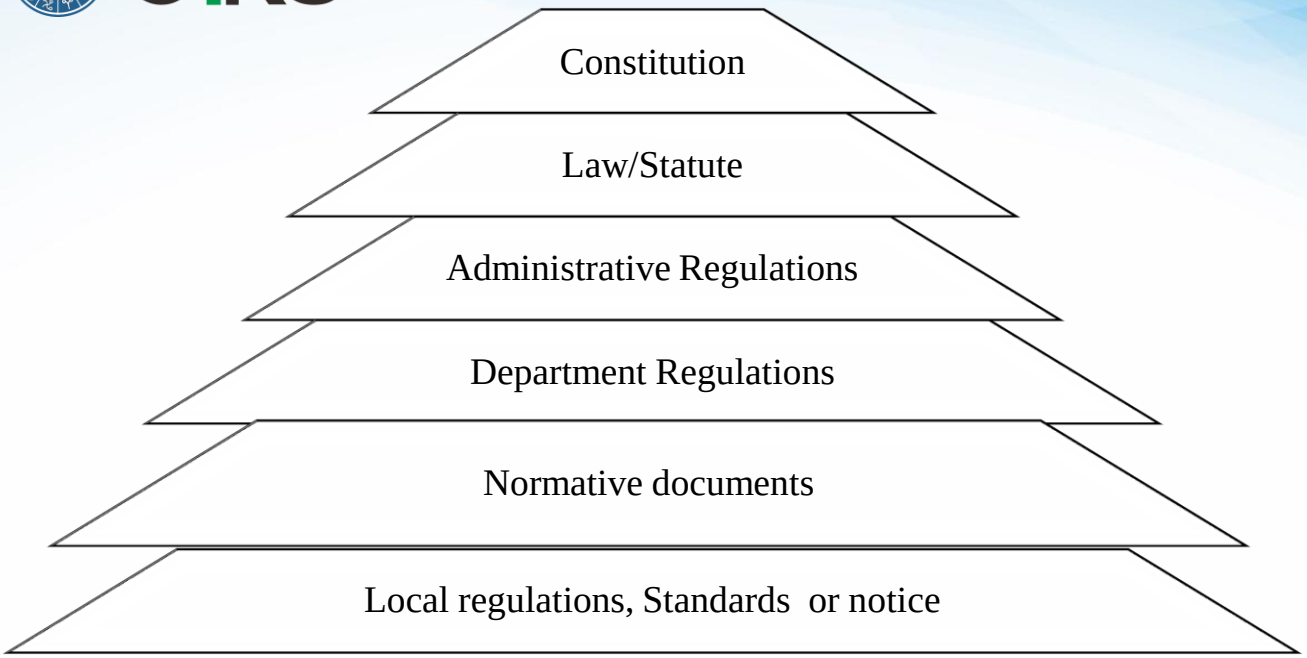
2. Regulation Overview

2.1 Regulation Frame

In 2013, after China officially joined the International Medical Device Regulators Forum (IMDRF), National Medical Products Administration (NMPA, former CFDA) issued the “Regulations on the Legislative Procedures of the State Food and Drug Administration” for the purpose of integrating with the international mainstream and better catching up with the development of the medical device industry. This regulation is issued to standardize the legislative process, ensure the quality of legislation, and improve the efficiency of legislation. Based on this rule, NMPA issued a new “*Regulation on the Supervision and Administration of Medical Devices*” in 2014 and revised it in 2017. The main changes in the new version are as follows:

1. The medical devices are classified and managed according to the degree of risk, and the medical devices are classified into I, II and III according to the risk from low to high.
2. The Class I medical device was changed to filing management, the Class II and III medical device continued to implement registration management; the Class I medical device production was changed to filing management, and the Class II and III medical device production continued to be license management.
3. Increase the control of product quality in the production and operation of medical devices, establish a system of inspection and sales records for operation and use, and establish the responsibility for the safety management of medical devices.
4. Strengthen the daily supervision duties of the regulatory authorities, standardize the regulatory activities such as continuing registration and sampling inspection, and establish three systems (medical equipment adverse event monitoring system, registered medical device re-evaluation system, medical device recall system), and improve the management system.
5. In terms of legal liability, NMPA increases penalties for serious violations by refining punishments, adjusting the scope of punishment, increasing the types of punishments, and enhancing operability.

The following is the hierarchical relationship of China's medical device regulations:



With the introduction of new supervision and management regulations, all medical device related laws and regulations have been greatly updated, the administrative system has been optimized, the supervision system has become more stringent, and medical device standards are also in line with international standards. However, China's changes in the regulation of medical devices are still proceeding rapidly. For applicants who enter the Chinese market for the first time or who do not have mature legal departments in the Chinese market, it is best to go to the NMPA website to determine the latest version of the rules and regulations. Applicant can consult a professional medical device legal and regulatory consulting company in China to avoid unnecessary losses.

Medical device regulation overview

Category	Regulations
Main Enabling Legislation	- The Regulations for the Supervision and Administration of Medical Devices
Registration	- Administrative Measures for Medical Device Registration - Administrative Measures for the Registration of In Vitro Diagnostic Reagents - Special Review and Approval Procedure for Innovative Medical Devices - The Guideline on Preparation of Medical Device Technical Requirements
Nomenclature & Classification	- The Provisions of Medical Device Nomenclature - The Provisions for Medical Device Classification
Labeling	- Administrative Rules for the Instructions and Labels of Medical Devices
Clinical trail	- The Quality Management Practices for Medical Device Clinical Trial (GCP) - The Technical Guidelines for In Vitro Diagnostic Reagents Clinical Trial - Technical guiding principle on medical devices clinical evaluation
Adverse Event Monitoring Re-evaluation	-The Guide for Medical Device Adverse Event Monitoring - The Provisions for Medical Device Recall - Administrative Measures for Medical Device Adverse Event Monitoring and Re-evaluation - Measures for Drug and Medical Device Unannounced Inspection
Import/Export	The Management Measures for Imported Medical Device Inspection and Supervision
Manufacture	- Administrative Measures for the Supervision of Medical Device Manufacturing - The guide on supplier audit for Medical Device Manufacturing Enterprise
Distribute Use	- Administrative Measures for the Supervision of distribution of Medical Devices - Administrative Measures for Medical Device Online Sales Supervision and Management - Administrative Measures for the Supervision of Medical Device Use
QMS	- The Quality Management Practices for Medical Device Manufacturing (GMP) - The Quality Management Practices for Medical Device Distributing (GDP or GSP) - The Quality Management Practices for Medical Device Use (GUP)

2.2 Chinese Regulatory Authorities

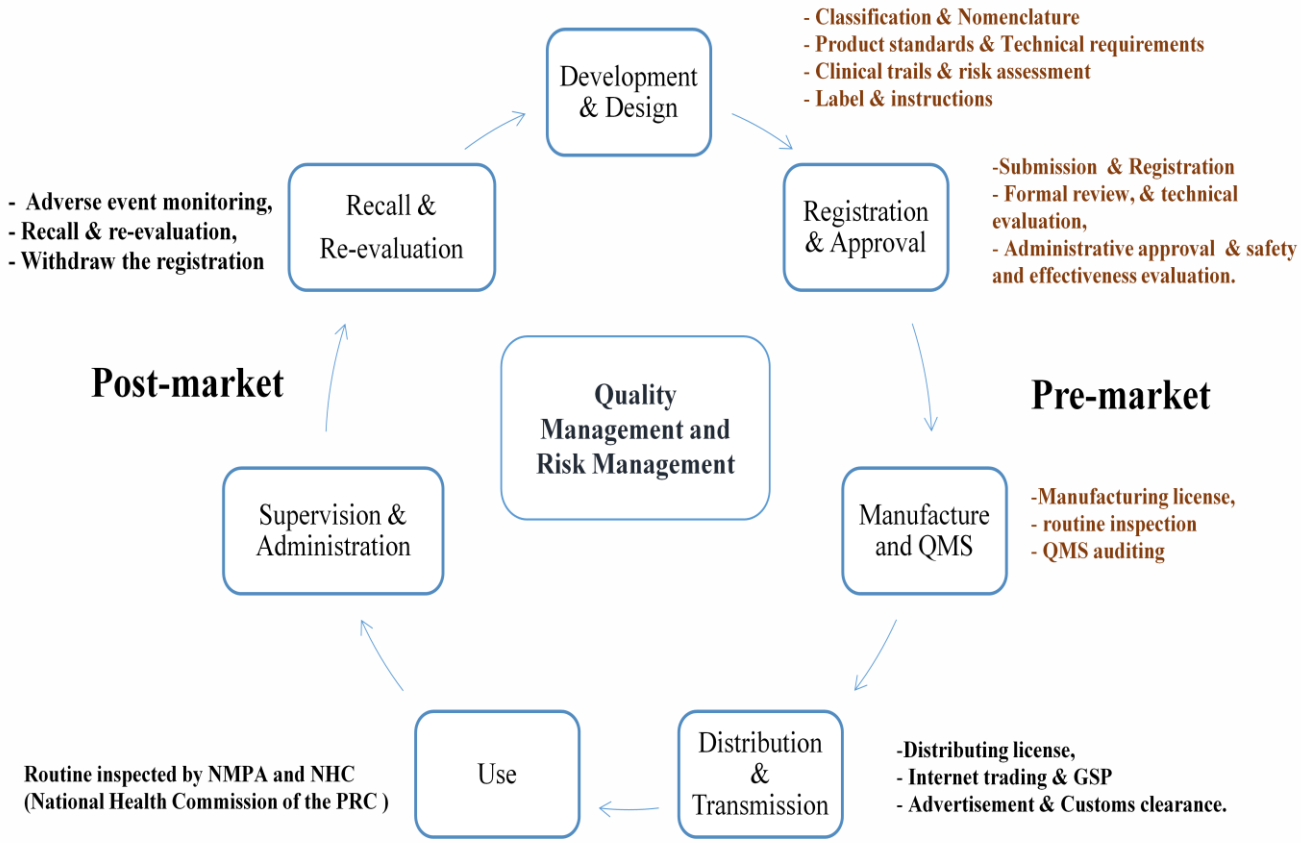
Since the introduction of the new regulations in 2014 and the reorganization of government organizations, the departments responsible for the registration, acceptance, testing, and approval of medical device in the Chinese government are the following three:

- National Medical Products Administration (NMPA): responsible for medical device safety supervision and management, headquartered in Beijing, set up offices in various provinces and cities.
- Center for Medical Device Evaluation (CMDE): Responsible for the examination and approval of imported

medical device products for registration.

- NMPA Center for Administration Services and Complaints & Reports: Production and delivery of documents related to the acceptance of pharmaceutical, medical device and cosmetic administrative matters and examination and approval results jobs.
- Center for Food and Drug Inspection (CFDI): Undertake medical device clinical trial supervision and inspection and production inspection, including overseas inspection.

2.3 Medical Device Lifetime Regulation Overview



1. Innovation & Development

- Innovitive Medical Deivce Fast Track
- Classification Determination

2. Production Testing

- Product Technical Requirements

3. Clinical Evaluation

- Clinical Trial Filing
- Cinical Trial Review
- Human Genetic Resources Review

4. Registration & Filing

- Product Filing
- Product Registration
- Recording Item Aleration
- Approval Item Alteration
- Certificate Renewal
- Priority Fast Track
- Registration Quality System Review

5. Manufacturing

- Manufacturing Filing
- File Item Alternation
- Manufacturing License

6. Distributing

- Distributing License Application
- Distributing License Alternation
- Distributing License Renewal

7. Use

- Large Medical Device operation License

8.Surveillance & Insepection

- Administrative Review

2.4 Medical Device Registrant vs MAH

To apply for a medical device registration/filling certificate in China, it is necessary for the applicant to have a medical device production license and production qualification. According to Article 9 of the “Administrative Measures for the Registration of Medical Devices” promulgated by NMPA in 2014: “Applicants of medical device registration shall establish a quality management system related to product development and

production and maintain effective operation.” It is said that before the medical device is registered, it is necessary to establish a production workshop and obtain a “Medical Device Production License” before applicant can produce samples and carry out further testing, clinical trials and final registration. However, this will cause great inconvenience to many domestic research institutions and overseas technology holders who have no production capacity, because they may not be able to manufacture their own products.

Therefore, in 2017, NMPA announced the trial of Marketing Authorization Holder in the Shanghai Pilot Free Trade Zone. The most direct change to MAH is to separate production licenses from marketing licenses. The “Implementation Plan for the Pilot Work of the Medical Device Registrant System in the China (Shanghai) Pilot Free Trade Zone” states: “If the registrant has the corresponding production qualifications and capabilities, it can produce it on its own or entrust the Shanghai medical device manufacturer to produce the product; If the registrant does not have the corresponding production qualifications and capabilities, he/she may directly entrust the Shanghai medical device manufacturing enterprise to produce the product. If the entrusted production enterprise does not have the corresponding production qualification, it may submit the registrant's medical device registration certificate to apply for the production license.” It should be noted that the city where the trial of MAH is now extended to Shanghai, Tianjin and some cities in Guangzhou, and at the National Medical Device Supervision and Management Conference held in January 2019, the State Drug Administration proposed to actively promote the development of innovative medical devices and steadily Promoting the pilot system of registrants.

The following is the difference between the current registrant system and the MAH: