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Distributed to: SESEC Partners,
EU standardization stakeholders
Date of issue: 10-10-2017

SESEC III

Special Report

Medical Devices Market in China

October, 2017

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Introduction to medical device market in China

1. Definition of medical device, in China

Medical devices are defined by the China Food and Drug Administration (CFDA)[1] as:

"Any instrument, apparatus, appliance, material, or other article – whether used alone or in combination, including the software necessary for its proper application – that does not achieve its principal action in or on the human body by means of pharmacology, immunology or metabolism, but which may be assisted in its function by such means".

2. Market overview

In recent years, China's medical device industry has increased significantly; sales doubled between 2010 and 2014, as shown in Figure 1 below.

The total sales volume for medical devices came to EUR 2.4 billion in 2001, and by 2014 had reached EUR 36 billion. The largest sales took place between 2013 and 2014: EUR 6.1billion.

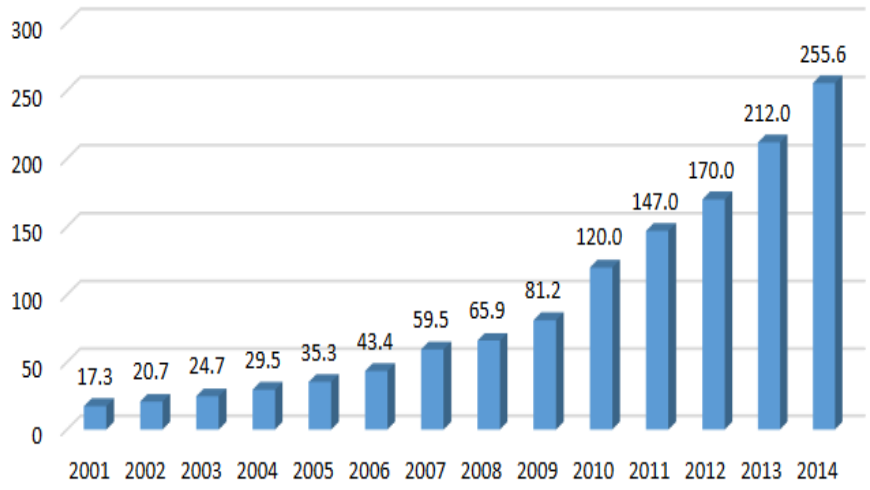


Fig. 1. Medical device sales in China

In 2014, the total import and export value of medical devices experienced an approximately 4% increase. In 2014, China's total import value of medical device showed a 5% increase over 2013, but this growth rate was 15% below that in 2013.[2] Diagnostic medical devices totaled approximately 70% of the medical device import value—the highest among all imported medical devices.

In 2014, 35 types of medical devices were imported to China, including:

- General diagnostic equipment;
- Ultrasound diagnostic apparati;
- Rehabilitation appliances;
- X-ray tomography instruments;
- Endoscopes for artificial joints;
- Orthopedic equipment;
- Fracture equipment;
- Medical accelerators;
- Medical catheters and Magnetic Resonance Imaging (MRI) equipment.

2.1 Importing regions

The top three importing regions in China in 2014 were Shanghai, Beijing and Guangdong, with percentages as follows:

- Shanghai imported over 10%, or 40% of all medical devices imported into China in 2014;
- Beijing imported over 24% of the total value of medical device imports;
- Guangdong imported over 11%, in 2014.[2]

Other cities with considerable import values were: Jiangsu, Zhejiang, Shandong, Liaoning, Tianjin, Fujian and Hubei.

2.2 Responsible authorities for Chinese market product validation

In China the authority responsible for the safety and authentication/validation of medical devices entering the national market is the China Food and Drug Administration (CFDA), which drafts laws, regulations, rules and policy under the authority of the State Council.

As a general overview CFDA covers regulatory guidelines for drug administration and supervision, medical devices, health food, and cosmetics and supervises safety (see Figure 2). The CFDA responsibilities for medical device are split between two departments:

- Department of Medical Device Registration (pre-market approval) – in charge of registration for imported medical devices and domestically produced Class III medical devices, classifications, the implementation of good practices, etc;

- Department of Medical Device Supervision (post-market supervision) – in charge of analyzing and tracking medical device safety, produces recommendations for testing systems, licensing, checking for defects, etc.

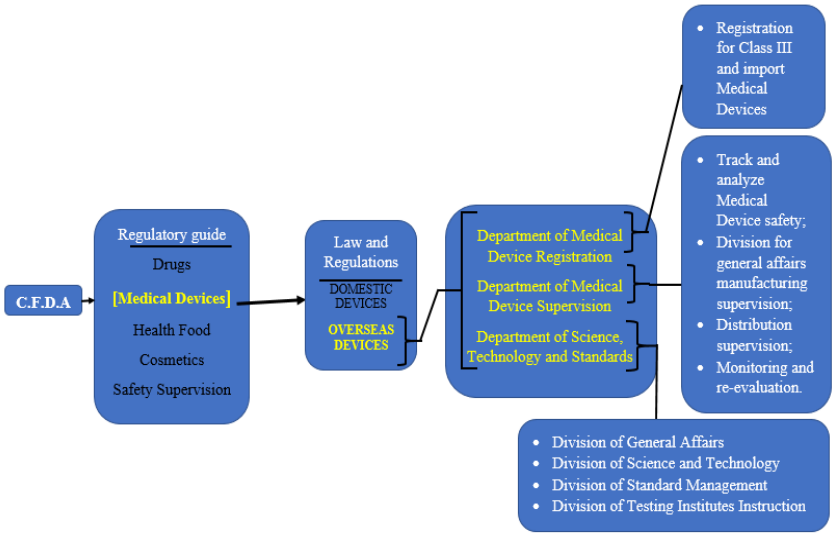


Figure 2. China Food and Drug Administration framework for medical device market access

2.3 Classification of medical devices

In China medical devices are divided into three classes (I, II and III) based on the risk level of the device (low to high).3 This classification is used for risk management, because different rules are implemented for different classes. The administrative department responsible for medical device classification follows the ''Regulation on Supervision and Administration of Medical Devices'' – Order 276/2002. In December 2013, CFDA released a draft amendment for the Classification Rules for Medical Devices and added a new category for the In-vitro Diagnostic (IVD) reagents. The entire classification process usually takes between 3 and 12 months.

Classes of medical devices:

Class I medical devices represent a low level of risk; safety and effectiveness are ensured through routine administration;

Class II medical devices represent a medium level of risk, and require safety and effectiveness;

Class III medical devices have high levels of risk, and have strict control and safety and requirements. The Regulations for the Supervision and Administration of Medical Devices call for a product to be filed as a Class I medical device before it can be distributed in China. For Class II and Class III medical devices, manufacturers must obtain approval from the CFDA.3

A medical device is further classified in to one of four categories, depending on its characteristics and in what way it touches the human body.

These categories are as follows:

Passive human body-contacting medical devices;

Passive non-human body-contacting medical devices;

Active human body-contacting medical devices;

Active non-human body-contacting medical devices

3. Regulatory bodies

The China Food and Drug Administration (CFDA) is the ‘’administrative and supervisory authority’’ for medical devices, food, drugs, and cosmetics, in China.

The CFDA:

- drafts regulations for medical devices;
- sets classification standards;
- inspects manufacturing, sales and distribution of medical devices;
- manages the import of medical devices.

There are a number of departments under the CFDA, including:

- Department of Medical Device Registration
- Department of Medical Device Supervision

Other organizations involved with the technical evaluation of medical devices and standards include:

- Center for Medical Device Evaluation;
- National Institute of Food and Drug Control

3.1 Policy and Regulations

There are a number of regulations concerning medical devices in China, but the Regulations for the Supervision and Administration of Medical Devices are the only regulations officially endorsed and approved by the State Council. After the latest version of the regulations was published on 7th March 2014, the CFDA released a series of specific provisions and regulations for medical devices in China. See Table 1 for detailed information regarding policies and regulations.

Table 1 Regulations and provisions for medical devices in China

Regulations and provisions	Brief description	Full Content
Regulations for the Supervision and Administration of Medical Devices	Class I medical device filing, Class II and Class III registration. (Decree No. 4)	http://www.sda.gov.cn/WS01/CL0784/97814.html
Special Procedures for Approval of Innovative Medical Devices	Defines innovative medical devices, regulates application process, sets documentation requirements and evaluation procedures.	http://www.sda.gov.cn/WS01/CL0845/96654.html
Provision for Supervision and Administration of Medical Device Distribution	Approval and filing procedures, distribution process and storage, and penalties for illegal practices. (Decree No. 8)	http://app1.sfda.gov.cn/WS01/CL0053/103760.html
Provision for Supervision and Administration of Medical Device Manufacturing	Sets conditions for manufacturers in the application process for licenses, including: technical staff, manufacturing equipment, quality control, management systems, post-sales service capacity.	http://app1.sfda.gov.cn/WS01/CL0053/103759.html
Rules on Administration of Manuals and Labeling of Medical Devices	Penalties for misapplying certain rules. (Decree No. 6)	http://www.sda.gov.cn/WS01/CL0053/103758.html
Provision for Administration of Registration of In-vitro Diagnostic Reagents	12 chapters with 90 provisions. Defines In-vitro Diagnostics, regulates registration and filing process and sets requirements for applicants. (Decree No. 5)	http://www.sda.gov.cn/WS01/CL0053/103757.html
Provision for Administration of Medical Device Registration	Issues certificate of validation, good for five years. Class I medical device filing, Class II and Class III registration procedures. Different validation process for innovative medical devices.	http://www.sda.gov.cn/WS01/CL0053/103756.html

Notice on Issuing Directory of Class III Medical Devices that need to Conduct Clinical Trials for Approval	Enumerates all Class III medical devices that require clinical trials throughout registration.	http://www.sda.gov.cn/WS01/CL0087/105374.html
Practice of Quality Management for the Operation of Medical Devices	Outlines the rules of the medical device trading process, including transportation, storage, personnel training, equipment maintenance, record keeping and post-sales service.	http://www.sda.gov.cn/WS01/CL1428/110920.html
Practice of Quality Management for Production of Medical Devices	Enforces the regulations for medical device production process: hardware and software, equipment, quality control, product recall. (Decree No. 7)	http://www.sda.gov.cn/WS01/CL0087/111642.html
Provisions for Medical Device Classification	Newest draft version released in 2015. (Decree No. 15)	http://www.sda.gov.cn/WS01/CL0053/24454.html

Other regulations:

- MD production: Decree No. 7;
- MD distribution: Decree No. 8;
- MD classification: Decree No. 15;
- MD recall: Decree of MoH No. 82;
- MD Good Manufacturing Practices;
- Classification Catalog of MD;
- Accreditation of MD testing bodies;
- GB 187 (88 compulsory, 99 recommended);
- YY 864 (376 compulsory, 488 recommended)

(MD – medical device)

3.2 Regulations for the supervision and administration of medical devices

These regulations are issued in order to guarantee safety by protecting human health. The processes cover: research and system development, manufacturing, distribution, use, and supervision of medical devices.

The regulation document contains six chapters, covering: General Provisions, Administration of Medical Devices, Administration of Production, Distribution and Use of Medical Devices, Supervision of Medical Devices, Penalties, and Supplementary Provisions (April 1, 2000).

3.3 Measures for medical device registration

In order to the enforcement of the registration regulations, the China Food and Drug Administration (CFDA) releases and revises:

- Medical device registration requirements
- Measures for the registration of in vitro diagnostic reagents
- Rules for instructions and labeling of medical devices
- Measures for the supervision of medical device manufacturing
- Measures for the supervision of the distribution of medical devices.

These five measures were adopted on June 27, 2014, and promulgated on July 30, 2014 as CFDA Order No. 4, Order No.5, Order No.6, Order No.7 and Order No. 8.

The provisions adopted in 2014 for the Provisions for Medical Device Registration contain: General Provisions, Essential Requirements, Product Technical Requirements and Registration Testing, Clinical Evaluation, Product Registration, Registration Alteration, Registration Renewal, Product Filing, Supervision and Administration, Legal Responsibilities, and Supplementary Provisions. These are valid for Classes I, II, and III of medical devices, covering 11 regulatory appliances.

3.4 Measures for the Administration of Registration of In-Vitro Diagnostic Reagents

The measures were issued to specify the product classifications, standards, development, clinical trial - registration applications, registration tests, altered registration / re-registration of in-vitro diagnostic reagents; implemented on June 1, 2007.

The provisions are applicable to all classes of in-vitro reagents with different approaches to the registration process, as follows:

Class I in-vitro diagnostic reagents are subject to filing administration; filing documents are to be submitted to the food and drug regulatory department (the same requirements as for medical devices);

Class II in-vitro diagnostic reagents are affiliated with the food and drug regulatory department of the provinces; certificate is issued after approval;

Class III domestic in-vitro diagnostic reagents are reviewed by the CFDA, and a certificate is issued after approval.

The provisions for in-vitro reagents contain 12 chapters: General Provisions, Essential Requirements, Product Classification and Naming Standards, Technical Requirements and Registration Testing, Clinical Evaluation, Product Registration, Registration Alteration, Registration Renewal, Product Filing, Supervision and Administration, Legal Responsibilities, and Supplementary Provisions.

Class II and Class III IVDs follow the same registration procedures as medical devices.

The majority of IVDs are considered an independent sub-category of medical devices. A few IVDs are considered drugs and regulated as such. The IVD products allocated to the medical device category conform to State Council Order No.650, which came into effect on October 1, 2014.

Type testing requirements for IVDs follow the same requirements as medical devices (testing centers follow the Product Technical Specification File drafted by the overseas manufacturer exporting the product). Several specifications of performance and safety should be included in the Product Technical Specifications.

Testing procedures for imputed IVDs follow the same requirements as medical devices.

Testing for Class I is not required to occur in China, but the manufacturer is required to file a notification of waiver and to be registered as not having been retested in China.

Testing for Class II IVDs requires a sample batch to be provided in China. Class III requires 3 batches of samples to be provided to a certified testing laboratory in China.

Product Registration: Clinical Trials for Class II and Class III IVDs:

- Other test/data are not accepted, except those tested in China
    - Minimum sample size: 1000 samples;
    - Samples can be collected from healthy volunteers or patients;
    - Comparison studies are required.

There are ten testing centers in China approved by the CFDA, and these have forty affiliations with other institutes.

The ten testing centers are:

- National Testing Institute (Beijing);
- Beijing Testing Institute;

- School of Dentistry, Beijing University;
- Shanghai Testing Institute;
- Tianjin Testing Institute;
- Jinan Testing Institute;
- Shenyang Testing Institute;
- Wuhan Testing Institute;
- Hangzhuo Testing Institute;
- Guangzhou Testing Institute.

Clinical trial exemptions will be applied if:

- The manufacturing process is mature, with clearly working mechanisms;
- The safety and efficacy has been proved by non-clinical evaluations;
- Safety and efficacy can be approved via clinical trials or data from similar products.

The clinical trial respects CFDA Decree No. 16, which requires a protocol design, a certain number of clinical sites, sample sizes, and statistical analyses.

Requirements for IVDs:

- Class I IVDs need not be registered, just filed;
- Must have been licensed for 5 years;
- Risk analysis report and technical analysis of the product performances;
- Time limit of 365 days.

3.5 Regulations for the administration of medical equipment instructions and labels

The CFDA conducts the inspection of instructions, labels and packaging, for nine kinds of medical devices. The inspection is implemented in according to;

- provisions for the Instructions, Labeling and Packaging of Medical Devices (Order No. 10);
- standards related to manufacturers;
- import agents, key distributors and users.

These have the objective of disclosing and rectifying major problems of medical device instructions, labeling and packaging.

The label content should include:

- Product model and specification;
- Name and contact information of registrant for imported medical devices;
- Registration certificate number of the medical device;
- Manufacturing address and production license number of medical device manufacturer;
- Manufacturing and production date, service life and expiry date;
- Power connection;
- Visual representations and other information, depending on the product;
- Warning labels;
- Storage and operation details;
- Warnings about possible negative effects on the environment and radioactivity/radiation emissions/consequences (in English and Chinese).

3.6 Measures for the supervision and administration of medical device manufacturing

The regulation was adopted by the CFDA as a provision on July 20, 2004 as Order No. 12 (Provisions for the Supervision of Medical Device Manufacturing).

The Provisions contains seven chapters: General Provisions, Application and Approval of Medical Device Manufacturing Enterprise Establishments, Supervision and Inspection, Legal Liabilities and Supplementary Provisions of License Management of Medical Device Manufacturing, and Management of Entrusted Medical Device Manufacturing.

4. Approvals of registration procedures for medical devices

4.1 Chinese agents

The responsibilities for guidance in China regarding the registration process can be performed by a legal agent if the manufacturer does not have the ability to enroll with the legal procedures for registration of medical devices. The agent must be a registered entity in China having the responsibility as a legal post-sale agent enrolled as an “Agent in China.”

4.2 Medical device regulatory authorities

In China two authorities that are responsible for medical device registration:

- China Food and Drug Administration (CFDA - Fig. 2) responsible for medical devices, drugs, healthcare, certification, cosmetics and food.

- General Administration of Quality Supervision, Inspection and Quarantine (AQSIQ): responsible for mandatory registration, certification, and inspection for certain devices.

For Class I medical devices in China, importers are required to fill out an application and a notification of filing, but are not required to carry out a clinical trial. In case of Class II and III devices, clinical trials for product approval are required, with exemptions for some devices.

The license for trial of a medical device on the Chinese market is valid for a period of five years. To extend the license the manufacturer has 365 days, but no more. In some cases a Quality Management System (QMS) may be required for registration.

4.3 Classification rules

Medical Device Classification rules:

- Kits that contain multiple devices will be classified according to the highest-class device;
- Classification of the device accessories are determined depending on their safety and effectiveness of use;
- MD software will have the same classification as the device;
- If a device is revised, it might need re-classification (if its function and/or purpose has changed). Medical dressings are classified as “functional” or “ordinary”;
- CFDA data base contains the proclaimed device;
- Classification is based on device structure, operation and conditions of use.

The medical device classification scheme can be seen above at paragraph 2.3.

4.4 Product Technical Requirements (PTRs)

The manufacturer is obligated to ensure and prepare a Product Technical Requirements (PTR) and Quality Management System (QMS) prior to the registration process, which can be approved by one country, unless it holds an ISO 13485 certificate.

A PTR is draft is based on:

- Device technical specifications;
- Applicable standards;
- Testing requirements (manufacturer’s own draft);

- Required safety and performance specifications;
- List of testing methods;

4.5 Types of Testing

For Class I IVDs, the CFDA will accept the foreign manufacturer's testing report.

For Classes II and III, the CFDA requires samples for type testing at the certified testing centers (the same centers as for IVDs). The testing centers will utilize the same testing methods for all the specifications listed in PRT (drafted by the manufacturer).

The CFDA requires the testing center to provide the report and comments from their test results, submitted together with the PRT.

The testing centers are the same as for IVDs (paragraph 3.4).

4.6 Product approval for classification and registration

The imported device's classification is approved respecting the regulations and requirements of the National CFDA for Classes I, II, and III.

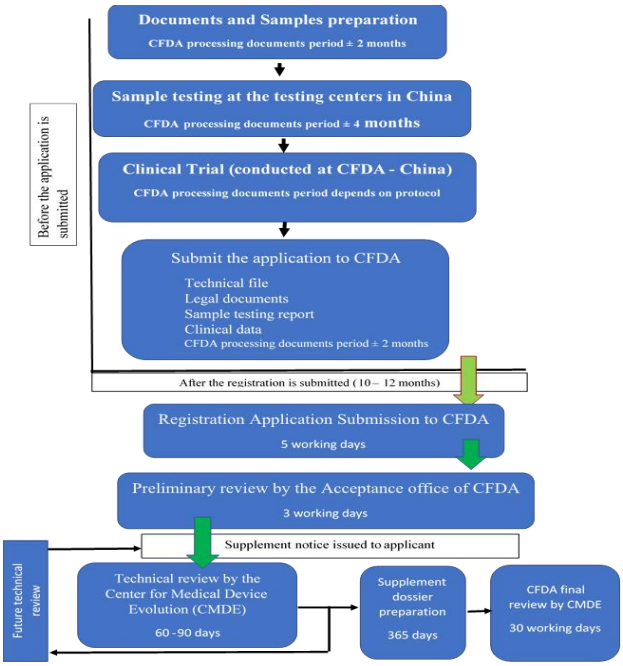
Class I devices are not required to fulfill the registration procedure; for these, filing the notification application with the CFDA is sufficient. The CFDA review is based strictly on the filing documents, and the consistency of the legal documents.

Product registration for Class I Devices requires that the application be submitted in the original, or as a notification body in English and simplified Chinese. For legal documents the CFDA requires the following content in the application:

- Product risk analysis document;
- Product Technical Specification/Requirements;
- Product testing report (manufacturer' s testing report or 3rd party report);
- Clinical evolution report;
- Key manufacturing information (process, flow chart, materials, etc);
- Design, artwork, product labels for the minimum selling unit;
- Legal documents (ISO13485, market authorization approval, authorization letter to the agent in China);
- Self declaration letter:
    - ✓ Letter to CFDA declaring that the requirements for Class I have been fulfilled by the institution;
    - ✓ Letter of conformity to Class I of Medical Devices;

- ✓ Declaration that the national and/or industry standards in China have been fulfilled (according to the list of conforming standards);
- ✓ Declaration that all the submitted documents are true.

4.7 Registration frame for imported medical devices Class II and Class III



4.8 Dossier requirements for registration

The CFDA requests several types of documents to be attached for submission:

- Legal Documents;
- Technical Documents;
- Testing report issued by CFDA-certificated testing center (the same centers as for IVDs)

Documents requested for product registration for imported medical devices:

1. Application form;
2. Legal documents;
3. Safety and efficacy specification list;
4. Summary data: - overview;
   - product description;
   - product model;

- description of the packaging;
- intended use and contraindications;
- predicate device, if available;
- any other relevant information

5. Research data: - product performance, evaluation data;
   - biocompatibility evolution data;
   - biosafety research data;
   - sterilization and disinfection process validation data;
   - shelf and package evaluation data;
   - software validation data;
6. Manufacturing information: manufacturing process description for active/inactive device, and manufacturing site description;
7. Clinical evaluation data;
8. Product list analysis data;
9. Product technical specifications;
10. Registration testing report: - testing report issued by CFDA-certified lab;
    - preliminary evaluation comments from testing lab.
11. Artwork for IFU and product label;
12. Self declaration documents.

A **supplementary review process** may be requested for future information after the technical review by the CFDA. Based on the supplementary notice, additional tests can be requested by the CFDA. The total time granted for the manufacturer to supply the supplementary documents is 365 days.

For Classes II and III medical devices, a local clinical trial is required for product approval. The clinical trial contain a list of exemptions:

- Exemption will be applied if the manufacturing process is mature and the working mechanisms are clear;
- Safety and efficacy can be proved by non-clinical evaluation;

- Safety and efficacy can be proved via clinical trials or data from similar products.

Class II medical devices can be exempted from a batch of clinical trials that are published in CFDA Notice No. 12; these include 488 categories of products. For Class III devices 79 categories are included in the CFDA exemption No. 13. Before conducting a clinical trial the clinical trial protocol should be validated by the Ethics Committee of the clinical site (CFDA Notice No.14 for Class III).

Good Clinical Practices (GCP) respect the regulation of Medical Device Clinical Trial Requirements for China and will be performed in accordance with international GDP standards.

Labeling requirements for medical devices are the same as for IVDs, presented above at paragraph 3.4.

Re-registration requirements that are enrolled before the validity of the product registration will expire within 6 months. The product registration for a medical device is valid for 5 years.

Country of origin approval: If the product is not registered in the originating country, it cannot be registered in China.

Raw Materials list required by CFDA is to be provided with information regarding the raw materials used in the medical device.

References:

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