国家药品监督管理局

NMPA

China Updates
Supervision and Administration of Medical Devices

China National Medical Products Administration

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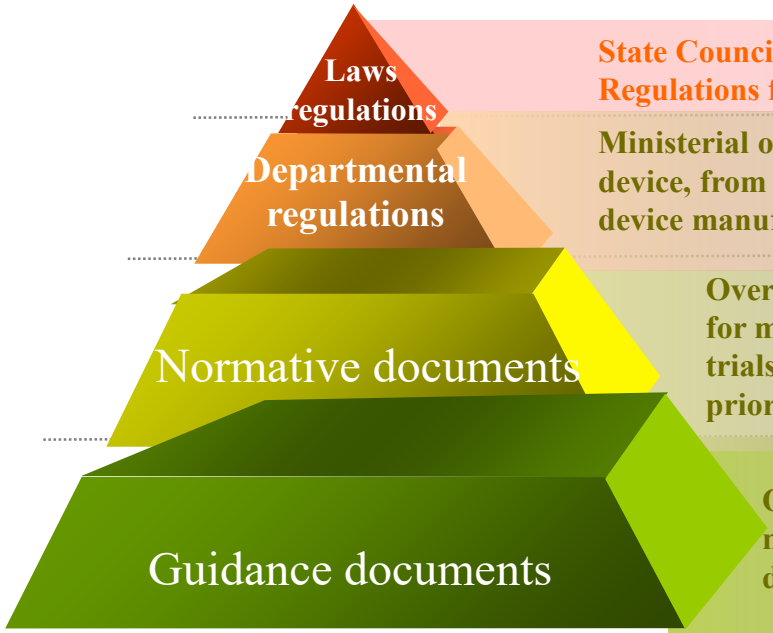
November 13, 2019

Regulatory System of Medical Devices



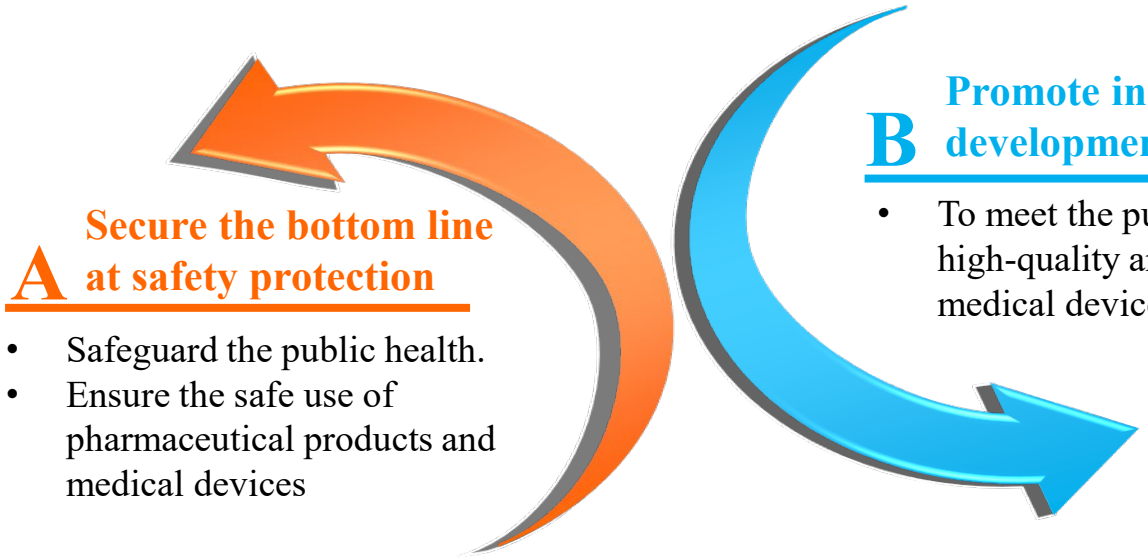
State Council-
Regulations for the Supervision and Administration of Medical Devices (No. 680).

Ministerial orders- 16 ministerial orders. Covering the whole life cycle of medical device, from medical device registration, IFU and labels management, medical device manufacturing and distribution to post market inspection and PMS.

Over 40 regarding the administration of the registration. Covering standards for medical devices, classification and naming, registration and filing, clinical trials, inspection and testing, production and operation, innovation and priority approval procedures.

Over 300 technical review guidance. Covering clinical evaluation method of medical devices, clinical trial design, registration unit designation and guidelines for specific product line.

Better Fulfillment NMPA Duties



A Secure the bottom line at safety protection

- Safeguard the public health.
- Ensure the safe use of pharmaceutical products and medical devices

B Promote innovation and development to the maximum

- To meet the public needs for high-quality and advanced medical devices.

I. Continuous deepening the reform of the evaluation and approval system

- Encourage innovation and development
- Optimize the review and approval mechanism;
- Promote the pilot project of the new system.

II. Continuous reinforcement of the foundation for the regulatory system

- Continuously improve the regulatory system;
- Optimize the standard system;
- Comprehensive classification catalogue;
- Accelerate UDI implementation.

III. Achievement in post-marketing surveillance

- Improve the risk management;
- Upgrade the supervisory inspection;
- Reinforce the foundation for the overall regulatory system

IV. Strengthening international exchange and cooperation

- Actively participate in related activities of international organizations and projects;
- Promote foreign communication;
- Provide China solution and China recommendations.

I. Continuous deepening the reform of the evaluation and approval system

The State Council - Opinions on Reforming the Review and Approval System for Drugs and Medical Devices in August 2015 (State Council [2015] No.44)

- To clear the backlog of registrations, to improve the quality of the generic drug;
- To improve the effectiveness of review and approval, to encourage the research and innovation of new drugs;
- To improve the transparency of review and approval.

To further encourage innovation, the General Office of CPC Central Committee and General Office of the State Council issued the Opinions on Deepening the Reform of the Review and Approval System to Encourage the Innovation of Drugs and Medical Devices in October 2017

- Focus on improving the quality of medical devices to meet the public needs;
- Further optimize the review and approval procedure.

(I) Notable achievements in encouraging innovation and development

- Special Review Procedure for Innovative Medical Devices, a batch of innovation product has been approved.
- Priority Review and Approval Procedure for Medical Devices, products with urgent clinical needs have been given priority review and approval.
- Adjustment of Certain Procedures for Administrative Review and Approval of Medical Devices, to simplify the review and approval process.
- More medical devices were added to the Catalogue of Medical Devices Clinical Trial Exemption.
- Clinical trial institute is qualified by filing rather than being approved.
- Accept the overseas clinical trial data to reduce unnecessary clinical trials.

(II) Pilot Marketing Authorization Holder Program (MAH)

In 2014, the Regulations on the Supervision and Administration of Medical Devices introduced MAH principle. According to document No.42 announcement (General Office of CPC Central Committee and General Office of the State Council), MAH pilot is underway and further expanded.

Medical device registrants shall bear all the legal liabilities for the design and development, clinical trials, production, sales and distribution and adverse event reporting of their marketed medical devices, ensure the authenticity, integrity and traceability of the study data and clinical trial data submitted by them. Continuously carry out study on the marketed medical devices, timely report the adverse events, evaluate the risks and put forward improvement measures.

In 2018, MAH system has been piloted in the Free Trade Zones of Shanghai, Tianjin and Guangdong. In August, the Notice of National Medical Products Administration on Expanding the Pilot Scale of Medical Device Registrant System was issued. Pilots had been carried out in 21 provinces, autonomous regions and municipalities directly under the Central Government, including Beijing, Hebei, Liaoning, Jiangsu.

To explore and build the management system of sub-contract production of medical devices, optimize resource allocation, and practice main body liability; to explore and improve the quality management system for medical devices registrants, and to build the quality management system for the whole life cycle of medical device registrants; explore innovation in medical device supervision.

II. Continuous improve the foundation for the regulatory system

1. Revise the Regulations for the Supervision and Administration of Medical Devices
2. Regulations for the Supervision and Administration of Customized Medical Devices (Interim)
3. Guidance for Registration Review of Medical Devices Used for Prevention and Treatment of Rare Diseases
4. Procedures for the Review of Medical Devices Used for Treatment of Life-Threatening Diseases and the Guidelines for the Conditional Approval of Medical Devices"

Continuously improving the regulatory system

Further Optimize Standard System

Improvement of organizational system

1. 26 technical committees for standardization of medical devices are established, all of which are compatible to the international standardization agencies (IEC, ISO).
2. Establishment of 3 standard jurisdiction units, focusing on the frontier technologies and strategic emerging industries, including medical material manufacturing technology, artificial intelligence medical devices.

Continuously improve the regulatory system

1. Provisions for Medical Device Standards and the Management Practice for the Development and Revision of Medical Device Standards, to enforce and refine the regulatory system;
2. Public the mandatory and recommendation standards, strengthen the implementation of standards.

Continuously improve the technical standard system;

1. 100 medical device standards are developed and revised each year. Total of 1652 valid standards for medical devices in China, including 220 national standards and 1432 industry standards.
2. Over 90% consistency with the international standards.

Implement New Classification Catalogue

The new Classification Catalogue of Medical Devices was issued and implemented as of August 1, 2018.
The overall framework was optimized, product categories were refined, product descriptions and intended use were added, and product coverage was extended.

Serial No.	Class I product category	Class II product category	Product description	Intended use	Example of product name	Management category
01	Ultrasonic surgical equipment and accessories	01 Ultrasonic surgical equipment	This equipment is generally composed of ultrasonic wave generator and hand-held component with surgical tip; each hand-held component is composed of an energy transducer, a connecting element and a treatment head tip.	It is used for soft tissue operations, such as cutting, hemostasis and plastic operation.	Ultrasonic surgery instrument for soft tissue, surgical ultrasonic surgery system, ultrasonic surgery system, ultracision harmonic scalpel system, ultrasonic surgery system for soft tissue, ultrasonic scalpel, and ultrasonic scalpel system	III
			This equipment is generally composed of main unit, energy transducer and vacuum suction device; It uses ultrasonic energy to optionally smash the human tissue, so that the tissue is emulsified, and it can also use negative pressure to suck the emulsified tissue cell.	The equipment is used for smashing and emulsifying the human soft tissue.	Ultrasonic fat emulsification apparatus, Ultrasonic Surgical Aspirator System, ultrasonic surgical instrument for soft tissue, ultrasonic surgical system for soft tissue	III

To better handle issues regarding product category conversion, and to strengthen the unity and authoritativeness in the implementation of the new Classification Catalogue for Medical Devices;
Explore and prepare the working mechanism for dynamic adjustment of the classification catalogue

Unique Device Identification (UDI) System

1. Issued the Rules for Unique Device Identification System.
2. Two industry standards issued for Basic Requirements for the Unique Device Identification. 2 more regarding UDI informative standards to be issued soon.
3. UDI database construction
4. Pilot UDI program

国家药品监督管理局
National Medical Products Administration

中国药品监管 中国药闻 中国药监APP 邮箱 政务信息报送

请输入关键字

国家药监局关于发布医疗器械唯一标识系统规则的公告（2019年 第66号）

2019年08月27日 发布

为贯彻落实《国务院办公厅关于印发治理高值医用耗材改革方案的通知》（国办发〔2019〕37号），规范医疗器械唯一标识系统建设，加强医疗器械全生命周期管理，依据《医疗器械监督管理条例》，国家药监局制定了《医疗器械唯一标识系统规则》，现予发布，自2019年10月1日起施行。

特此公告。

附件：医疗器械唯一标识系统规则

国家药监局

2019年8月23日

国家药品监督管理局
National Medical Products Administration

中国药品监管 中国药闻 中国药监APP 邮箱 政务信息报送

请输入关键字

国家药监局综合司 国家卫生健康委办公厅关于印发医疗器械唯一标识系统试点工作方案的通知

药监综械注〔2019〕56号

2019年07月03日 发布

各有关单位：

为加强医疗器械全生命周期管理，提升医疗器械监管和卫生管理效能，进一步保障公众用械安全，国家药品监督管理局会同国家卫生健康委员会开展医疗器械唯一标识系统试点工作。现将《医疗器械唯一标识系统试点工作方案》予以印发，请认真贯彻执行。

国家药监局综合司 国家卫生健康委办公厅

2019年7月1日

Risk Assessment and Consultation Mechanism

- ✓ Risk consultation meeting quarterly, multi-departments involved in the discussion on the relevant risk signals identified and collected during daily inspection, monitoring and from other aspects, focusing on the products and the companies where risks are found, making the supervision more targeted.
- ✓ Issue the annual analysis report on quality and safety of medical devices.
- ✓ Strengthen the risk analysis and evaluation of innovative products, timely organize reevaluation and sampling inspection.

GMP Oversea Inspection

In 2019, overseas on-site inspection is initiated for 24 import enterprises. The inspection is currently underway and will be completed by the end of the year. The results will be publicized on the NMPA website.

Intelligent Supervision and Administration

01

Promote the construction of an intelligent platform with big data risk analysis and visual operation interface, where the medical device production is well supervised, covering the whole life cycle data of the manufacturer, inspection dynamic data and inspector data.

02

Promote the construction of the online transaction monitoring platform, expand the monitoring scope to mobile APPs, WeChat, one-line mini stores and so on, where the network sales are fully monitored.

03

Upgrade the filing and approval system for production and distribution license, to realize on-line handling of application for production and distribution. Simplify the administrative procedures.

04

Integration of regulatory platforms to realize intelligent supervision of medical devices by comprehensive analysis of the inspection data, sampling testing data, adverse event monitoring data and recalls information. Evaluate and assess the risks.

III. Science-based Supervision

- Strengthen the construction of a scientific regulatory system and set up the necessary organizational systems.
- Carry out research by focusing on the issues regarding to policies and cutting-edge technologies that the supervision agencies face.
- Carry out research on drug-device combinations, artificial intelligence, new materials, real-world evidence etc.
- Accelerate promotion of intelligent supervision and electronic submission(e-RPS).

IV. International exchange and cooperation

1 Joined IMDRF in 2013. The outcome documents of the working groups of the IMDRF such as "Specifications for Product Application", "Single Review Procedure for Medical Devices" and "Good Review Practice - Requirements for Evaluator Capacity and Training" have been transformed.

2 Promote the international exchange of risk warning information by joining in the information exchange mechanism of IMDRF National Competent Authority Report (NCAR).

3 Continuously to strengthen international exchanges and cooperation, learn from the advanced international management concepts.

4 Participate in the activities of Asian Harmonization Working Party (AHWP), and contribute to the Asian harmonization work.

Contribution to IMDRF

In 2018, China was the rotating chair of IMDRF, successfully held the 13th and 14th conferences of IMDRF Management Committee, and performed its duties as Chair country.

March 2018 in Shanghai

September 2018 in Beijing

In March 2018, China proposed two new projects: Clinical Evaluation of Medical Devices and Updating Recognized International Standards List. .

In September 2019, IMDRF approved the three guidance documents

- **Clinical Evidence - Key Definitions and Concepts**
- **Clinical Evaluation**
- **Clinical Investigation**

Participation and Contribution in AHWP

NMPA highly value the role of AHWP in global regulatory system, and will continue to engage in AHWP activities. Working together with other members to promote and achieve the mission and the goal of AHWP.

Open
Cooperation
Innovation
Sharing