IMDRF International Medical Device Regulators Forum

Update on China Medical Devices

Regulatory Regulations

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Catalogue

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2. To adjust and optimize matters related to the production of imported medical devices in domestic enterprises in China
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catalogue

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1

Preparation of the Medical Device Management Law

- After several rounds of revision work and public consultation, the Medical Device Management Law has been submitted for review, which has been submitted to the higher-level department for review.

- The medical device management law builds broad consensus, and deeply grasps the major relationship between balanced development and safety, vitality and order, efficiency and fairness.

2

To adjust and optimize matters related to the production of imported medical devices in domestic enterprises in China

- In 2020, NMPA issued the Announcement on Matters related to the Production of Imported Medical Devices in China Enterprises, which optimized the requirements of relevant registration documents for the production of imported medical device enterprises in China, and accelerated the marketing process of corresponding products.

- Since the announcement was released, about 113 imported medical devices have been produced by Chinese enterprises.

- This revision is based on the development and change of the industrial situation and the regulatory needs to revise, and constantly optimize and improve the relevant policies.

- The main optimization content is to expand the scope of application of the announcement, further unify the registration data requirements, and more support foreign-invested enterprises to invest and production in China.

3

The Opinions on Comprehensively Deepening the Regulatory Reform of Drugs and Medical Devices and Promoting the High-quality Development of the Pharmaceutical Industry were issued

- In 2024, we issued "comprehensively deepen the reform of drug medical device regulation to promote the development of the pharmaceutical industry high quality opinion", focusing on high quality development, high level safety, high efficiency management, high standard, put forward increasing support for medical device innovation, improve the quality of medical device review approval, build more adapt to meet the needs of industry development and safety regulatory system.

4

Innovative medical devices

1

In 2024,65 innovative medical devices were approved (329 in total)

2

Four key areas, including medical robots, high-end medical imaging equipment, artificial intelligence medical devices and new biomaterials, were selected to study the integrated innovation support policies of the whole chain.

3

Support the carbon ion, proton therapy system

Carbon ion and proton therapy systems have been introduced in multiple hospital systems, which provide accurate radiation therapy through innovative technologies to provide patients with more advanced treatment options.

5

Revised Quality Management Practice for Medical Device Operation

The newly revised Quality Management Practice for Medical Devices (GSP) was released on December 4,2023 and implemented on July 1,2024.

- New regulatory elements are identified and supplemented to adapt to the new regulatory methods. The requirements of the aspects of unique identification of medical devices in product acceptance, outbound review and computer system, the electronic licenses issued by relevant government administrative departments have the same legal effect as the paper certificates, and enterprises are encouraged to use information technology to transfer and store the electronic license data.

- **Identify the new forms of business and new business modes that appear, and supplement the blind area of quality management in business links. For example, new automatic selling machine quality management, direct quality management, sales product management after clinical confirmation management, multi-warehouse coordination management, etc.**

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Thank you for listening