IMDRF International Medical Device Regulators Forum

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China

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Update on China Regulatory

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NMPA

Work achievements in recent years

- First, to improve the system of regulation and standard. Regulations on Supervision and Administration of Medical Devices was revised for the third time. China has established the MAH system, and reconstructed the clinical evaluation system. Today China has improved the regulatory system by centering on the Regulation as the core and 13 Provisions as the support. At present, there are nearly 2,000 national standards for medical devices in China, reaching over 90% consistency with international standards. There are 534 technical guidances for evaluation, which guide the R&D and evaluation of medical devices.

- Second, to deepen the reform of review & approval system. Up to now, 192 innovative medical devices including surgical robots and 131 products for clinically urgent needs have been approved.

- Third, to strengthen the full life cycle regulation. Focusing on certain products with high risks, NMPA carried out in-depth investigations and special programs to address potential risks. NMPA issued documents on tiered regulation of medical device, enhanced active surveillance on adverse events. NMPA also promotes the vigilance project, and conducts international exchanges of safety information within NCAR.

- Fourth, to carry out international cooperation in regulation. NMPA actively participated in IMDRF, and took the lead in setting up medical device clinical evaluation working group and issued related guidelines, and made timely application to China's regulatory practice. In GHWP, NMPA is also deeply involved, including serving as Vice Chair and leading 2 working groups, enhancing the strategic framework of GHWP.

Classification of IVD

2023.3.8 The revised IVD classification catalogue is open for comments on NMPA website, till to the 2023.4.12

Background: In the past decade, the IVD industry has rapid growth, with new technologies, new methods and new targets emerging. The old version of catalogue can’t fully meet the regulatory and industrial requirements, and some IVD calssification are not completely consistent with the Classification Rules for IVD, which was issued in October 2021.

Main change: New revision catalogue absorb and adopt the achievements of the IMDRF IVD classification working group, especially the corresponding guidance. Compared with the old version, The structure of the new catalogue is adjusted into five parts: "serial number, primary product category, secondary product category, intended use, and management category", iclude 25 primary product category, 2023 secondary product category.

The content of "intended use" includes the tested object and its main clinical use. Its purpose is to determine the management category of the product.

serial number

primary product category

secondary product category

Intended Use

management category

序号	一级产品类别	二级产品类别	预期用途	管理类别
01	与致病性病原体抗原、抗体以及核酸等检测相关的试剂	001 志贺氏菌属诊断血清	用于检测人体样本中的志贺氏菌。临床上用于诊断志贺氏菌属各型菌种。	Ⅲ
		002 鲍氏志贺菌诊断血清	用于检测人体样本中的鲍氏志贺氏[illegible]临床上用于鲍氏志贺菌群分型。	Ⅲ
			[illegible]	

IVD related to detection of pathogenic pathogen antigen, antibody and nucleic acid

Diagnostic serum of Shigella

It is used to detect Shigella in human samples. It is clinically used to diagnose various types of Shigella.

Promote the implementation of Medical Device standards

IEC 60601/GB 9706 serials standards

➢In order to better integrate with the international standards, further improve the level of China's medical device industry, 2020.4.9 the GB 9706.1-2020 (Medical electrical equipment—Part 1:General requirements for basic safety and essential performance (IEC 60601-1;2012,MOD))had been published, as the mandatory national standards and will implement on 2023.5.1

➢Parallel standards and special standards of GB 9706.1 are being issued in succession

➢the medical device should comply with the general standards requirements after 2023.5.1, but if the medical device has the applicable special standards, it can comply with the general standards after the applicable special standards

- According to the National Standardization Law, manufacturer should ensure that the products produced and sold after the implementation of the standards meet the requirements of the standards.

But, For the registred medical electrical equipment , the registrant shall apply for registration alternation in time and complete within 3 years from the date of implementation(2023.5.1 or applicalbe special standards implementation date) . Corresponding measures will ensure the smooth transition of the implementation of relevant standardsensure a smooth transition.

Announcement of the NMPA on the implementation of GB 9706.1-2020 and parallel standards and special standards can find on NMPA website.

Continue to promote UDI implementation

UDI recent years in China

Establish a complete system

- Incorporated into the Regulations on the Supervision and Administration of Medical Devices and supporting regulations
- Rules for UDI system of medical devices
- published 4 industry standards, for example: YY/T 1630-2018 Basic requirements for UDI of medical devices
- Established Medical device UDI database

Gradually promote comprehensive implementation

- The first batch of implementation: 2021.1.1, 69 varieties in 9 categories
- the second batch of Implementation of : 2022.6.1, except for the first batch of 69 types of Class III medical devices (including IVD)

2023.2.17 the third batch of implementation 103 class II varieties in 15 categories, for these medical devices:

- produced from June 1, 2024 shall have the UDI of medical devices;

- Applying for registration from June 1, 2024, the registration applicant shall submit the product UDI information of the minimum sales unit of its product in the registration management system;

- manufactured from June 1, 2024, Before the products are put on the market, the registrant shall upload the product UDI and relevant data of the minimum sales unit and higher level packaging to the UDI database of medical devices according to the relevant standards or specifications.

International Cooperation

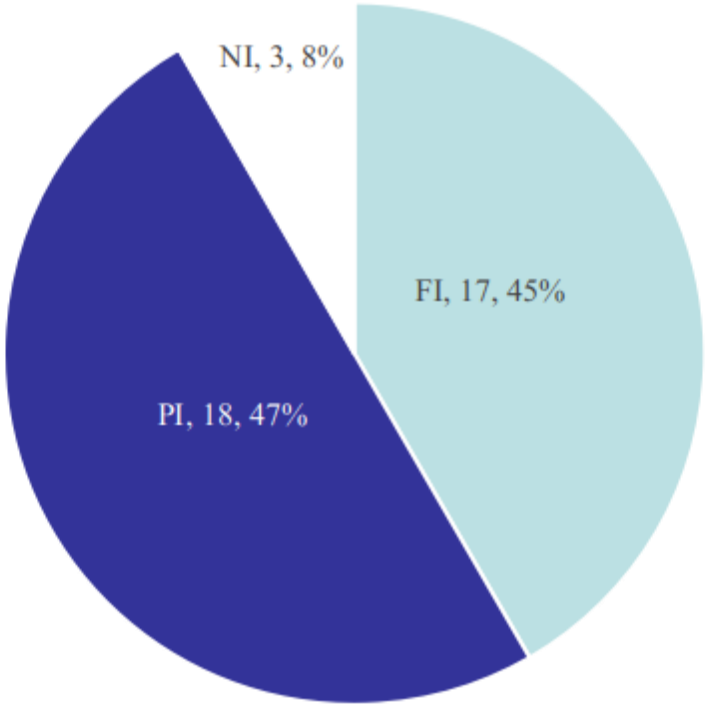
Ø From February 13 to 16, 2023, the 26th Technical Committee Meeting and Annual Meeting of the GHWP was held in Riyadh, Saudi Arabia. Xu Jinghe, Deputy Director of the State Drug Administration.

Ø The GHWP technical committee meeting includes closed meeting and open meeting. The nine GHWP working groups introduced the latest progress of their work and discussed the focus and development direction of the next step. The meeting elected Xu Jinghe, Deputy Director of the State Drug Administration, as the chairman , representatives of NMPA participated in the election of the Vice-Chairman of the Technical Committee, the Chairman of Working Group 7 and Working Group 9 and were elected.

Ø This work will help to further deepen the technical exchange between China's medical device regulation and international medical device regulation, and better promote the coordination and trust of global medical device regulation.

- **IMDRF guidance implementation**

Ø According to the statistics of the implementation of the 38 technical documents issued by the IMF in member countries, 17 guidances were fully implemented in China, and 18 guidances were partially implemented, 3 guidances not implemented



Conclusion

1.Recent years, NMPA improve the system of regulation and standard, deepen the reform of review & approval system, strengthen the full life cycle regulation,carry out international cooperation in regulation.

2.The revised IVD classification catalogue is open for comments for 30 days.

3.Announcement of the NMPA on the implementation of GB 9706.1-2020 and parallel standards and special standards can find on NMPA website.

4.The third batch of UDI implementation for 103 class II varieties in 15 categories

5.Continue to carry out international cooperation