China Regulation of Medical Device Supervision and Management (MDR)

Newly Released State Council Order 739

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Regulation of Medical Device Supervision and Management (MDR, NO. 739)


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

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索引号	FGWJ-2021-10001	主题分类	法规文件 / 法律行政法规
标题	医疗器械监督管理条例		
发布日期	2021-03-18		

医疗器械监督管理条例

文章来源：新华社 发布时间：2021-03-18

（2000年1月4日中华人民共和国国务院令第276号公布　2014年2月12日国务院第39次常务会议修订通过
根据2017年5月4日《国务院关于修改〈医疗器械监督管理条例〉的决定》修订　2020年12月21日国务院第119次常务会议修订通过）

- Revised and adopted at the 119th executive meeting of the State Council on Dec. 21 2020. Published on Mar. 18th 2021 in NMPA. Formal effective on **Jun. 1st 2021**
- Total **107** articles in **8** chapters including the general rules, product registration and filing, production, operation and use, handling of AE and Recall, Supervision and Inspection, legal liability and attached rules in new NO. 739
- **Lower level regulations like NO4 Measures for Administration of MD Registration, NO5 Measures for Administration of IVD Registration, NO7 Measures for Administration of MD Production, NO8 Measures for Administration of MD Operation, NO25 MD GCP and NO 30 Amendment to IVD Registration Regulation** will be revised in next 3~6 months*
- NO6 MD IFU and Label Regulation, No15 MD Classification, NO19 MD Nomenclature, NO32 Decision on Adjusting the Approval Procedure of MD Administration Items and NO33 MD Standard Management Regulation revision is not required for the moment*
- There are 13 normative documents will be revised accordingly*

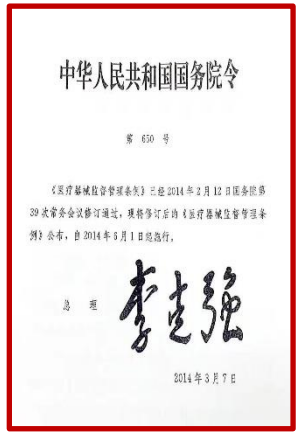
* Source: NMPA online publicity meeting on 8th April
https://www.nmpa.gov.cn/xxgk/fgwj/flxzhfg/20210318084145148.html

CHINA REGULATION REFORM

2000.1.4

1st MDR SC Decree 276

- 1st IVD registration regulation published in 2007



2014.2.12

1st Revision MDR SC Decree 650

2015

SC document No. 44 Regulatory Reform

《关于改革药品医疗器械审评审批制度的意见》

国发〔2015〕44号)

2017

SC document No. 42 deepen Regulatory Reform

“两办”

《关于深化审评审批制度改革鼓励药品医疗器械创新的意见》

(厅字〔2017〕42号)

2017

2nd Revision MDR SC Decree 680

2020.12.21

3rd Revision MDR SC Decree 739

SC = State Council

Overview of SC MDR Decree 739

Implementation the reform requirements of the evaluation and approval system for drugs and medical devices, and consolidate the main responsibility of enterprise

Consolidation the achievements of the reform “Streamline administration, delegate power and improve services”, unleash the innovative vitality of the market innovation

Strengthen the supervision of the whole life cycle and whole process of medical device to improve the efficiency of supervision and administration

To increase the intensity of punishment of illegal acts, increase the penalty

Chapter I General Provisions

What's New?

- Article 1 — **New Role & Responsibility of NMPA**: NMPA takes on the role of promoting medical device industry development.
- Article 4 — **Local country government leadership role** in supervision of medical device
- Article 5 — **New principle for medical device supervision**: Risk base, life-cycle, scientific Base, social co-governance.
- Article 8 — **New focus from central government on medical device industry development** – development plan and strategy from state level.
- Article 9 — **Support medial device and technology innovation** from credit, tendering or procurement aspects
- Article 10 — **Focus on use of informatics in supervision**

Chapter II Registration and Filing of Medical Device Products

What's New?

- Article 13 Registration Applicant's (LM) responsibility throughout product life-cycle
- Article 14 **Type report could be self-testing report or testing report from qualified testing labs**
- Article 15&16 **COO could be waived only for innovative medical device granted by NMPA**
- Article 15&18 Publish approval/filing info. Within 5WDs on NMPA public service platform
- Article 19 **Conditional Approval & Emergency Use Authorization (EUA) pathway**
- Article 20 **Role & Responsibility for registration applicant (LM) or** imported device local affiliate
- Article 21 Change application related to design, raw material etc. to be applied with approval authority, other changes to be file for record or report
- Article 24 &25 **Clinical evaluation exemption criteria**, clinical evaluation guidance to be developed by NMPA, if clinical evaluation is not enough to support the safety and efficacy, clinical trial is then needed
- Article 28 Informed consent is needed
- Article 29 Emergency use of clinical trial products pathway

Chapter III Production of Medical Devices

What's new?

- Article 38 Newly added UDI requirements

The state shall, according to the category of medical devices, implement a unique identification system for medical devices step by step so as to achieve traceability of medical device.

- Article 39 Instruction for Use, label need listed below items,

(2) **Names, addresses and contact information** of the registrants (LM), filing applicant and **entrusted manufacturers of medical** devices;

(3) Data of manufacturer**(DOM), shelf life or expiration**

Chapter IV Distribution and Use of Medical Device

What's new?

- Article 41

Class II medical device whose product safety and effectiveness are not affected by the circulation process may be exempted from business filing.

- Article 45

Medical device distributors and users shall purchase medical device from medical device registrants, filing applicant, manufacturer or distributors with legal qualifications.

- Article 53

Allow clinical institutions develop and use IVD reagent with no same category products marketed in China in their own units.

- Article 57

It is forbidden to import expired, invalid, obsolete and other medical devices that have been used.

Chapter V Treatment of Adverse Events and Recall of Medical Device

What's new?

- Article 66

The **registrant (LM) and filling applicant** of a medical device shall, based on the reevaluation result, take corresponding control measures to improve the listed medical device, and change the registration or record according to the provisions. Where the reevaluation results show that the listed medical device cannot guarantee safety and effectiveness, the registrant or filing applicant of the medical device shall actively apply for cancellation of the registration certificate of medical device or cancel the record; where a medical device registrant or filing applicant fails to apply for the cancellation of the medical device registration certificate or the cancellation of the record, the department in charge of drug supervision and administration shall cancel the medical device registration certificate or the records.

Chapter VII Legal Liability

- Implement the requirement of "**punishing the responsible person**". For the responsible persons of enterprise that have seriously violated the relevant laws, their income from these entities during the period of violation should be confiscated and may also be given a fine 3 times the income at maximum and banned from engaging in related activities for 5 years to life.

- **Increase the punishment** for prohibiting entry into the industry and the market by imposing punitive measures, such as revoking the license of the entities that violated the relevant laws and prohibiting them from engaging in relevant activities for a certain period of time based on the extent of their violations; if an overseas registrant or filing entity refuses to perform administrative punishment decisions, the **import** of its medical devices **shall be prohibited for 10 years**.

- **Significantly increase the fines,** and a fine of up to 30 times the value of the goods can be imposed on an entity for serious violations involving quality and safety.

Thank you

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