


OVERVIEW OF THE REGULATORY LANDSCAPE IN CHINA

Yuan peng
2018.3.19

- 
- Organization
 - Structure of regulatory
 - Reformation

Organization

CFDA:

administration and supervision of food (including food additives and health food, the same below) safety, drugs (including traditional Chinese medicines and ethno-medicines, the same below), medical devices and cosmetics

Organization



Medical device registration	<ul style="list-style-type: none">• Pre-market• Base work(UDI classification standard)
Medical device supervision	<ul style="list-style-type: none">• Post-market• Surveillance, reevaluation, inspection
Bureau of Investigation and Enforcement	<ul style="list-style-type: none">• investigation and punishment on major and serious cases pertaining to food, drug, medical device , cosmetic safety and so on

Medical device registration

- Pre-market
- Base work(UDI classification standard)

Medical device supervision

- Post-market
- Surveillance, reevaluation, inspection

Bureau of Investigation and Enforcement

- investigation and punishment on major and serious cases pertaining to food, drug, medical device , cosmetic safety and so on

Organization

Directly affiliated organizations

CMDE: review the medical device registration application, and give the technical advices, which the medical device can be marketed.

CMDSA: give the technical advices about the classification of medical device and manage the medical device standards

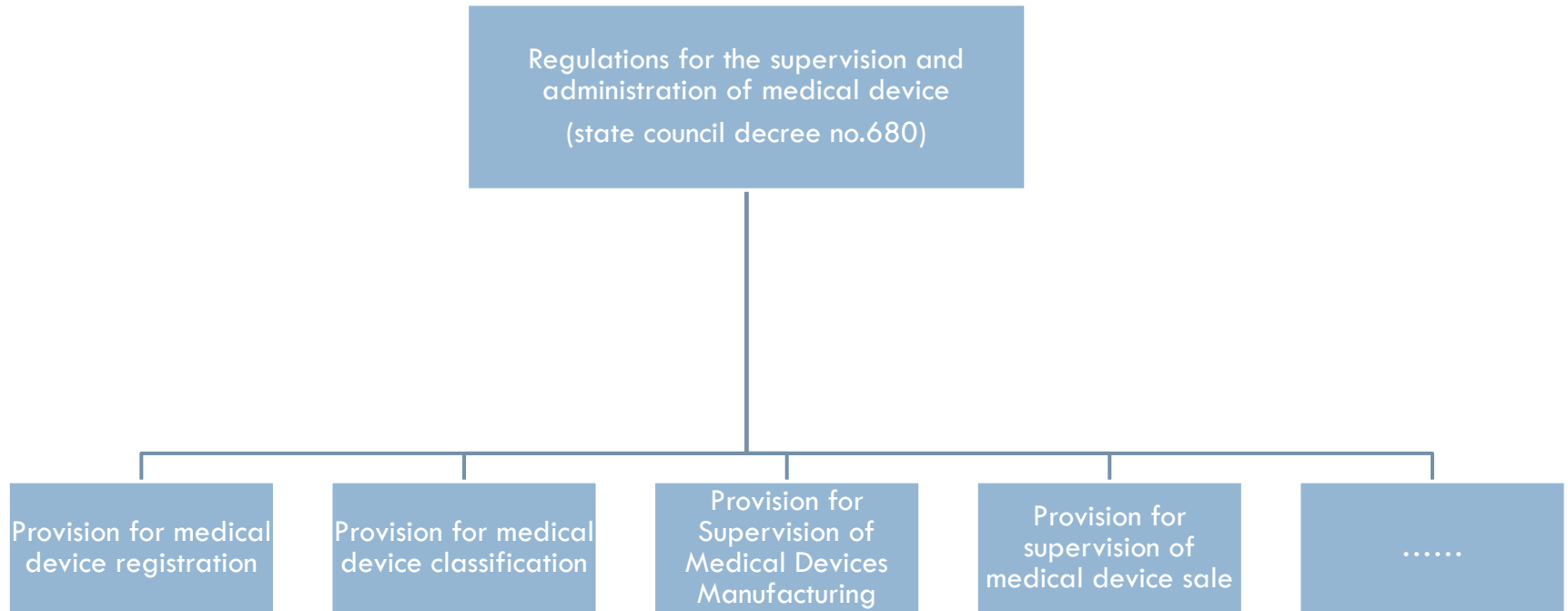
Organization



CFDI: on-site inspection. Organizing and implementing overseas inspection.

CDR: Medical device adverse event monitoring

Structure of Regulatory



Structure of Regulatory



- Regulations
- departmental regulations
- Normative files
- Technical rules

Structure of Regulatory

Departmental regulations

- Provision of medical device registration
- Provision of IVD registration
- The procedure, materials for registration, time limitation, and how to manage
- IVD device should comply with the provision of medical device registration
- IVD reagents should comply with the provision of IVD registration

Structure of Regulatory

Normative files:

New edition of “Catalogue of medical device classification”.
2017.8 CFDA announcement 2017 No.104

- The new catalogue further optimizes the overall framework, refines the product category, expands the product coverage, adjusts the product management category reasonably.
- And significantly improves the scientificity and guiding significance of the catalog.

Structure of Regulatory



Technical rules: guidance, mandatory standards

More than 270 guidance, and more than 1300 standards(national standards and industry standards)

Structure of Regulatory

- Technical rules

Guiding principles of security technology review for medical devices

Guiding principles for technology review of mobile medical devices,

Together with the previously released guidelines for the review of medical device software technology, A complete system of software and mobile medical devices is established.

Reformation

2015

Propositions on reforming drug and medical device approval

Issued on 2015.4

General Office of the State Council, 2015
No.42

Reformation

- Adjust the classification of medical device
- Develop the Consistency level of medical device standard with international standard
- Innovation medical device should approved in priority

Reformation

2017

Propositions on deepening approval system reformation and encouraging drug and medical device innovation

Issued on 2017.10

General Office of the Central Committee &
General Office of the State Council, 2017 No.44

milestone document

Reformation

Adjust the requirements for clinical trials,
for example,

- the clinical trials institution, from approval to filing, in order to increase the quantities of clinical trials institutions
- accept the clinical trials data from the abroad
- Accept the decision from the regional IRB, reduce the time of IRB approval
- Allow the extended clinical trials

Reformation

- Emphasize special approval procedure again
- Special approval procedures for innovative medical devices
- Prior approval procedure for medical device, for medical device for urgent clinical use and so on.

Reformation



Push the development of Authority license holder of medical device, and the AHL should hold more responsibilities, for example, should implement the reevaluation of medical device, should response for the whole lifecycle of medical device, and so on

Reformation



International cooperation

Overseas on-site inspection

This year, CFDA will do our best to ensure the requirements of No.44 will be implementation.