CFDA 国家食品药品监督管理总局
China Food and Drug Administration

INTRODUCTION TO MEDICAL DEVICE SUPERVISION AND ADMINISTRATION IN CHINA

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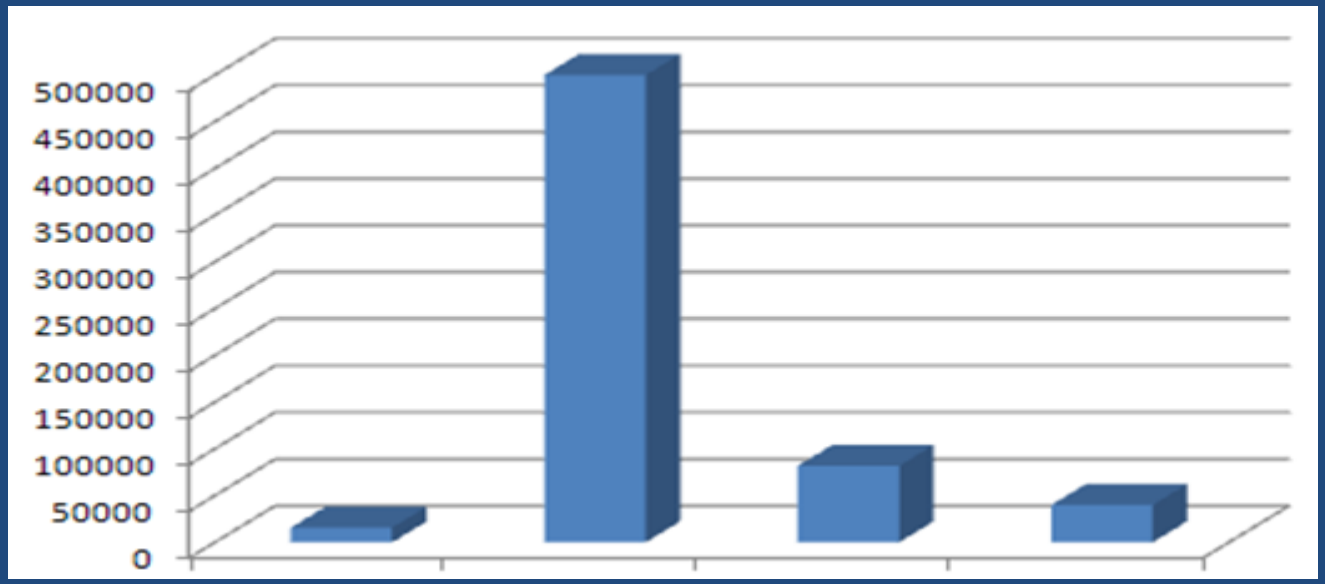
Context

1. THE DEVELOPMENT OF MEDICAL DEVICE INDUSTRY IN CHINA
2. OVERVIEW OF MEDICAL DEVICE SUPERVISION & ADMINISTRATION IN CHINA
3. PROSPECT OF MEDICAL DEVICE SUPERVISION IN CHINA

I. THE DEVELOPMENT OF MEDICAL DEVICE INDUSTRY IN CHINA

- In 2016, total medical device market size $76 billion
- Recent years, CGAR >20%
- In 2019, estimated medical device market size >$91 billion
- 5 Key Areas: Imaging device, lab test device, cardiovascular device, orthopedics device and information device
- imaging device accounts for 1/ 3, IVD accounts for 15%

I. THE DEVELOPMENT OF MEDICAL DEVICE INDUSTRY IN CHINA



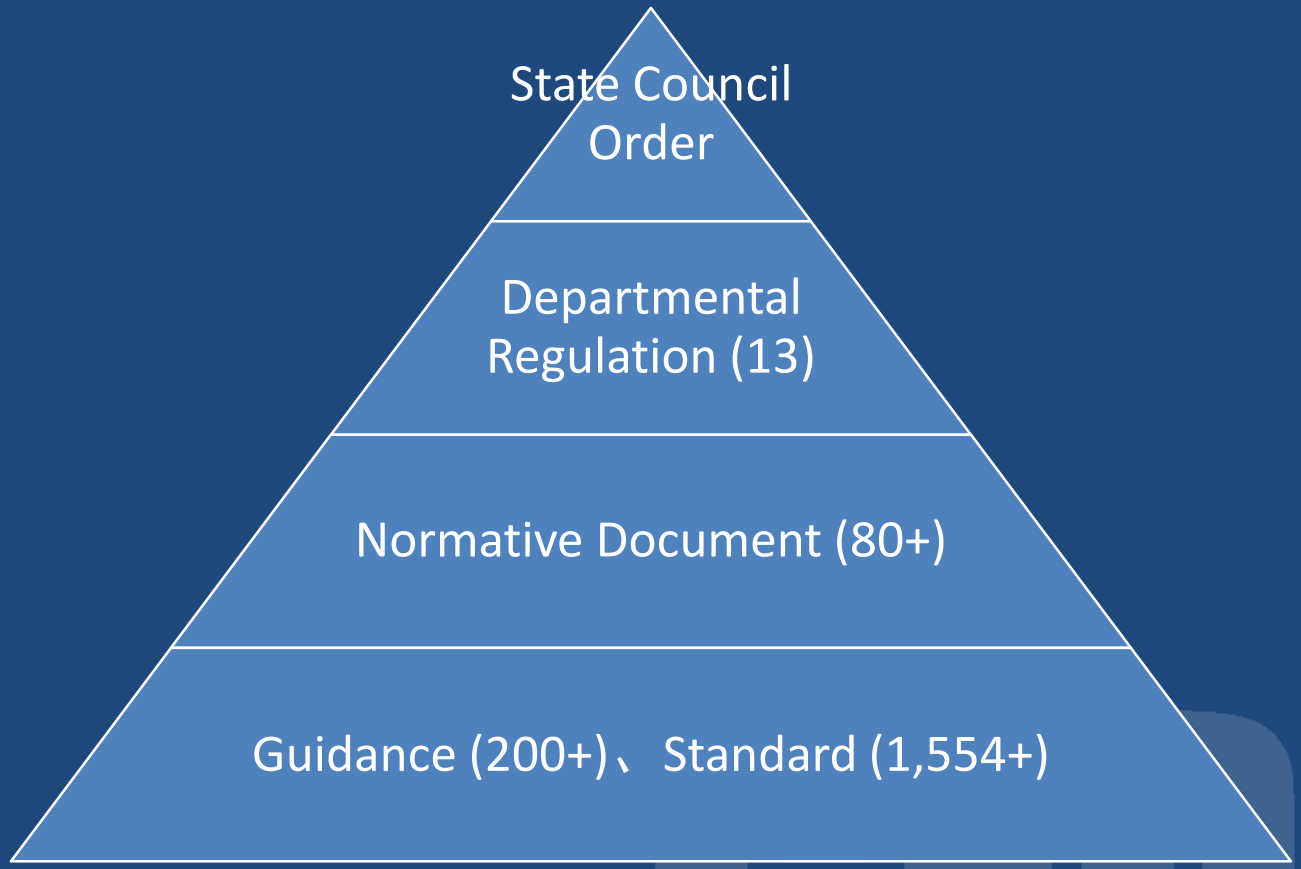
Statistics of China Medical Device Industry

II. OVERVIEW OF MEDICAL DEVICE SUPERVISION AND ADMINISTRATION IN CHINA

No.	CFDA Departmental Regulations	CFDA Order	Effective By
1	Medical Device Registration Regulation	No.4	2014.10.01
2	IVD Registration Regulation	No.5	2014.10.01
3	Medical Device IFU and Label Regulation	No.6	2014.10.01
4	Medical Device Manufacture Regulation	No.7	2014.10.01
5	Medical Device Distribution Regulation	No.8	2014.10.01
6	Medical Device Classification Rules	No.15	2016.01.01
7	In-use Medical Device Quality Supervision Regulation	No.18	2016.02.01
8	Medical Device Generic Name Naming Rule	No.19	2016.04.01
9	Medical Device GCP	No.25	2016.06.01
10	Medical Device Recall Regulation	No.29	2017.05.01
11	Amendment of IVD Registration Regulation	No.30	2017.01.25
12	Opinion on adjusting some administrative review procedure for medical device review and approval	No.32	2017.07.01
13	Medical Device Standard Regulation	No.33	2017.07.01

II. OVERVIEW OF MEDICAL DEVICE SUPERVISION AND ADMINISTRATION IN CHINA

4-TIERED MEDICAL DEVICE REGULATORY SYSTEM



II. OVERVIEW OF MEDICAL DEVICE SUPERVISION AND ADMINISTRATION IN CHINA

POST-MARKET SUPERVISION：

- fully implemented the GMP and GSP of medical devices
- Annual full item inspection of class III medical device manufacturers and class II sterile medical device manufacturers
- In 2015, overseas manufacture quality management system inspection
- In 2016, inspection of the overseas quality management system for medical device under registration review
- Increase unannounced inspection triggered by complaints & reports, inspection results will be disclosed to the public

II. OVERVIEW OF MEDICAL DEVICE SUPERVISION AND ADMINISTRATION IN CHINA

ADMINISTRATION OF MEDICAL DEVICE REGISTRATION

- **Establish technical committee for medical device classification:**
  - 36 members in the executive committee
  - 288 members in 16 subordinate professional groups.
  - comprised by well-known academicians, clinical medical experts, engineering experts and experienced professionals
- **Amend and Published** Classification Catalogue (2017 Version)
  - 22 sub-directories
  - 206 primary categories
  - 1,157 secondary categories
  - 2,000+ entries of product description and intended uses
  - 6,609 product names presented.
  - 40 products down classified

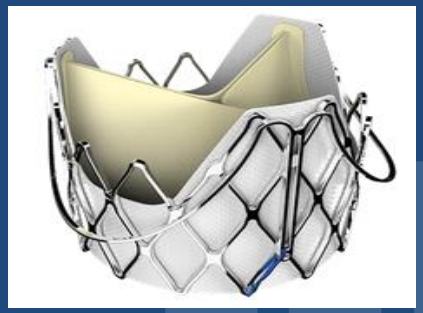
II. OVERVIEW OF MEDICAL DEVICE SUPERVISION AND ADMINISTRATION IN CHINA

ADMINISTRATION OF MEDICAL DEVICE REGISTRATION

➢**Implement innovation-driven development strategy and encourage enterprise innovation.**

- Special Review and Approval Procedures for Innovative Medical Devices：29 innovative device got approved
- Prioritized Review and Approval Procedure of Medical Devices: 9 priority product enrolled

China Manufacture, Global New



China New

Priority Channel

II. OVERVIEW OF MEDICAL DEVICE SUPERVISION AND ADMINISTRATION IN CHINA

ADMINISTRATION OF MEDICAL DEVICE REGISTRATION

➢ **Reform the management of clinical trials, improve review quality and efficiency and stimulate industrial activity**

- Change the qualification of the clinical trial institution to the filing management
- Published 3 batches of clinical trial exemption list, enlisted 1,090 product kind.
- enlarge the scope of use the new Review Model, conduct group review the innovative medical device, priority review device and clinical trial pre-approval device applications.
- From 2015, began clinical trial supervision and random inspection of registration applications under review

➢ **More frequent international cooperation.**

- Participated in International Medical Device Regulatory Forum (IMDRF) Management Committee
- Participated in the Sino-EU Economic and Trade Working Group Conference
- Actively participated in Asian Harmonization Working Party (AHWP),

III. PROSPECT OF MEDICAL DEVICE SUPERVISION IN CHINA

Consolidate the foundation and strengthen the management of product life cycle

- In the next 5 years， formulating and revising 500 standards, 200 guidelines, and developing 150 national reference material for IVD products
- Amend the special review and approval procedures for innovative medical devices，further improve the review efficiency for innovative medical devices
- For every two years, a full-item inspection of the remaining class II and I device manufacturers will be conducted once
- Annual overseas inspection for 30-40 foreign manufacturers
- Monitor 100 key medical devices
- Establish a safety monitoring and evaluation system
- Formulate UDI rules and standards, advance implementation per risk level

III. PROSPECT OF MEDICAL DEVICE SUPERVISION IN CHINA

CONTINUOUS DEEPEN THE REVIEW AND APPROVAL SYSTEM REFORM

- Oct. 2017， published <the Opinions on Deepening the Reform of the Review and Approval System to Encourage Pharmaceutical and Medical Device Manufacturer Innovation ([2017] No. 42)>
- Working to study and revise the Regulations for the Supervision and Administration of Medical Devices.
  - improving MAH system
  - reforming the clinical trial management
  - Optimize approval procedures
  - Optimize and rationalize the post-market regulatory requirements
  - Strengthen the construction of the supervision team, and
  - Implement accountability system.

III. PROSPECT OF MEDICAL DEVICE SUPERVISION IN CHINA

STRENGTHEN INTERNATIONAL EXCHANGE & COOPERATION

- CFDA willing to make its own efforts and contributions to the harmonization and convergence of international medical device supervision and regulation.
- As host of the 2018 IMDRF, CFDA will actively prepare and promote international legal harmonization.
- CFDA will continue to participate actively in the AHWP and play an even greater role

Communicate-Develop-Share

THANK YOU

FOR YOUR ATTENTION!

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