China Update

AHWP 23nd annual meeting
Oct 25th, 2018

Ⅰ. Overview of Medical Device industry in China

1.Reform of the Chinese Regulatory Authority

In accordance with the reform of the Chinese government, the National Medical Products Administration has been set up with the main responsibility of registering and supervising drugs, cosmetics and medical devices.

2.Overview of Medical Device Market

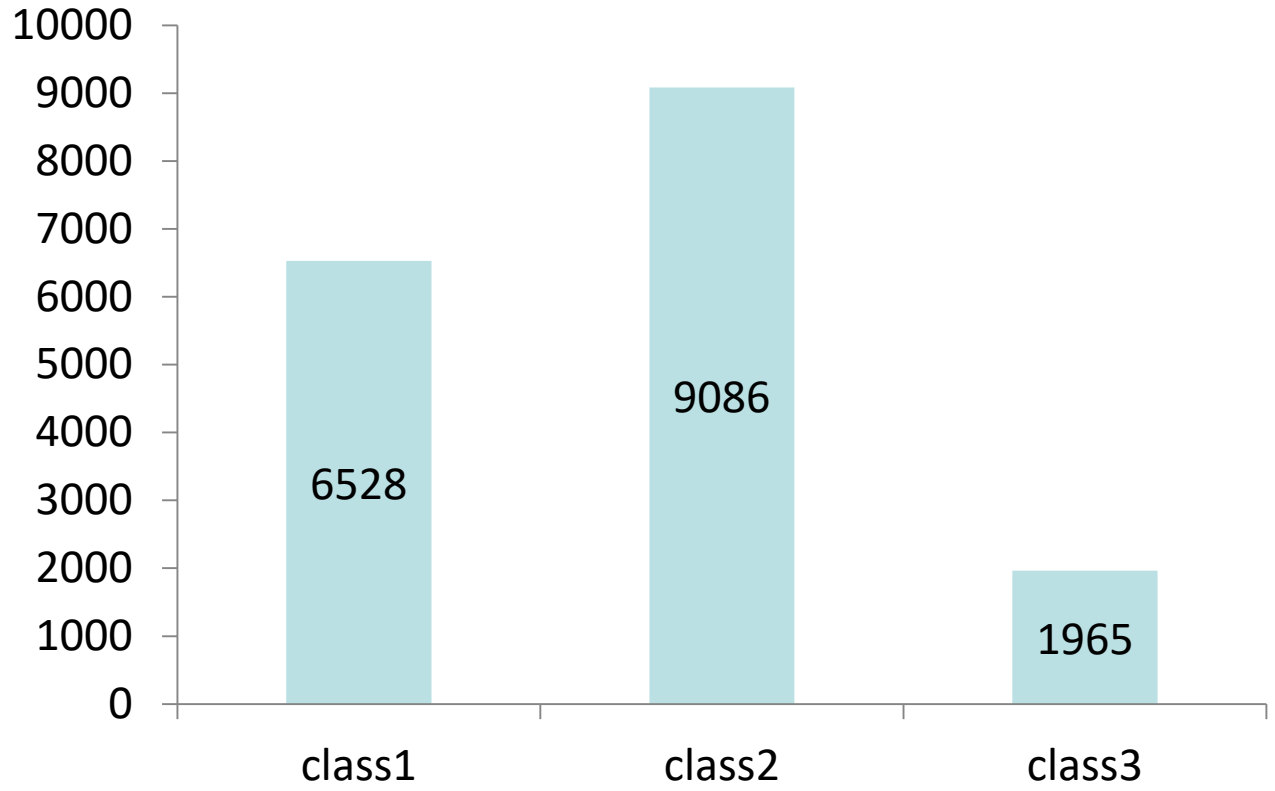
- In 2017, The market for medical devices is over 400 billion RMB.

- In recent years, the annual compound growth rate has exceeded 20 %

- In 2020, it is expected to exceed 700 billion RMB

3.Status of Medical Device Manufactures in China

- By May 2018, there were over 15000 medical device Manufactures in China.



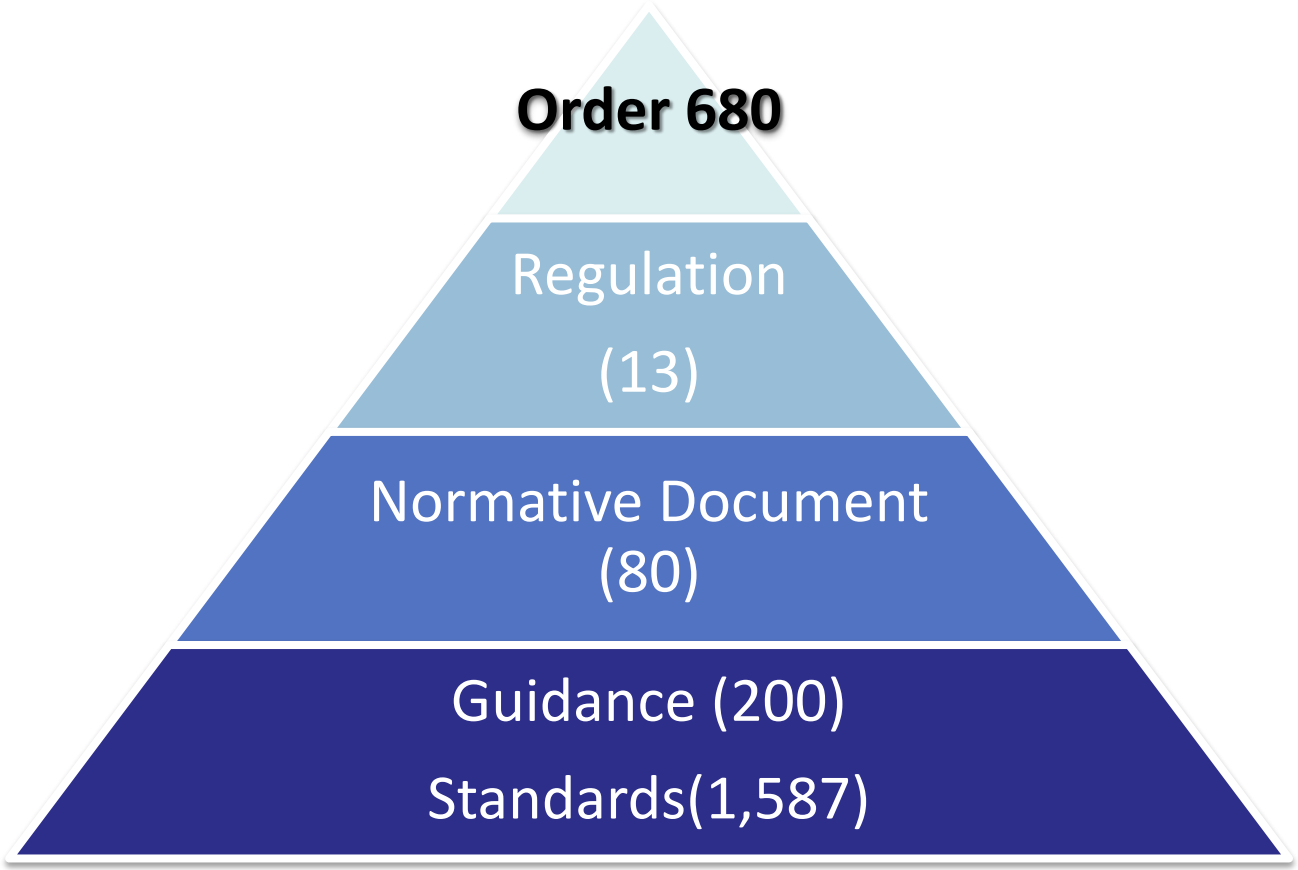
4.Status of Medical Devices Registration

- By May 2018, 120,000 medical devices were registered or filed

Ⅱ. Overview of Medical Device Regulation system

1.Level of Medical Device's Legislation system

Four Tiered Policy System



2.Reform Of Review And Approval System

Oct 1st,2017

Opinions on Deepening the reform of the review and approval system and encouraging the innovation of drugs and medical devices

To improve the quality of medical Device as the core;

To meet the needs of the patient as the goal;

To further optimize the review and approval process

3.Amendment of MD Regulations

June 25th, 2018, the draft of amendment to MDR was Published for public comments.

- Further clarify the MAH （marketing authorization holder） system;
- Clearly stipulate the obligations of agents of imported products;
- Change the approval of clinical trials from “Express permission“ to “implied permission”;
- Optimize the Clinical evaluation;
- Accept overseas clinical trial data;

4.Amendment of MD Regulations(con't)

- For Innovative medical devices not marketed at domestic and abroad, Import approvals no longer require overseas marketing certificates;
- The sale of some Class II medical devices is exempt from listing;
- prohibit the import and sale of used medical devices
- Cancel medical device advertising approval;
- Establish professional inspector team;
- add penalties for responsible natural persons, such as Legal representative, Person in charge of enterprise.

5.Promoting Medical Devices Innovation

On February 7,2014,the former CFDA issued special examination and approval procedures for Innovative medical devices.

959 applications, 184 access routes, 45 approvals

Revised "Special Approval Procedure for Innovative Medical Devices" for public consultation

PET-MR

EGFR/KRAS/BRAF/PIK3CA\ALK\ROS1 gene mutation test kits

6.Revision Of Special Approval Procedures For Innovative Medical Devices

- Detailed patent review requirements
- Applicable to Class II and III
- 5 year valid period
- Termination of the review process

7.Rules for Unique Device Identification System


国家食品药品监督管理总局 CFDA

中国政府法制信息网

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首页> 立法意见征集公告

国家市场监督管理总局关于公开征求
《医疗器械唯一标识系统规则（征求意见稿）》意见的通知

日期：2018-08-22　来源：中国政府法制信息网　【字体：大 中 小】　视力保护色：

为加强医疗器械研制、生产、经营和使用环节的监督和管理，提高监督管理效能，国家市场监督管理总局起草了《医疗器械唯一标识系统规则（征求意见稿）》。现就征求意见稿向社会公开征求意见，社会各界可于2018年9月21日前登录中国政府法制信息网（网址：http://www.chinalaw.gov.cn），进入首页主菜单的“立法意见征集”栏目提出意见和建议。

国家市场监督管理总局

2018年8月22日

- First, Open for comments on February 26, 2018
- Second, Open for comments on August 22, 2018
- UDI construction content identified

8.Rules for Customized Medical Device

国家药品监督管理局 国家市场监督管理总局

关于征求《定制式医疗器械监督管理规定（试行）》（征求意见稿）意见的函

食药监械管便函〔2018〕44号

2018年09月29日 发布

各省、自治区、直辖市食品药品监督管理局，中国医疗器械行业协会，有关单位：

为规范定制式医疗器械注册监督管理，保障定制式医疗器械的安全性、有效性，满足患者个性化需求，经过广泛调研和深入研究，我司组织起草了《定制式医疗器械监督管理规定（试行）》（征求意见稿），现向社会公开征求意见，请于2018年10月26日前通过以下途径和方式反馈意见：

电子邮件：qxzcec@163.com。发送邮件时，请务必在邮件主题处注明“定制式医疗器械监督管理规定反馈意见”。

联 系 人：周雯雯，边旭

联系电话：010-88331482，88331422

附件：定制式医疗器械监督管理规定（试行）（征求意见稿）

- Open for comments on September 29, 2018
- Customized Device definitions, Classification, registration, manufacture supervision

9.Further Improving Clinical Trail Practice

- Implemented Good Clinical Practice for clinical trials of medical devices , refer to ISO14155
- Change of qualification of clinical institutions for Medical Device to filling system
- Strengthen Clinical trial supervision and inspection

10.Supervision for Agents Of Imported Medical Devices

Provisions for the supervision and administration of agents of imported medical devices - August 1st 2018, public consultation

- Foreign MAH shall designate an agent in China
- address and contact information of the agent shall be clearly stated in the marketing certificate/filing notification.

11.Supervision For AE Monitoring And Re-evaluation

- Provisions for medical device AE monitoring and re-evaluation

  August 13th 2018, Enforce on January 1, 2019
- MAH direct reporting system
  - Establish a system of direct reporting of adverse events
  - Suitable internal organization and personnel
  - Register in Monitoring information system
  - Conduct investigation, analysis and evaluation
  - Continuous and periodical risk analysis

12.Supervision for AE monitoring and re-evaluation

- Improved re-evaluation system

  MAH shall

  – Conduct active re-evaluation according to the scientific progress and the assessment of adverse events;

  – actively revoke the marketing approval and notify the public according the re-evaluation results;

  The authority can withdraw the marketing approval when MAH fails to apply for revoke.

13.Strengthen MD Post-Market supervision

- Continue to strengthen on-site inspections of medical devices Manufactures, including domestic and overseas enterprises
- Continue to carry out sampling and spot-check of medical devices
- Strengthen the supervision of online sales of Medical Devices

14.International Exchange and Cooperation

1

To undertake the work of the IMDRF rotating chairman in 2018.

2

Organize the declaration of new IMDRF project in 2018, and the clinical evaluation of medical devices and the international standard list

3

Successful organization of half-yearly meetings of the AHWP Technical Committee

4

Actively participate in the activities of AHWP as Vice-chairman

Thank you!