China Update

IMDRF Open Stakeholder Forum
September 18th, 2018

Overview

- Amendment of Regulations for the Supervision and Administration of Medical Devices
- Revision of special approval procedures for innovative medical devices
- Simplify the renewal requirements for product registration certificate
- Provisions for the supervision and administration of agents of imported medical devices
- Provisions for medical device AE monitoring and re-evaluation

Amendment of Regulations for the Supervision and Administration of Medical Devices

- Oct 1st,2017
  opinions on Deepening the reform of the examination and approval system and encouraging the innovation of drugs and medical devices

- To implement relevant policies and measures for medical devices
  June 25th, 2018, the draft of amendment to MDR was Published for public comments.

Amendment of regulations for the supervision and administration of medical devices

- 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;

Amendment of regulations for the supervision and administration of medical devices

- 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.

Revision of special approval procedures for innovative medical devices

- Feb 7,2014 special examination and approval procedures for Innovative medical devices (interim)
- May 4, 2018 public consultation

  Feedback is currently being investigated

  Revised procedure will be issued in the near future
- Detailed patent review requirements
- Applicable to Class II and III
- 3 year valid period
- Termination of the review process

Simplify the renewal requirements for product registration certificate

- August 19th , 2018

  Notice on Revising the Renewal Requirements for the Registration of Medical Devices

  bulletin No. 53 of 2018
- Summary report and supporting data if required by the original certificate;
- Cancel the requirement of Marketing certificate of the origin country(region) for clinical trial application;
- Agreement issued by ethics committee of leading institution in multi-center clinical trial.

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;
- Agent information clearly stated in the marketing certificate.

Provisions for the supervision and administration of agents of imported medical devices

- Define the obligations of agent, such as:

  Liaison between the authority and the overseas MAH

  Monitoring and reporting adverse events

  Recall

  Consumer complaints

  Joint legal responsibility with MAH

- Set up certain penalties

Provisions for medical device AE monitoring and re-evaluation

- August 13th 2018, Dcree1 of SAMR
- 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

Provisions for medical device 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 the MAH fails to apply for revoke.

Thank you!