Update on China regulatory

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NMPA

Regulation on medical device supervision and administration

（State council degree No. 680）

✓is revising, according to the procedure, the Ministry of Justice P.R.C are reviewing the draft document, then they will submit the document to state council.

✓The regulation is the base medical device regulation in China.

✓Is revising corresponding provisions and Normative documents of the Regulations.

- **Regulatory Science Action Plan**

- In order to promote the Drug and Medical Device Regulatory Science research, NMPA start the Regulatory Science Action Plan.
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- The plan focus on the reform and innovation of drug and medical device review and approval system, and closely tracking the development frontier of international supervision.

- In 3-5 years, formulate a number of innovation regulatory policies, technical guidelines for evaluation, inspection, evaluation technology and technical standards

The objective:

Solve the problems affecting and restricting the innovation and quality of drugs and speed up the modernization of the drug and medical device management system and capacity.

The first batch items include 9 items, 4 items are involving the field of medical devices:

- the AI medical device evaluation study,
- the medical device new materials research,
- the combination products evaluation study,
- the Real-world data use for medical device clinical evaluation study.

- On March 26, NMPA approved the "glaucoma drainage tube" of Allergan company.
- It is the first medical device product using domestic real world data was approved in China.
- This is also a new progress in medical device regulatory science research

Promote UDI pilot in China

•2019, NMPA carried out the UDI pilot in China

•Mar. 2020, NMPA shared the UDI database for public

•Jul. 2020,summarized the progress and effectiveness of the pilot work of the unique identification system of medical devices, studied and deployed the next stage work:

➢Increase training of UDI

➢establish UDI demonstration exchange mechanism, and udi demonstration point in the production, operation, use and supervision of medical devices

➢focus on the utilization of UDI in medical treatment and medical insurance

guidelines for medical device manufacturer to carry out adverse event monitoring (No. 25 of 2020)

- The manufacturer shall take the primary responsibility of medical device adverse event monitoring. It shall establish a medical device adverse event monitoring work system, collect, report, investigate, analyze and evaluate medical device adverse event actively.

- The imported manufacturer shall also establish an information exchange mechanism with the designated agent to timely exchange the monitoring and re evaluation information of medical device adverse events.

- **Covid-19 Epidemic prevention and control**

- Up to now, NMPA had approved 44 COVID-19 IVD kits for 35 manufacturer, including 23 nucleic acid IVD kits and 21 antibody IVD kits.

- And these products had been exported more than 80 countries to support the world wide ovid-19 Epidemic prevention and control.

- NMPA will continue to strengthen the cooperation with WHO and other regulators， provide information on time.

- NMPA and local MPA also approved a large number of mask, PPE products.

- **Connection with the world wide regulation or standard**

➢ **Implementation of IMDRF guidelines**

- As a member of IMDRF, China actively promotes the implementation of the IMDRF guidelines in China. Up to now, among the 31 IMDRF guidelines, the 14 guidelines had been fully implemented in china, and 14 guidelines had been partly implemented in china.

- NMPA will continue to strengthen cooperation with IMDRF and contribute to the work of IMDRF.

- **GB 9706.1 (IEC 60601-1 Edition 3) had been published on April 2020.**

NMPA will Continue to strengthen the integration with international standards and Improve the rate of international standard adoption. the manufacturer can also use the new version standard according to the standardization law in china.

- **APEC CoE**

APEC RHSC officially approved the APEC Center of Excellence(CoE) in medical device supervision by Sichuan University on June 15. NMPA will consider to train IMDRF documents through the center of excellence in futrure.

Thank you

1. The Regulation on medical device supervision and administration expected be published in future.
2. Push the regulatory science action plan
3. Serve for Covid-19 Epidemic prevention and control
4. Continue to promote UDI pilot in China
5. Guide the adverse event monitoring
6. Connection with the world wide regulation or standard