REGULATORY REFORM on DRUG and MEDICAL DEVICES and INTERNATIONAL COOPERATION

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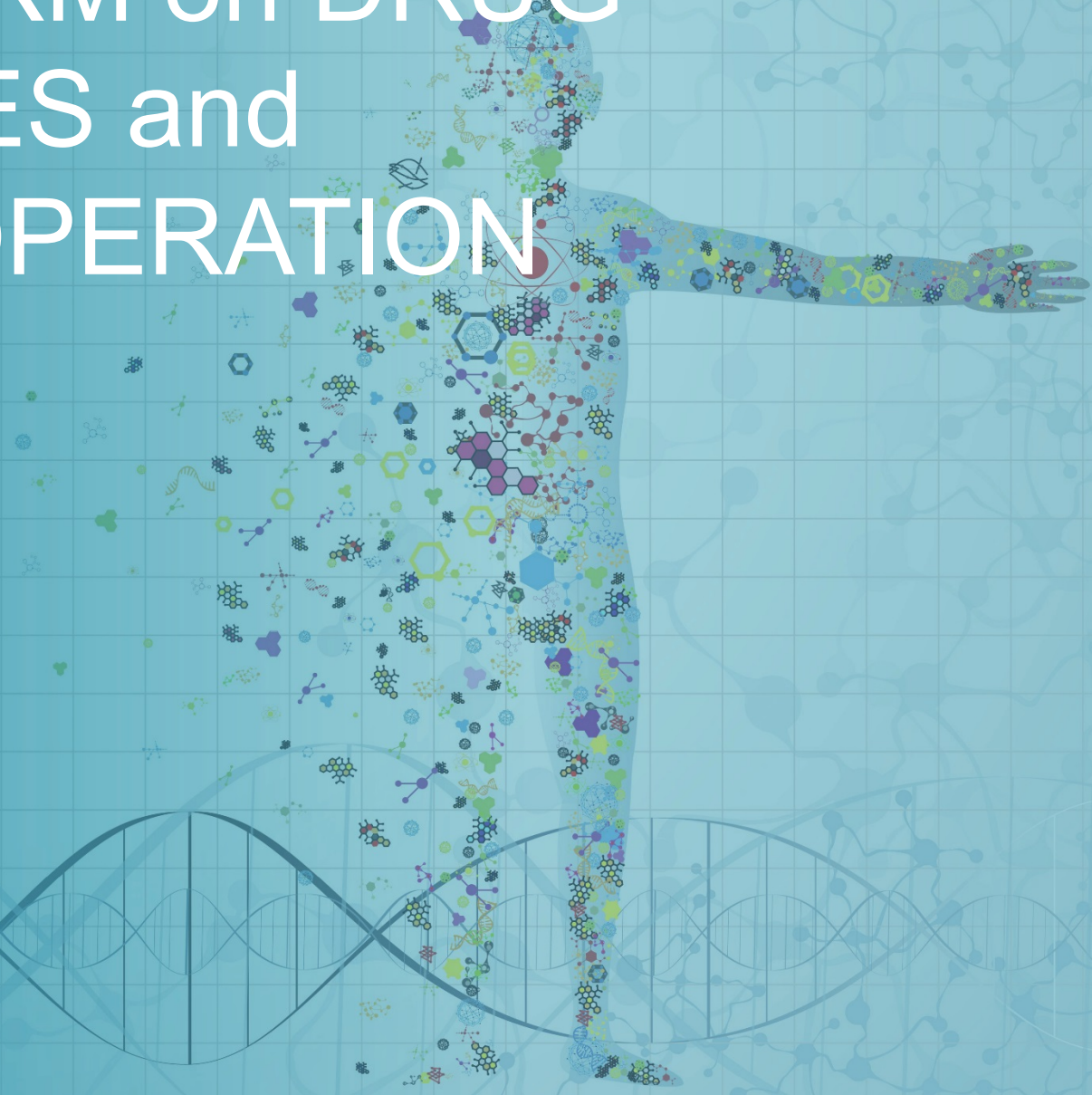

DIA

I. Improving quality & solving backlog

In 2015, Chinese government issued the “Opinions on Reforming the Examination, Approval, and Evaluation System for Pharmaceuticals & Medical Devices.

Five major reform objectives:

1. Improve the quality of review and approval
2. Resolve the backlog of registration applications
3. Improve the quality of generic drugs
4. Encourage research and development of new drugs
5. Increase transparency of review and approval

12 work tasks :

1. standards upgrade
2. consistency assessment of generic drugs
3. accelerate review and approval of innovative drugs
4. pilot program on MAH

5.applicant take main responsibilities

6. information release

7.improve clinical trials review method

8. punish clinical data falsification

9.simplify review process , improve re-registration

10. improve medical device evaluation and approval

11. improve quality control system

12. information sharing with pulic

II . Encouraging innovation and deepening the review and approval

In October 2017, China issued document “Opinions on Deepening the Reform of Reviewing, Approving System, and Encouraging the Innovation of Drugs and Medical Devices”.

- 6 areas and 36 measures:

1) clinical trial management.

- record-filing system for the accreditation
  - support institutions and investigators to conduct clinical trials
  - improving the ethics committee mechanism
  - improving ethics review efficiency
- optimizing the review and approval procedures
- accepting overseas clinical trial data
- supporting extended clinical trials
- investigating and cracking down of falsifying data

2) accelerating the review and approval.

- accelerating review and approval for urgent medical needs
- supporting research and development for rare diseases
- strictly controlling the review and approval of injections
- implemented linked review and approval regime
- supporting the inheritance and innovation
- establishing priority review and approval system

3) promoting innovation and development of generic drugs.

- establishing a list of marketed drugs
- exploring and establishing a drug patent linkage system
- launching pilot programs
- improving and implementing clinical data protection system
- promoting drug production
- promoting enterprises innovation
- supporting clinical application

4) strengthening the regulation of the entire lifecycle.

- facilitating implementation of marketing authorization holder system
- determining its responsibilities
- holder directly report adverse effect and adverse event system
- carrying out re-evaluation
- improving re-evaluation system
- regulating academic promotion activities

5) technical support capabilities.

- improving technical review system
- implementing confidentiality obligations
- enhancing capacity building for review and inspection
- implementing the inspection responsibilities
- building professional teams of inspectors
- strengthening the international cooperation

6) strengthen the implementation.

- organization coordination and cooperation
- publicity

III . Institutional Reform

- State Administration for Market Regulation
- National Drug Administration

Ⅳ. The continuous deepening of mutually beneficial international cooperation

Cooperated partner: 66 countries, 46 international organizations, signed 26 documents.

International Medical Device Regulatory Agency Forum (IMDRF)

13th meeting of its Management Committee in Shanghai, in March 2018.

Participants: regulatory agencies from 10 countries , WHO APEC LSIF RHSC , Asian Harmonization Working Party, Pan American Health Organization

Main discussions:

- Regulated Product Submission (RPS) - Canada
- Medical Device Patient Registries - USA
- Medical Device Adverse Event Terminology - Japan
- Good Regulatory Review Practices - USA
- Standards - USA
- Personalized Medical Devices-Australia
- Unique Device Identification - EU

Open session and Closed session:

more than 300 participants.

updates presentations and reports about:

- China Association for Medical Devices Industry (CAMDI)
- Global Diagnostic Imaging, Healthcare IT & Radiation Therapy Trade Association (DITTA)
- Global Medical Technology Alliance (GMTA)
- WHO
- APEC
- AHWP
- PAHO
- Saudi Arabia

outcomes:

- approved revised Final N9 ,N13,N46 document
- approved 2 proposed documents
- approved revised “Medical device clinical evaluation, List of International Standards Recognized
- agreed to direct the Standards Working Group to undertake this Item (USA ,China co-chair)
- updated revision of ToR, webpage listing full names, main activities on the IMDRF website
- agreed explore NWIP pertaining to medical device cyber security for consideration next
- proposed IMDRF-14 to be held in Beijing, China, in September 2018
- Singapore has volunteered to serve as the 2020 Chair of the IMDRF.

Ⅴ、International Technical Registration for Pharmaceuticals for Human Use (ICH)

In 2017, CFDA became the eighth member of ICH. 2018, China issued the “Announcement on the Application of ICH Secondary Guidelines. It applies:

- M4:The common Technical Document
- E2A:Clinical Safety Data Management: Definitions and Standards for Expedited Reporting
- E2D:Post Approval Safety Data Management: Definitions and Standards for Expedited Reporting
- M1:MedDRA
- E2B(R3): Implementation: Electronic Transmission on Individual Case Safely Reports

●From 1st ,Feb,2018,the classification for chemical drugs registration Type 1, Type 5.1,and the application of biological products for therapeutic use Type 1 and biological products for Prophylaxis use Type 1 are applied to *M4:the Common Technical Document(CTD).*

●From 1st ,May,2018, reporting on drugs within clinical research time appeared severe and unexpected adverse drug reaction is applied to *E2A:Clinical Safety Data Management: Definitions and Standard for Expedited reporting;M1:MedDRA;*

E2B(R3):Implementation: Electronic Transmission on Individual Case Safety Reports.

●From 1st,July,2018, reporting on adverse post-marketing drug reaction is applied to *E2D:Post Approval Safety Data Management: Definitions and Standard for Expedited reporting.*

●From 1st ,July,2019,reporting on adverse post-marketing drug reaction is applied to *M1:Implementation:Electronic Transmission on Individual Case Safety Reports.*

From 1st,July,2019,adverse post approval drug reaction is applied to above guidelines.

Conclusion:

- reform continues
- meet public needs
- protect people's health

Thank you ！