Reflections on the drug regulatory reform in China from an industry perspective

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Agenda slide 1

1. Introduction and setting the scene
2. Impressive changes in the regulatory environment
3. Transition challenge in the drug regulatory reform
4. Changes in the regulatory environment - examples
5. The Marketing Authorisation Holder System principles
6. Capacity and competency building, examples
Setting the scene

Opinions of the State Council on Reforming the Review and Approval System for Drugs and Medical Devices

Impressive changes in the regulatory environment

The CFDA organisation has:
- published more than 100 new guidelines/regulations in 2016
- hired additional staff e.g.:
  CDE* staff increased from 115 in Dec. 2014 to ~600 Dec. 2016
- Reduced the backlog of applications from +20000 in Dec. 2015 to 8200 Dec. 2016
- focus on capacity and competency building in relation to the reform

*Center for Drug Evaluation
New reformed regulatory framework
- Drug Registration Regulation (DRR)
- New guidelines implementing the DRR
- GMP and GCP
- CFDA working procedures and SOPs
- Training of existing employees

New additional employees hired
- Suitable candidates
- High numbers
- On boarding
- Training of new employees

Big workload in transition phase
- Reduction of the backlog
- Reduce the Clinical trial applications timeline
- Inspections (GCP, GMP)
- New Drug Applications
We observe changes in the regulatory environment in China

😊 The China Food and Drug Administration (CFDA) steps up international engagement e.g.:
😊 attending some ICH workshops
😊 observer at the European Pharmacopeia
😊 member of ICMRA and IMDRF
😊 interaction with individual agencies e.g. the Danish Medicines Agency

😢 BUT will it lead to international harmonised requirements and approaches?

ICH: International Conference on Harmonisation
ICMRA: International Coalition of Medicines Regulatory Authorities
IMDRF: International Medical Device Regulatory Forum
We observe changes in the regulatory environment in China continued

😊 Marketing Authorisation Holder (MAH) pilot as of 1 December 2015
😊 BUT for domestic companies only, plan for foreign companies not known

A medicinal product may only be placed on the market in the EU when a Marketing Authorisation has been issued:

- the competent authority of the Member State(s) (MS) or by the European Commission (EC)
- based on proof that requirements related to quality, safety and efficacy are fulfilled throughout development

- Good Manufacturing Practices (GMP)*
- Good Laboratory Practice (GLP)
- Good Clinical Practice (GCP)
- Good Pharmacovigilance Practice (GVP)

*A pre-requisite for the Manufacturing Authorisation
Key principles in the MAH system

GMP, GCP, GLP and GVP:

- quality and validity of data ensured during development and throughout the life cycle

Well defined processes, timelines and requirements

- transparency, predictability, responsibility

Science based requirements – “one size does not fit all”

- reflecting development and life cycle phase
- considering risk, benefit, population, therapeutic area etc.

Risk/benefit balance decision making
Capacity and competency building example 1

Clinical site inspections before New Drug Application (NDA) approval

😊 Improved quality of Clinical Trial data
😊 Increased focus on implementing Good Clinical Practice
😊 Currently a “one size fits all” without a risk based approach
😊 Lack of clear inspection criteria, scientific guidance, training of inspectors

Opportunity: Competencies related to GCP and scientific aspects
Benefit versus risk is in focus:

1. throughout the development process by:
   - especially the sponsor
   - regulatory authorities

2. before the decision by the sponsor to submit the regulatory file

3. during the regulatory approval process by the authorities

Several initiatives are started to develop/establish benefit risk assessment tools

Opportunity:
Copenhagen Center of Regulatory Science (CORS) have experts and activities within this field
Benefit risk balance in short

**Benefit**
- Efficacy
- Quality of Life

**Risk**
- Tolerability
- Potential to harm patients (Safety)
- Vulnerability of target population

- Disease seriousness
- Available treatments
Thank you for your attention

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