Generic drug regulations and regulatory convergence

Chandrashekar Ranga
Deputy Drugs Controller (India)
CDSCO, India
2nd Oct. 2017

Outline

- Mission and Vision
- Regulatory Structure
- Major requirements for generic drugs
- e-Governance
- Regulatory convergence
- Quantitative methods and Modelling

VISION

To protect and promote public health in India

CDSCO

MISSION

To safeguard and enhance the public health by assuring the safety, efficacy and quality of drugs, cosmetics and medical devices.

CDSCO

Regulatory structure

- Drugs regulated under the Drugs and Cosmetics Act, 1940 and Drugs and Cosmetics Rules, 1945
- The Act is a Federal Act, enforced by both Central and State Governments
- Powers are shared between the Center and the States
- Uniform implementation
- Regulatory requirements are common for domestic and export markets

Major requirements for generic drugs

- Chemical and Pharmaceutical information
- Drug substance
- Dosage form related information
- Specifications
- Stability data
- Comparative dissolution studies
- BA/BE studies
- Package insert

e-Governance

- Launched e-Governance in Nov. 2015
- All registrations/licenses for import of drugs, medical devices & cosmetics are online
- Processing and approvals online
- Clinical trials, Vaccine MA, BA/BE etc
- Paperless in next six months
- Various databases at www.cdscoonline.gov.in
- More than 40, 000 applications received

Regulatory convergence

- Harmonization Vs Convergence
- Joined ICH as observer in Feb.2016
- Participation at global fora such as WHO, ICMRA, ICDRA etc.
- Access to affordable generic drugs
    - Max requirements for all markets
    - Single reference product
    - Avoid multiple testing
    - Recognise approvals of SRA

Quantitative Methods & Modelling

- Rely upon the statistical tools for comparative evaluation
- Applicant free to utilize quantitative methods or models
- Need to identify proven methods & models
- Identify best practices from global experiences
- Challenges:
  - Universal models
  - Access to Innovator data and experience

Thank you