Regulatory Measures to Promote Fast Patients Access in India

A.K.Pradhan
Joint Drugs Controller (India)
CDSCO
01.02.2023

Access to Medicines - Importance of CT & ND

- Research in the area of drug discovery is an important tool to promote accessibility of newer, safer and more efficacious drugs for the benefit of humanity.

- Clinical trials is absolutely necessary to establish the safety and efficacy of any new drug.

- Regulatory measures play important role to promote clinical research and development of new drugs while ensuring that rights, safety and well-being of trial subjects are protected and the data generated is scientifically valid

Regulation of CT & ND- Access to medicines

- Before, 19.3.2019, clinical trials were regulated under Part X-A of the Drugs and Cosmetics Rules,1945 and Schedule Y to the Rules.

- Now clinical trials are regulated under the New Drugs and Clinical Trials Rules, 2019, notified on 19.3.2019

- The new rules contains various provisions for promoting ethical and scientific clinical research and development of new drugs for improving access to medicines

Regulatory measures to promote accessibility-

ND & CT Rules, 2019

SCOPE

- These rules apply to NDs, INDs for **human use**, CT,BA,BE and **regulation of ethics committee relating to CT,BA/BE study and biomedical health research**.

- Definition of new drugs has been modified to incorporate novel drug delivery system (NDDS), **living modified organism, monoclonal antibody, stem cell derived product, gene therapeutic products and xenografts.**

New Drug

- **A modified or sustained release form of a drug or novel drug delivery system of any drug approved by the Central Licencing Authority**
- *vaccine,*
- *recombinant Deoxyribonucleic Acid (r-DNA) derived product*,
- **monoclonal anti-body,**
- **stem cell derived product,**
- **gene therapeutic product or**
- **xenografts, intended to be used as drug**

will always be considered as new drug

Orphan Drug

- **A drug intended to treat a condition which affects < <u>five lakh persons in India</u>**
- **Provision for accelerated/expedited approval process**
- **Provision for waiver of local CT**

Post-trial access of IND / new drug

- **On investigators recommendation**
- **Where no alternative therapy is available**
- **No liability to sponsor for post-trial use (patient commits in writing).**
- **After approval by the Ethics Committee for clinical trial**
- **Free of cost by sponsor**

Timelines for application of CT

A. In case of CT, as part of discovery, research and manufacture and marketing in India

- Permission /Rejection/Query in 30 working days

- Deemed approval, if no reply in 30 working days.

B. For other applications for CT

- **Permission /Rejection/Query in 90 working days**
- **Deemed approval, if no reply in 90 working days**

However, in case of deemed approval, the applicant has to intimate CLA about initiation of the trial.

Import of unapproved new drug

- **Medical Officer of Govt hospital may import**
- **Approved for marketing in the country of origin**
- **For patients suffering:**
  - **-From life threatening disease or**
  - **-Disease causing serious permanent disability or**
  - **-For unmet medical needs**

Manufacture of unapproved ND under CT

- **For treatment of patient of Serious/life threatening disease in Govt. Hospitals/ institution**
- **No satisfactory therapy available in the country**
- **Can be approved to be manufactured in limited quantity**

Approval of New Drug

- Disposal of New drug applications within a period of 90 working days.
- Provision for Accelerated approval with condition of requirement of Post Marketing Trial
- Provision for application by Sponsor for Expedited Review
- In case of modified or new claims and NDDS the non clinical and clinical data requirement may be relaxed omitted under certain conditions.
- Permission /Rejection/Query in 90 working days

Animal Toxicology Requirements

- Flexibility given to adopt General Guidance under the Rules or ICH
- Studies **may be planned, designed and conducted as per the ICH**
- **To promote safe, ethical development of new drugs in accordance with**

  - 3R (Reduce / Refine / Replace) principles.

Waiver of local CT-Accelerated Approval

- **For serious/ life-threatening condition or disease, unmet medical needs/No alternatives available for a disease, taking into account its severity, rarity, or prevalence**
- **Surrogate endpoint shall be considered which are reasonably likely to predict clinical benefit**
- **Marketing approval may be based on Phase II clinical trial data, if remarkable efficacy observed in Phase II CT**
- **Phase IV CT mandatory to validate the anticipated clinical benefit.**

New Provisions for predictability of regulatory pathways

- Pre and Post- submission meeting

- The applicant can ask for Pre and Post-submission meeting with payment of fees.

To promote research on Orphan Drugs academic research and MSME :

- No application fee for CT of Orphan Drugs
- Fee for MSME 50% of the specified fee
- For Govt./ Autonomous institution, no fee for application to conduct CT

Thank You