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These rules shall 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 cells, gene therapeutic products, xenografts, etc.
Definitions

- academic clinical trial
- bioavailability study
- bioequivalence study
- biomedical and health research
- Pharmacovigilance
- post-trial access
- similar biologic
- Orphan drugs
Clinical Trial, Bioavailability and Bioequivalence Study of New Drugs & Investigational New Drugs
In case of an application of a new drug discovered in India; or R & D of the drug are being done in India and also the drug is proposed to be manufactured in India,

- Such application shall be disposed of within a period of thirty working days from the date of the receipt of the application by the said Authority:
  - Where no communication has been received, the permission to conduct clinical trial shall be deemed to have been granted.

In case of CT of a new drug which is already approved and marketed in a country, the application, shall be disposed of within ninety working days
• Post-trial Access of New Drug or Investigational New Drug
  ➢ Where any investigator of a clinical trial has recommended post-trial access of the said drug after completion of clinical trial to any trial subject and the same has been approved by the Ethics Committee, the post-trial access shall be provided by the sponsor of such clinical trial to the trial subject free of cost, -
    ➢ if the clinical trial is being conducted for an indication for which no alternative therapy is available and the investigational new drug or new drug has been found to be beneficial to the trial subject by the investigator; and
    ➢ the trial subject or legal heir of such subject, as the case may be, has consented in writing to use post-trial investigational new drug or new drug; and the investigator has certified and the trial subject or his legal heir, as the case may be, has declared in writing that the sponsor shall have no liability for post-trial use of investigational new drug or new drug.
• Academic Clinical Trial

➢ No permission for conducting an academic clinical trial is required where,-

✓ the clinical trial in respect of the permitted drug formulation is intended solely for academic research purposes of new indication or new route of administration or new dose or new dosage form of approved drug; and

✓ the clinical trial has been initiated after prior approval by the EC,

✓ The approved academic clinical trial shall be conducted in accordance with the approved clinical trial protocol, ethical principles specified in National Ethical Guidelines for Biomedical Research on Human Participants, notified by the Indian Council of Medical Research.
Compensation & Medical Management

- In case of an injury, the sponsor, shall provide free medical management as long as required or till such time it is established that the injury is not related to the CT, whichever is earlier.
- If the death or the injury is related to CT, the compensation is payable as per the formula specified in the Schedule to the Rules.
Import or Manufacture of New Drug for Sale or for Distribution
Approval of New Drug

- Disposal of New drug applications by 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.
- The animal toxicity studies may be planned, designed and conducted as per ICH Guidelines.
Waiver of local CT

➢ The local clinical trial may not be required to be submitted along with the application if,-

✓ the new drug is approved and marketed in a countries specified by the Central Licensing Authority and if no major unexpected serious adverse events have been reported; or

✓ the application is for import of a new drug for which the Central Licensing Authority had already granted permission to conduct a global clinical trial which is ongoing in India and in the meantime such new drug has been approved for marketing in a country; and

✓ there is no probability or evidence, on the basis of existing knowledge, of difference in Indian population of the enzymes/gene involved in the metabolism of the new drug or any factor affecting pharmacokinetics and pharmacodynamics, safety and efficacy of the new drug; and

✓ the applicant has given an undertaking in writing to conduct Phase IV clinical trial to establish safety and effectiveness of such new drug as per design approved by the Central Licensing Authority:
Waiver of local CT

Provision to relax the condition of Phase IV CT, where the drug is indicated in life threatening/serious diseases or diseases of special relevance to Indian health scenario or for a condition which is unmet need in India such as XDR tuberculosis, hepatitis C, H1N1, dengue, malaria, HIV, or for the rare diseases for which drugs are not available or available at a high cost or if it is an orphan drug.
Manufacture of Unapproved New Drug for Treatment of Patients in Government Hospital and Government Medical Institution
• **Permission to Manufacture unapproved new drug for patient or government hospital**

➢ Where any medical officer of a Government hospital or Government medical institution prescribes in special circumstances any new drug for a patient suffering from serious or life threatening disease for which there is no satisfactory therapy available in the country and which is not yet approved by the Central Licencing Authority but the same is under clinical trial in the country, then, such new drug may be approved to be manufactured in limited quantity subject to provisions of these rules.

➢ Where any manufacturer intends to manufacture new drug, he shall obtain the consent in writing from the patient to whom the unapproved new drug has been prescribed or his legal heirs and make an application to the Ethics Committee of the Government hospital or medical institution, as the case may be for obtaining its specific recommendation for manufacture of such unapproved new drug.

➢ After obtaining the recommendation of the Ethics Committee, the manufacturer shall make an application to obtain the permission to the Central Licencing Authority for manufacturing specific new drug.
Permission to manufacture unapproved ND- Contd…

- The application shall be accompanied by consent in writing from the patient or his legal heirs regarding use of such unapproved new
- Disposal of such application within a period of ninety days, from the date of application made.
- The quantity of any single new drug manufactured on the basis of permission granted shall not exceed one hundred average dosages per patient.
Separate Schedules in the rules for -

• General principles and practices for clinical trial
• Requirements and guidelines for permission to import or manufacture of new drug for sale or to undertake clinical trial with special provisions for expedite review, accelerated approval process like in case of unmet medical need, etc.
• Conduct of clinical trial
• Formulae to determine the quantum of compensation in case of clinical trial related injury/permanent disability or death.
• Requirements and guidelines for conduct of bioavailability and bioequivalence study of new drugs or investigational new drugs.
• Post marketing assessment of new drugs
Pre and Post-submission meeting

• To improve transparency, accountability and predictability in the regulatory process of approval of new drug and clinical trials, the applicant can ask for Pre and Post-submission meeting with payment of fees.
Thank You