Salient features of the Draft for finalization of the New Drugs and Clinical Trials Rules, 2019 are as under:

- These rules shall apply to the clinical trial, bioavailability or bioequivalence study, new drugs and regulation of ethics committee relating to clinical trial and biomedical health research.
- Objective of New Rules:
    1. To promote Clinical Research in India
    2. To have predictable, transparent and effective regulations for Clinical Trials
    3. To make faster accessibility of New drugs to Indian Population
    4. To prevent duplication of studies. Data generated outside countries will be acceptable.
- These rules provide for:
    - Disposal of clinical trial applications by way of approval or rejection or seeking further information **within a period of 90 days** for drugs developed outside Inida.
    - However, in case of application to conduct clinical trial of a new drug or investigational new drug **as part of discovery, research and manufacture in India, the application is to be disposed of within a period of 30 days. In case of no communication from DCG (I) the application will be deemed to have been approved.**
    - Requirement **of local clinical trial may be waived** for approval of new drug if the **new drug is approved and marketed in any of the countries to be specified by the DCG(I) with approval of Government** from time to time and certain other conditions
    - **Local clinical trial may also be waived** if the application is for import of a new drug **for which the DCG (I) had already granted permission to conduct a global clinical trial which is ongoing in India and in the meantime the new drug has been approved for marketing in a country specified by the DCG (I)** and certain other conditions as above..
    - **pre submission and post submission meetings of the applicant with DCG(I) after payment of fees to improve the transparency, efficiency and predictability of the system**.

- In case of injury to clinical trial subject, **medical management is to be provided as long as required as per the opinion of the Investigator or till such time , it is established that the injury is not related to the Clinical Trial whichever is earlier**
- **Formulae to determine the quantum of compensation presently followed under administrative orders has been incorporated as a Schedule to the rules**.
- Compensation in cases **of death and permanent disability or other injury** to a trial subject will be decided by **the DCG (I)**
- Post-trial access – provisions for providing the investigational drug to the trial subjects after completion of clinical trial under certain conditions, if found beneficial, with the recommendations of the ethics committee and the investigator.
- constitution of expert committee or group by the DCG (I) with the approval of Government.
- debarment of the applicants for submission of fake documents to the DCG(I)

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