No clinical trials in India for new drugs

Union Ministry of Health and Family Welfare has allowed waivers on conducting trials for new drugs in India in case the drug is approved and marketed in countries specified by — the Central Drugs Standard Control Organisation (CDSCO).

Regulation

- New drugs approved for use in select developed markets will be automatically allowed in India provided global trials included Indian patients.
- This waiver would **also extend to drugs** that receive these marketing approvals even **while a trial is underway in India**.
- **Data generated(clinical trial) outside the country will be acceptable**.
- Providing post-trial access of the drugs to the patients that require it have been defined for the first time.
- It removed a clause in the clinical trials that mandated the sponsor (the entity initiating the trial) to pay 60% of compensation upfront in case of death or permanent disability of a patient.
- Now companies will pay the total amount once it is proven that the injury occurred because of the trial.
- Compensations in cases of death and permanent disability, or “other” injuries to a trial participant will be decided by Drug Controller General of India(DCGI).
- It removed regulations on tests conducted on animals in case of drugs approved and marketed for more than two years in well-regulated overseas drug markets.

Significance of New Rules

- It will **end the unnecessary repetition of trials** and speed up the availability of new drugs in the country.
- It will **lower the cost of drugs**.
- It will improve the ease of doing business for drug makers.

Criticism of new regulations

- India is a country of **vast ethnic diversity** and most of the trials are done in the West. There is need of bridging trials for ethnically diverse populations to check drug suitability population.
- Waiver should be only for drugs required **urgently for national emergency**.
- Proving injury due to the trial is problematic and it is prone to manipulation.

Central Drugs Standard Control Organisation (CDSCO)

- The CDSCO is the Central Drug Authority for discharging functions assigned to the Central Government under the **Drugs and Cosmetics Act**.
- Major Functions:
    - Regulatory control over the import of drugs, **approval of new drugs and clinical trials**.
    - Approval of certain licences as Central Licence Approving Authority
- **Drug Controller General of India(DCGI)**
- DCGI is responsible for **approval of licences of specified categories of drugs** such as blood and blood products, IV fluids, vaccines and sera in India.
- It comes under the Ministry of Health & Family Welfare.