




## No clinical trials in India for new drugs

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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

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- 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

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- 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

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- 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.