Drug and Clinical trial rules 2019

April 3, 2019

Manifest Pedagogy

Health has been a topic often in news more specifically the pharmaceutical industry. Issues like drug pricing, clinical trials, new authorities related to Homeopathy etc are highly relevant for this year

In news

Govt notifies new rules for drugs and clinical trials

Pacing it in the syllabus

Indian society: Health(not mentioned explicitly)

Indian Polity : Health

Static dimensions

Meaning of Clinical trials

Current dimensions

- Drugs and Clinical trials Rules 2019 provisions
- Importance of the rules

Content

What are clinical trials?

- Clinical trials are research studies performed in individuals that are aimed at evaluating a medical, surgical, or behavioral intervention.

- They are the essential way that scientists see whether another treatment, similar to another medication or diet or therapeutic gadget (for instance, a pacemaker) is protected and successful in individuals.
- Frequently a clinical preliminary is utilized to learn if another treatment is progressively successful or potentially has less unsafe reactions than the standard treatment.

Drugs and Clinical TrialS Rules 2019

Aim

To promote clinical research in the country

Applicability of the rules

The new rules apply to:

- All new drugs.
- Investigational new drugs for human use,
- Clinical trials.
- Bio-equivalence studies and
- Ethics committees.

Important provisions

- The new rules will change the regulatory landscape for the approval of new drugs and conduct of clinical trials in the country.
- **Reduction in time for approval:**The new rules reduced the time for approving applications to 30 days for manufactured in India and 90 days for those developed outside the country.
- The rules mentioned that in case of no communication from Drugs Controller General of India, the application will be deemed to have been approved.
- **Waiving of trial: It is stated that the requirement of a**

local clinical trial may be waived for approval of a new drug if it is approved and marketed in any of the countries(EU, UK, Australia, Japan and US) to be specified by the Drugs Controller General with the approval of the government.

- **Patient safety**: the new rules will ensure patient safety, as they would be enlisted for trials with informed consent.

- **Monitoring of trials: The ethics committee will monitor the trials and decide on the amount of compensation in cases of adverse events.**
- The compensation in cases of death and permanent disability or other injuries to a trial subject will be decided by the Drug Controller General.
- Conditions for providing post-trial access of drugs to patients who require it have been defined for the first time. In a first, orphan drugs have been defined as a drug intended to treat conditions which affects not more than five lakh persons in India.

Importance of the rules

- **Benefit to the patients:** As stated by Indian council of Clinical Research(ISCR) the new Clinical Trial Rules are well balanced and will further the conduct of ethical and quality clinical trials in the country which, in turn, will benefit patients.
- **Protect the rights and safety of patients**: The new principles secure the rights, wellbeing of patients while guaranteeing a solid scientific base for the lead of clinical trials.

- **Boost for clinical research: experts hope that the rules will help to maintain stability and growth in clinical research being done in India.**
- Fee waivers for orphan drug trials will encourage more trials for rare diseases in India.