Waiving Clinical Trials for Drugs Approved in Select Countries

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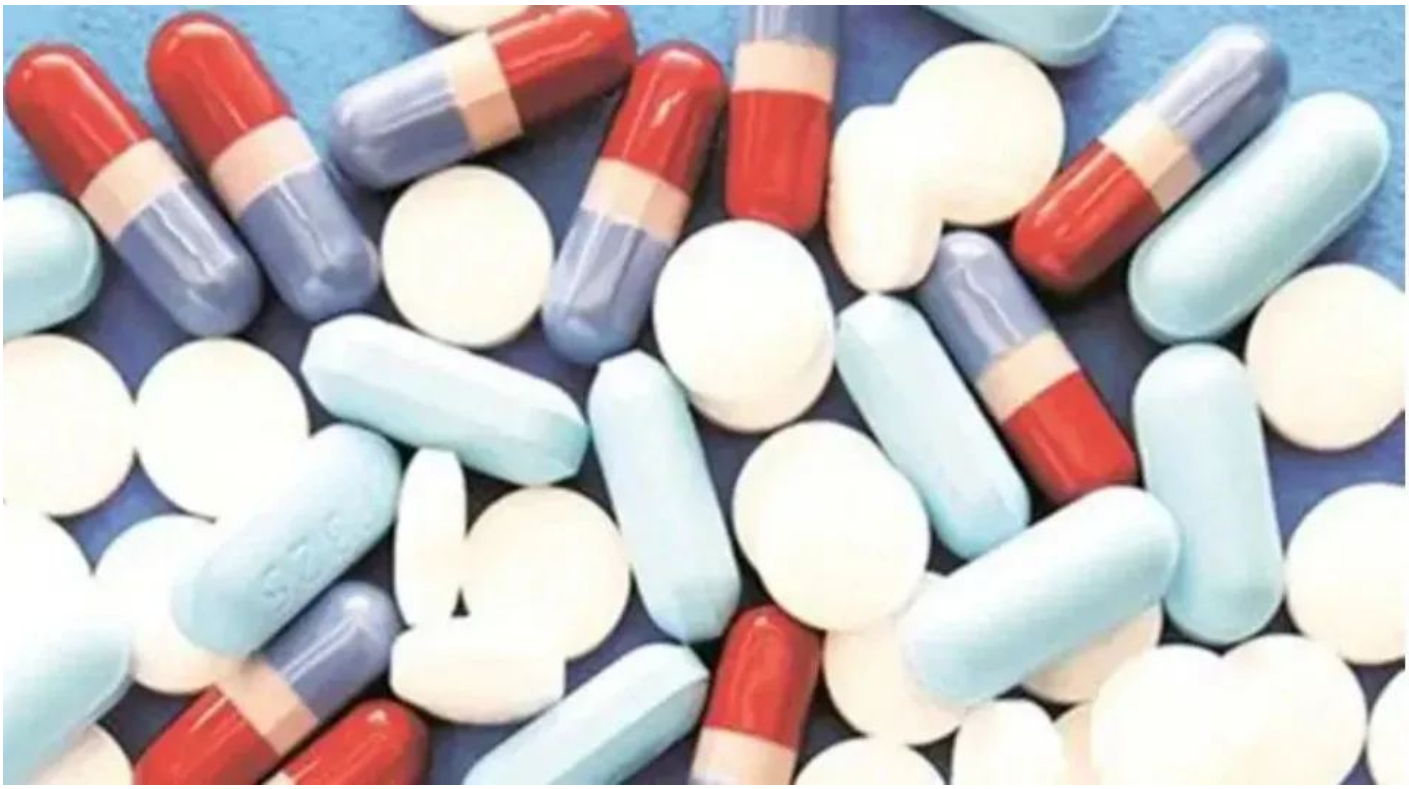

What's in today's article?

Why in News?

- The Central government has decided to waive the need for clinical trials in India if the drugs are approved in the US, UK, Japan, Australia, Canada, and EU.
- This move could make drugs made outside of India more accessible and affordable in the local market.

What are Clinical Trials?

- **In a clinical trial**, investigators enrol participants who meet certain qualifying criteria, then administer the intervention being tested, and finally measure the outcomes.
- **Trials can test drugs**, medical devices, and even procedures, which should help investigators determine the **safety and efficacy of the intervention** to a reasonably high degree of confidence.
- In India, the **Indian Council of Medical Research (ICMR)** maintains an online public-record system called the **Clinical Trials Registry-India (CRTI)**.
    - Hosted by the ICMR's National Institute of Medical Statistics, the CTRI is a free, online public-record system **to register clinical trials** being conducted in India.
    - It was launched in **2007** for use on a voluntary basis and in **2009** the Drug Controller General of India (DCGI) mandated all trials to be registered here.

Present Situation of Clinical Trials in India:

- Several medicines already approved by other regulatory authorities in the US, the UK and the EU are **not immediately available** for Indian patients.
- **This is because of certain regulatory requirements** under the **Drugs and Cosmetics Act** and rules made thereunder.
- **These include the requirement** of conducting a local clinical trial and generating safety and efficacy data before marketing authorisation in India.
- **This leads to a delay in launching a new or novel medicine** in India, which is anywhere between 5-20 years when compared to western markets.

Waiving Clinical Trials in India:

- **Legal provisions:**
    - According to an order issued by India's drug regulatory agency – Central Drugs Standard Control Organisation (CDSCO), the Central government has authorised the exemption of local clinical trials for approval of new drugs, '**as per Rule 101**'.
    - **The Rule 101 of New Drugs and Clinical Trial Rules 2019** empowers the Central Licensing Authority (with approval of the Central govt) –
        - To specify the name of the countries (from time to time) for considering waiver of local clinical trial for approval of new drugs and
        - For grant of permission for conduct of clinical trials.
- **5 categories of drugs that will be considered under the waiver:**
    - Orphan drugs for rare diseases,
    - Gene and cellular therapy products,
    - New drugs used in pandemic situations,
    - New drugs used for special defence purposes, and
    - New drugs having significant therapeutic advances over the current standard care.
- **Need for the waiver:** It has been a long-standing demand of the pharmaceutical companies and health experts for enhanced drug accessibility for patients and for research.
- **Significance of the waiver for Indian patients:**

- This will significantly benefit both domestic and foreign drug manufacturers by **expediting the approval process and facilitating faster access** to essential medications for treating diseases like –
  - Cancers, and
  - **Rare diseases** like Spinal Muscular Atrophy (SMA) and Duchenne Muscular Dystrophy (DMA), and autoimmune conditions.
- There will also be a **considerable reduction in the cost** of various advanced medicines.
- This will **potentially transform** both the pharmaceuticals and the healthcare landscape in India by promoting **indigenous innovation and shift from volume to value.**

Q.1. What are the New Drugs and Clinical Trial Rules 2019?

The New drugs and Clinical rules 2019 set specific requirements for the ethics committee (EC) to forward their report to the Central Licensing Authority (CLA).

Q.2. What is the Indian Council of Medical Research (ICMR)?

The ICMR is the apex body in India for the formulation, coordination and promotion of biomedical research. It is one of the oldest and largest medical research bodies in the world.

Source: Clinical trial: Government announces waiver for several drugs approved from select countries|

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