Emergency Use Approval: Covid-19 Vaccines

Why in News

Recently, three vaccine developers have made applications to the **Central Drug Standard Control Organisation (CDSCO)**, seeking **emergency use approval** for their candidate **Covid-19 vaccines.**

- The vaccine for which the developers are seeking approval are still **under trial.**

Key Points

- **Candidates for Covid-19 vaccines:**
  - **COVISHIELD**: By a Pune-based Serum Institute of India.
    - Phase-III trials going on.
  - **COVAXIN**: By Bharat Biotech, a Hyderabad-based company.
    - Phase-III trials going on.
  - **BNT162b2**: By US pharmaceutical major Pfizer in collaboration with BioNTech.
    - No trials in India so far.
- **Regulatory Provisions for Approval of Vaccines in India:**
  - Clinical trials of new drugs and vaccines, and their approvals, are governed by the **Drugs and Clinical Trials Rules, 2019.**
- **Emergency Provisions:**
  - There is nothing such as **emergency use approval** in Indian rules, however the **2019 rules** provide for **"Accelerated Approval Process"** in several situations that would include the one like the current **pandemic.**
  - In such situations, there is a **provision** for granting approval to a drug that is still in **clinical trials** provided the product is of **meaningful therapeutic benefit.**
  - **Accelerated approval** may also be granted to a new drug if it is intended for the treatment of a **serious, or life-threatening condition, or disease of special relevance to the country, and addresses unmet medical needs.**
  - A new drug, or a vaccine, can be considered for approval if **remarkable effectiveness** is reported even from **phase-II trials.**
  - In such cases, **additional post licensure studies** may be required.
  - The approval granted to drugs or vaccines that are still in **clinical trials** is temporary, and valid only for **one year.**

Clinical Trial

- A clinical trial is **a systematic study to generate data for discovering or verifying the clinical and pharmacological profile** (including pharmacodynamic and pharmacokinetic) or **adverse effects** of a new drug on humans.
- **Phases of Clinical Trials:**

- Clinical trials are carried out in **four phases.**
- **Phase I or clinical pharmacology trials or "first in man" study:** This is the first time where the new drug is administered to a small number, a minimum of **2 healthy, informed volunteers** for each dose under the close supervision of a doctor.
    - The purpose is to determine **whether the new compound is tolerated by the patient's body and behaves in the predicted way.**
- **Phase II or exploratory trials:** During this phase, the medicine is administered to a group of approximately **10-12 informed patients in 3 to 4 centers to determine its effect and also to check for any unacceptable side effects.**
- **Phase III or confirmatory trials:** Purpose is to **obtain sufficient evidence about the efficacy and safety of the drug in a larger number of patients,** generally in comparison with a standard drug and/or a placebo as appropriate. In this phase, the group is between **1000-3000 subjects.**
- **Phase IV trials or post-marketing phase:** Phase of surveillance after the medicine is made available to doctors, who start prescribing it. The effects are monitored on thousands of patients to help identify any unforeseen side effects.
- **Regulatory Mechanism in India:**
    - Clinical trials in India are governed by the **following acts: Drugs and Cosmetics Act, 1940,** Medical Council of India Act, 1956 **and Central** Council for Indian Medicine Act, 1970.
    - Prerequisites of conducting a clinical trial in India are:
        - Permission from the **Drugs Controller General, India (DCGI).**
        - Approval from the respective **Ethics Committee** where the study is planned.
        - Mandatory registration on the **The Indian Council of Medical Research (ICMR)** maintained website.

Central Drugs Standard Control Organisation (CDSCO)

- **CDSCO** is under Directorate General of Health Services, Ministry of Health & Family Welfare, Government of India is the **National Regulatory Authority (NRA) of India.**
- The **Drugs & Cosmetics Act, 1940** and **Rules 1945** have entrusted various responsibilities to central & state regulators for regulation of drugs & cosmetics.
- Under the **Drugs and Cosmetics Act, CDSCO** is responsible for approval of Drugs, **Conduct of Clinical Trials.**
- Further CDSCO along with state regulators, is jointly **responsible for grant of licenses of certain specialized categories of critical Drugs such as blood and blood products, I. V. Fluids, Vaccine etc.**

Source:IE