Covaxin Approved for Human Clinical Trials

Why in News

The **Central Drugs Standard Control Organisation (CDSCO)** has granted **approval to Bharat Biotech** to conduct **human clinical trials for 'Covaxin',** making it the **first indigenous Covid-19 vaccine candidate** to receive this approval.

- Covaxin has been developed by the company Bharat Biotech in collaboration with the **Indian Council of Medical Research (ICMR)**. It is an **inactivated vaccine** manufactured in the company's **Bio-Safety Level 3 (BSL-3)** High Containment facility located in Hyderabad (Telangana).
- The permission was granted after the company submitted results from pre-clinical studies of the vaccine that demonstrated its safety and immune response. **Phase I and II clinical trials** will start across India in July 2020.

Key Points

- Clinical trials in humans are classified into **three phases: phase I, phase II and phase III** and in certain countries formal regulatory approval is required to undertake any of these studies.
- The **phase I** clinical studies carry out initial testing of a vaccine in small numbers (e.g. 20) of healthy adults, to test the properties of a vaccine, its tolerability, and, if appropriate, clinical laboratory and pharmacological parameters. Phase I studies are primarily **concerned with safety.**
- **Phase II** studies involve larger numbers of subjects and are intended to provide preliminary information about a vaccine's ability to produce its desired effect (usually immunogenicity) in the target population and its general safety.

- Extensive **phase III** trials are required to fully assess the protective efficacy and safety of a vaccine. The phase III clinical trial is the pivotal study on which the **decision on whether to grant the licence is based** and sufficient data have to be obtained to demonstrate that a new product is safe and effective for the purpose intended.
- An application for market authorization may be submitted to the National Regulatory Authority (NRA) on the basis of the data from phase III testing and if approved, the vaccine then becomes commercially available in that particular country.

  The **Central Drugs Standard Control Organisation (CDSCO)** under Directorate General of Health Services, Ministry of Health & Family Welfare is the **National Regulatory Authority (NRA) of India.**
- According to the **World Health Organisation (WHO)**, out of 200 Covid-19 vaccine candidates, **15 have entered clinical trials.**
  - **AstraZeneca** is the world's leading Covid-19 vaccine candidate and has reached the final stage in terms of development. It is being developed by researchers at the **University of Oxford (UK).**
  - **US Firm Moderna's vaccine (MRNA-1273)** will go into phase III clinical trials in July.

Source: TH