COVISHIELD and COVAXIN Approved for Restricted Use

Why in News

Recently, the **Drugs Controller General of India's (DCGI)** approved **COVISHIELD** and **COVAXIN** vaccines for **restricted use** against **Covid-19** in the country.

> **COVISHIELD, COVAXIN** and **BNT162b2** applied to the **Central Drug Standard Control Organisation (CDSCO)**, seeking **emergency use approval.**

Key Points

- **Type of Approval:**
  - Both vaccines have received a **restricted use approval** in an **emergency situation.**
  - This means the **vaccines have been approved** for use **despite the companies not having completed clinical trials.**
  - This approval is, however, subject to regular submission of **safety, efficacy and immunogenicity data** from their ongoing trials.
    - The **immunogenicity** of a vaccine is its ability to prompt an immune response.
    - The efficacy, in this case, is a measure of its ability to bring down the number of symptomatic Covid-19 cases.
- **Reason for the Emergency Approval:**
  - Given the pandemic, the government wanted a **vaccine ready to use at the earliest.**
  - Another growing concern is the **mutation of the SARS-CoV-2 virus** in **countries like the UK** which are now starting to spread to other parts of the world, including India.

- **COVISHIELD:** It is the name given to an **Oxford-AstraZeneca** Covid-19 vaccine candidate which is technically referred to as **AZD1222 or ChAdOx 1 nCoV19.**
    - **Produced By:**
        - It is a version of the vaccine **developed by the University of Oxford** in collaboration with **Swedish-British drugmaker AstraZeneca.**
        - **Serum Institute of India (SII)** is the manufacturing partner in India.
    - **Constituents and Action:**
        - It is **based on a weakened version of a common cold virus** or the adenovirus that is found in chimpanzees.
        - This viral vector **contains the genetic material of the SARS-CoV-2 spike protein** (protrusions) present on the outer surface of the virus that help it bind with the human cell.
        - The **body's immune system** is supposed to **recognise this protein** as a threat, and work on **building antibodies against it.**
    - **Significance:**

        It had triggered an immune response in humans against the **novel coronavirus** in early trials and is considered to be one of the global frontrunners for the Covid-19 vaccine.

- **COVAXIN:** It is India's only indigenous **Covid-19** vaccine.
    - **Produced By:**

      Developed by **Bharat Biotech,** Hyderabad in collaboration with the **Indian Council of Medical Research's National Institute of Virology,** Pune
    - **Constituents and Action:**
        - It is an **inactivated vaccine** which is **developed by inactivating (killing) the live microorganisms** that cause the disease.
        - This **destroys the ability of the pathogen to replicate,** but keeps it intact so that the immune system can still recognise it and produce an immune response.
        - It is expected to **target more than just the spike protein.**
        - It also **aims to develop an immune response to the nucleocapsid protein** (the shell of the virus that encloses its genetic material).
    - **Significance:**
        - **COVAXIN** is more likely to work against newer variants of the virus, **including the UK variant,** as it contains **immunogens (epitopes)** from other genes in addition to those from Spike protein.
            - **Immunogen** is a stimulus that produces a humoral or cell-mediated immune response, whereas antigens are any substance that binds specifically to an antibody.
            - All immunogens are antigens, but all antigens may not be immunogens.
        - Approval of **COVAXIN** ensures India has an additional vaccine shield especially against potential **mutant strains** in a dynamic pandemic situation.

Vaccines out, but data missing

The efficacy data of the Phase-3 trials conducted in India for the two vaccines approved for restricted public use on Sunday have not been made public yet

COVISHIELD

- A vaccine developed by the Serum Institute-Pune based on the AstraZeneca-Oxford vaccine has been given 'conditional approval'
- The vaccine's efficacy is reported to be 70.4% based on the Phase-3 trials conducted in the U.K. and Brazil
- The efficacy data of the Phase-3 trials conducted on 1,600 volunteers in 17 Indian cities have not been made public yet

COVAXIN

- A vaccine developed by Bharat Biotech and the Indian Council of Medical Research has been approved for restricted emergency use in clinical trial mode
- During the first two months after the roll-out, the firm has to inform drug regulators every fortnight about the adverse effects of the vaccine
- Phase-1 and 2 trials were conducted on 800 volunteers to determine the safety and immunogenicity of the jab
- **The efficacy data of the ongoing Phase-3 trials with 22,500 volunteers have not been made public yet**

Source:IE