



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.

Source:IE

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