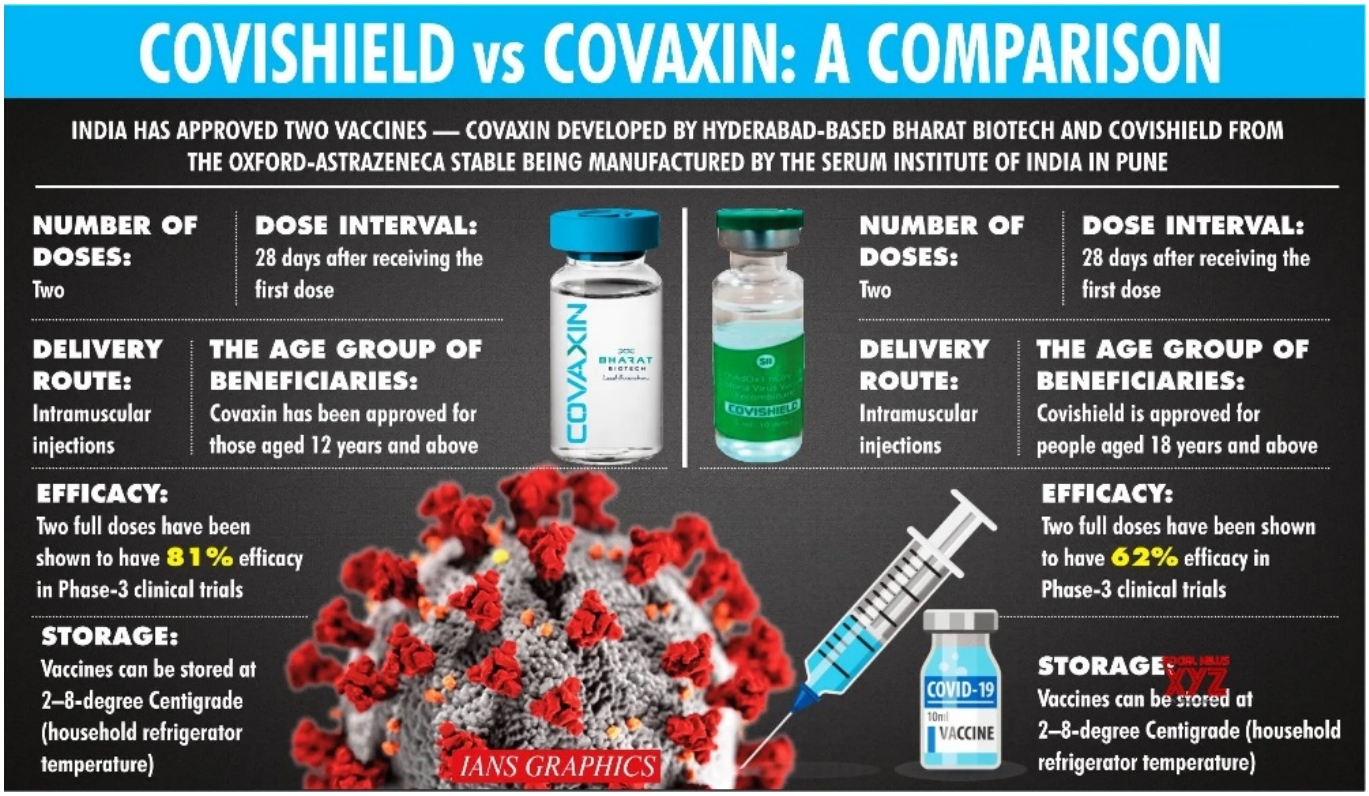
WHO’s Suspension of Supply of Covaxin

What is the issue?

WHO has confirmed the suspension of supply of Covaxin (Bharat Biotech) through UN procurement agencies.

What is Covaxin?

- Covaxin is India's indigenous COVID-19 vaccine developed by Bharat Biotech in collaboration with the Indian Council of Medical Research (ICMR) - National Institute of Virology (NIV).
- The vaccine is developed using **Whole-Virion Inactivated Vero Cell** derived platform technology.
- It is an “inactivated” vaccine that uses the dead virus.
- It is incapable of infecting people but still able to instruct the immune system to mount a defensive reaction against an infection.
- It is a 2-dose vaccination regimen.
- It is a vaccine with no sub-zero storage and is stable at 2-8 ℃.
- The efficacy against COVID-19 disease is shown to be 81%.
- It has proven to neutralize the variants – Alpha, Gamma, Zeta, Kappa, Beta and Delta.



What are the stages of testing vaccines?

- Vaccines are meant to follow a testing process of four stages
- **Pre-Clinical**- In this phase medical professionals use cell or tissue culture systems and animal testing to determine whether the candidate vaccine will produce immunity.
- **Clinical Development-** Now, a sponsor, usually a private company, applies for approval of the vaccine.
- Once the proposal has been approved, the candidate vaccine needs to three trial stages of human testing.
    - **Phase I**- A small group of people is injected with this candidate vaccine to determine how safe it is and to learn more about the responses it provokes among test subjects.
    - **Phase II**- A group of more than hundreds of human test subjects are injected to determine more information about immunogenicity, safety, dose size, and immunization schedule.
    - **Phase III**- In this phase, more than thousands of human test subjects are injected to determine rare side effects which sometimes don't appear in smaller groups.
- **Regulatory review and approval**- Once a vaccine passes all the phases, the vaccine developer submits a license application to the regulatory authority.
- **Quality control**- The firm has to continue monitoring the use of its vaccine on patients and submit post-marketing surveillance details, which checks for any long-term unintended adverse effects.

Why has the WHO taken this step now?

- Covaxin had got emergency use listing (EUL) from the WHO in November 2021 as it met the standards set by the WHO for protection against the coronavirus disease.
- The WHO's EUL is also a prerequisite for a vaccine to be part of supply under COVAX initiative
- The licence thus paved the way for Bharat Biotech to supply Covaxin to UN agencies including through COVAX.

- At the time the EUL for Covaxin was granted, however, the WHO had not done an inspection.
- The inspection was done in March 2022, based on which the WHO has announced the suspension of supply of Covaxin through UN procurement agencies.
- **Findings of WHO-** The data available to WHO indicate that Covaxin is effective and there is no safety concern.
- However, WHO has asked the company to address deficiencies in good manufacturing practice (GMP).
- When the company received emergency use authorisation from India's drug regulator, it repurposed its existing facilities, some of which were used for producing a polio virus vaccine, rabies vaccine and Japanese encephalitis vaccine.
- The WHO has asked the company to upgrade facilities specifically for manufacturing Covaxin.

COVAX is co-led by the Coalition for Epidemic Preparedness Innovations (CEPI), Gavi and the WHO, alongside key delivery partner UNICEF.

Its aim is to accelerate the development and manufacture of COVID-19 vaccines, and to guarantee fair and equitable access for every country in the world.

How does the order impact the supply of Covaxin?

- The company announced a temporary slowing down of production of Covaxin across its manufacturing facilities.
- The suspension does not impact the supply of Covaxin as
    - The company has not received any orders from UN agencies, including the GAVI-COVAX facility
    - The company has already fulfilled its supply commitments in countries where Covaxin has been given emergency use authorisation
    - The company has also stockpiled vaccines required for India's inoculation drive

References

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