



Govt allows all foreign vaccines in India

- By Ankit Agrawal

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India Clears Way For Foreign-Made Vaccines, Wants Applications Soon

Russian-made Covid vaccine Sputnik V has been cleared for emergency use by the Drugs Controller General of India.

[All India](#) | Edited by [Anindita Sanyal](#) | Updated: April 13, 2021 7:17 pm IST

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WHAT HAS HAPPENED?

With an aim to fast-track approvals for foreign manufacturers to market their Covid-19 vaccines in India,

The government on Tuesday announced that vaccines that have been granted emergency approvals by US, UK and Japanese regulators, and those listed by the World Health Organization (WHO), may be granted emergency use approvals in India.

The move comes at a time when vaccine shortages are being reported from various parts of the country.

The Centre said the decision will facilitate quicker access to foreign vaccines in India.

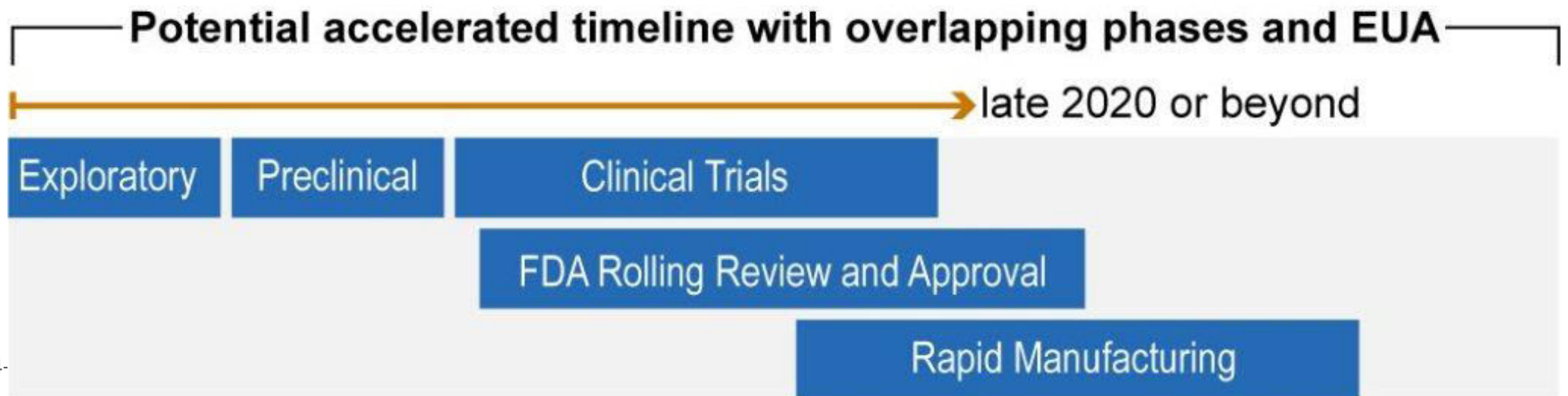
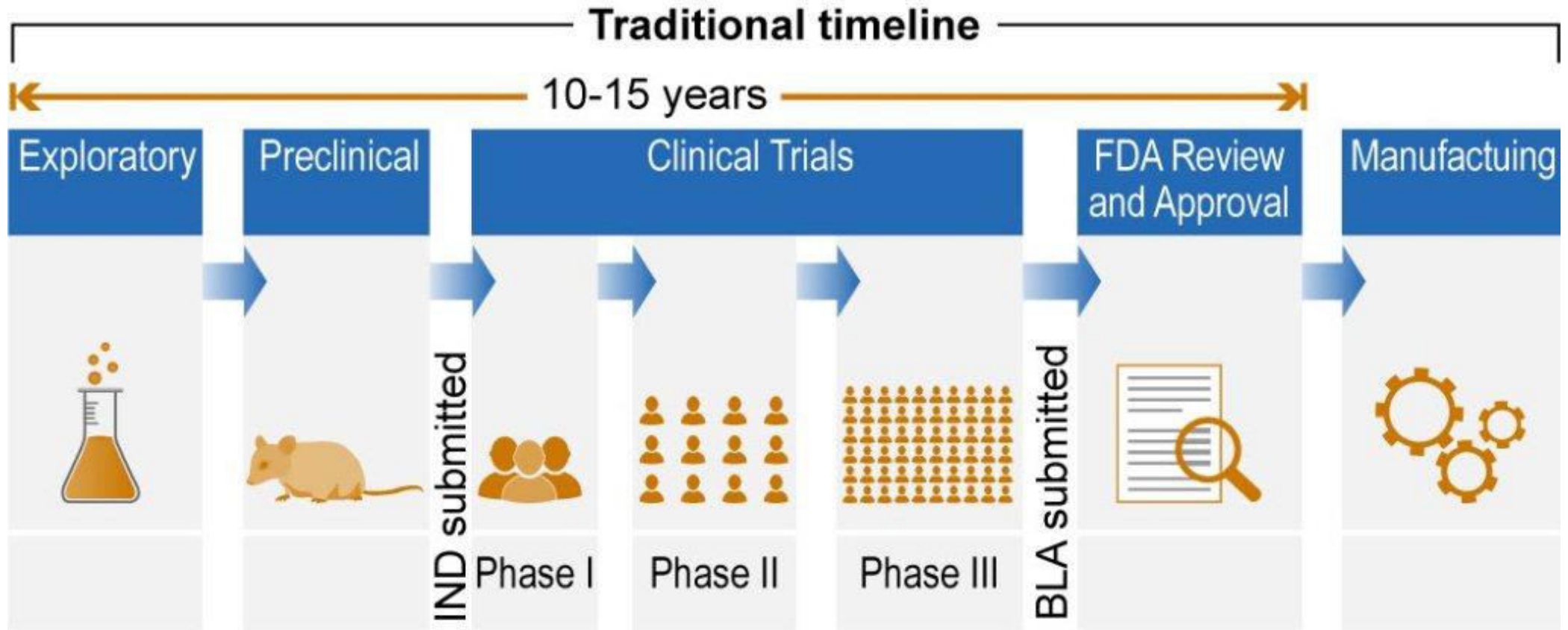
India's current vaccination programme involves two vaccines — Covishield (Serum Institute of India) and Covaxin (Bharat Biotech) — while the expert body of the national regulator has recommended emergency use approval for Russia's Sputnik V.

WHAT ARE THE RULES FOR FOREIGN COVID-19 VACCINES?

The New Drugs & Clinical Trials **Rules, 2019** mandate that whenever a **foreign manufacturer** applies for emergency use authorisation of vaccines,

It has to **submit the result of local clinical trials.**

These trials are called **bridging trials**, in which the **manufacturers conduct phase 2/3 studies** to collect safety and immunogenicity data.



Since the efficacy data is already established at a foreign site, limited participants are enrolled (around 1,000) and a clinical trial is conducted to ascertain if the vaccine is safe in the Indian population.

On the basis of this rule, Serum Institute conducted a bridging trial of Covishield, which is a version of the vaccine developed by the University of Oxford and AstraZeneca, and Dr Reddy's conducted an **bridging trial** of the Sputnik V vaccine from Russia.

The **Rules also empower the regulator to relax the rules** if the vaccine has been approved by the national regulator of another country.

These relaxations are invoked **if there “no major unexpected serious adverse events** have been reported” in the vaccine; and

If the vaccine is indicated **“in life-threatening or serious disease”** or “special relevance to Indian health scenario”; and for an **“unmet need in India”**.

SO, WHAT HAS CHANGED NOW?

This clause has now been invoked; India has technically waived the pre-condition to conduct phase 2-3 trials at Indian sites.

Thus any vaccine manufacturer whose Covid-19 vaccine has received approval for restricted use by the foreign national regulators USFDA, EMA, UK MHRA or PMDA Japan, or

Which are listed in WHO (Emergency Use Listing), can come directly to India and get emergency approval for the vaccine.

HOW WILL THE REGULATOR THEN ASSESS THE SAFETY OF THESE VACCINES?

It has introduced a special condition, under which foreign manufacturers have to **assess the first 100 beneficiaries for seven days for safety** outcomes,

Before it is rolled out for further immunization programmes in India.

After approval, a parallel bridging clinical trial will continue and the manufacturers have to submit the safety data to the regulator.

WHICH COMPANIES ARE LIKELY TO BENEFIT?

US pharma giant **Johnson & Johnson**, the **only manufacturer** with a **single-dose** Covid-19 vaccine **was soon to begin bridging trials.**

With Tuesday's decisions, **it can directly use this route** to introduce its product in India.

The **J&J vaccine has run into a hurdle in the US**, where the regulator has temporarily paused its use following reports or **blood clots.**

This does not affect the company's application to India, as it received approvals from the WHO on March 12.

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Johnson & Johnson Vaccinations Halt Across Country After Rare Clotting Cases Emerge

Federal health officials call for a pause in the use of Johnson & Johnson's coronavirus vaccine while they study serious illnesses that have developed in six American women.

The new move **may also see Pfizer reapply** for emergency use authorisation for its **mRNA Covid-19 vaccine**, which it had **earlier withdrawn** after the regulator sought more data.

India could also see the **US-based Moderna** entering the market.

The move opens up a door for **Serum Institute to seek speedier approval for Covovax**, its version of the Covid vaccine developed by **Novavax**.

Q. Which among the following is NOT a vaccine-preventable disease?

A) Pneumococcal infections

B) Rubella

C) Mumps

D) Hepatitis C



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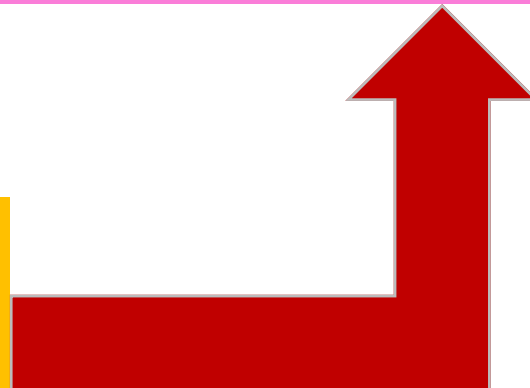
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