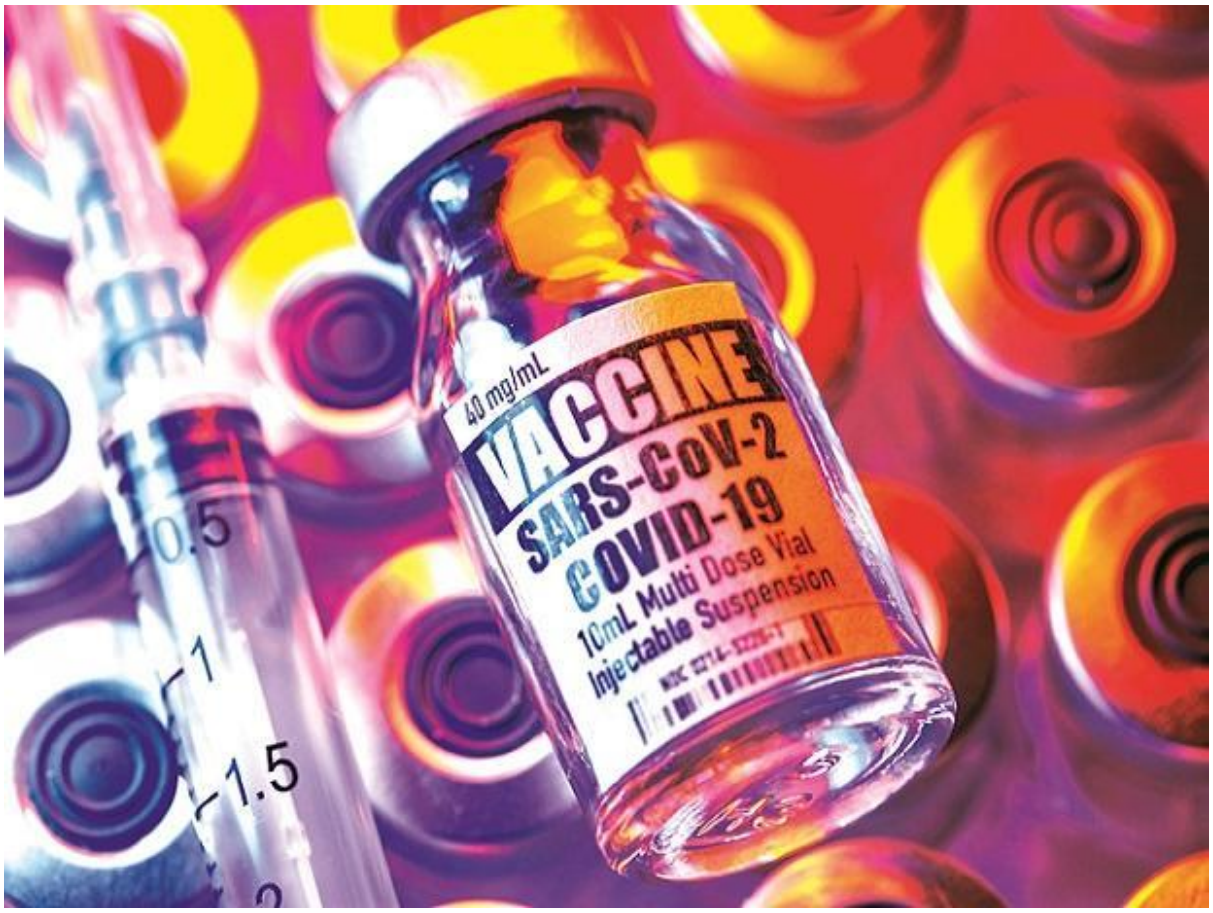
Decision in 3 working days after foreign Covid-19 vaccine firms apply



The Indian health regulator will take a decision within three working days of a foreign vaccine maker seeking emergency use approval, the Centre said on Thursday in a definite move to accelerate the inoculation process.

Also, the Central Drugs Standard Control Organisation (CDSCO) will work in a time-bound manner for every step connected to vaccine approval. For instance, import licence and registration certificates will be processed within three working days of the approval. In addition, bridging clinical trial protocols must be cleared within seven working days for vaccines approved by international regulators.

Sources, however, indicated that price negotiations are likely to happen with the health ministry before a vaccine is allowed entry into the Indian market. “The government is looking for multiple Covid-19 vaccines here. It wants a portfolio of vaccines to improve supplies. However, pricing is an important factor and the Centre would negotiate that with the firms,” said a source in the know. Even after vaccines are granted commercial approval to sell in the private market in future, the pricing regulator is likely to keep a close watch.

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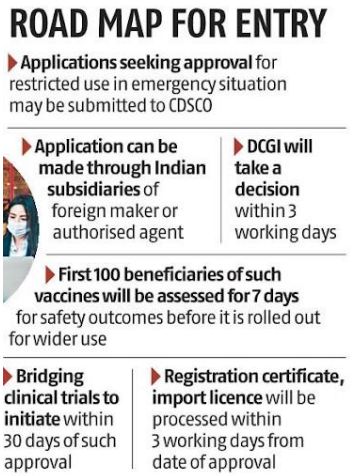
Another source claimed that both Pfizer and Johnson & Johnson have initiated talks with the government. The firms did not respond to queries. It is learnt that US major Moderna is in talks with the salt-to-software conglomerate Tata Group to bring its vaccine here.

J&J’s single shot vaccine, however, has received a setback in the US as the USFDA has paused further usage pending investigation of the blood clotting incidents reported in individuals immediately after vaccination. So, technically, the vaccine does not meet the Indian criteria for approval at the moment.



According to the roadmap issued on Thursday, a foreign vaccine maker can submit an application to CDSCO seeking approval for ‘restricted use in emergency situation’ either through its Indian subsidiaries or authorized agents. The Drugs Controller general of India (DCGI) will consider such applications and take a decision within three working days.

In keeping with the guidelines outlined in the National Covid-19 Vaccination Programme, the first 100 beneficiaries will be assessed for seven days before a vaccine is rolled out for others. The applicant can initiate bridging clinical studies on Indian volunteers within 30-days of approval. The CDSCO needs to approve such applications for clinical trials within seven days.

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The drug regulator, however, has added some caveats.

For example, the Central Drugs Laboratory (CDL) at Kasauli will approve each batch of the vaccine that is to be released for use in the national Covid-19 vaccination programme. The applicant will need to submit safety data on 100 beneficiaries of the vaccine to the CDSCO after it gets the CDL approval.

The DCGI will review the permission granted for restricted use in emergency situations after it receives the results of the bridging study.

Vaccine