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REGULATOR CLEARS BHARAT BIOTECH, SERUM SHOTS FOR EMERGENCY USE

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India on Sunday authorized the emergency use of Serum Institute's Covishield and Bharat Biotech's Covaxin vaccines, clearing the way for millions of health workers and other vulnerable groups to start receiving their first shots in the next few days.

The formal authorization by the Drugs Controller General of India (DCGI) follows recommendations of an expert panel. The vaccines will be first administered in two doses to health workers across the country.

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The authorization is a major milestone in India's battle against the coronavirus pandemic, which has claimed nearly 150,000 lives and brought economic activity to a near standstill, costing crores of rupees in lost output and millions of jobs. With the approval, India became the first country in South Asia to authorize a shot for mass vaccination.

"CDSCO (Central Drugs Standard Control Organization) has decided to accept the recommendations of the expert committee and, accordingly, vaccines of Serum and Bharat Biotech are being approved for restricted use in an emergency situation," said DCGI Dr V.G. Somani, who also heads CDSCO, the regulator for medical products in India.

The government is now likely to roll out the covid-19 mass immunization programme as early as this week. Adding to the government's concerns are reports of a fast-spreading strain of the virus, which was first detected in the UK in December and has now spread to other countries.

The National Expert Group on Vaccine Administration for covid-19 had recommended that the vaccine be first given to frontline healthcare workers comprising emergency medical staff, and integrated child development services workers, nurses and supervisors, medical officers, paramedical staff, support staff and students.

Welcoming the authorizations, Adar Poonawalla, chief executive of Pune-based Serum Institute of India, said "all the risks (the company) took with stockpiling the vaccine have finally paid off. Covishield, India's first covid-19 vaccine, is approved, safe, effective and ready to roll out in the coming weeks."

Senior government officials said the procurement deals with manufacturers will be signed this week and that the immunization programme is likely to start in the next 7-10 days.

Considering that the two vaccines have been given emergency authorization for restricted use, and not full approval, people intending to take the vaccines will have to sign an informed consent form while receiving the doses.

A senior CDSCO official on condition of anonymity said that the authorization to Bharat Biotech's vaccine has been given based on its strong safety and immunogenicity data due to the emergency situation created by the new UK mutant strain, while efficacy is still being established

as the company's phase 3 trial continues.

"Anybody who is taking the vaccine, even outside clinical trials, will have to sign an informed consent form. Otherwise, they will not be given the vaccine. We are in the process of finalizing the protocol for the informed consent," the official said.

The Bharat Biotech protocol will have certain criteria for eligibility, which will have to be met by the beneficiaries, the official said.

Some experts expressed shock at the authorization given to Bharat Biotech despite the lack of efficacy data. Government officials, however, said that the vaccine would only be used as a backup in the wake of the situation following the discovery of the new mutant strain.

"While this vaccine addresses an unmet medical need during this pandemic, our goal is to provide global access to populations that need it the most. Covaxin has generated excellent safety data with robust immune responses to multiple viral proteins that persist," Bharat Biotech chairman and managing director Krishna Ella said in a statement.

On Sunday, the CDSCO also gave permission to Zydus Cadila to conduct its phase 3 clinical trial for establishing efficacy. In a statement, the company said it will now be initiating phase 3 clinical trial in around 30,000 volunteers. The vaccine, branded ZyCoV-D, was found to be safe, well-tolerated and immunogenic in phase 1 and 2 clinical trials, the company said.

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