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GOVT RUBBISHES REPORTS ON APPROVAL FOR COVAXIN DUE TO POLITICAL PRESSURE

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COVID-19 vaccine Covaxin maker Bharat Biotech said there was no external pressure on the firm to speed up its development. Photo: Special Arrangement

The Union Health Ministry on November 17 termed as “misleading” and “fallacious” media reports which claimed that regulatory approval for COVID-19 vaccine Covaxin was rushed due to political pressure.

It said scientific approach and prescribed norms were adhered to in approving COVID-19 vaccines for emergency use authorisation.

There have been media reports claiming that Bharat Biotech, manufacturer of the indigenous COVID-19 vaccine Covaxin, “had to skip certain processes” and “speed” up clinical trials due to political pressure, the Ministry said.

The reports further claimed that there were several irregularities in the three phases of the clinical trials conducted for the vaccine.

“These media reports are completely misleading, fallacious and ill-informed. It is clarified that Government of India and the national regulator i.e. CDSCO have followed a scientific approach and prescribed norms in approving COVID-19 vaccines for emergency use authorisation,” the Ministry stated.

The Subject Expert Committee (SEC) of the Central Drugs Standard Control Organisation (CDSCO) met on January 1 and 2, 2021 and after due deliberations made recommendations in respect of proposal for Restricted Emergency Approval of COVID-19 virus vaccine of Bharat Biotech.

Before Covaxin was approved for restricted emergency use in January 2021, the Subject Expert Committee reviewed the data on safety and immunogenicity of the vaccine and recommended for grant of permission for restricted use in emergency situation in public interest as an abundant precaution, in clinical trial mode, to have more options for vaccinations, especially in case of infection by mutant strains.

The SEC’s approval for commencement of phase 3 clinical trial of proposed dose of Covaxin

was based on scientific data presented by Bharat Biotech and established practices in this regard, the Ministry said.

Moreover, the purported ‘unscientific changes’ in clinical trials of Covaxin, as claimed in the news reports, were made after submission made by Bharat Biotech in CDSCO, compliance of due process in CDSCO and with approval from the DGCI.

Based on further submission made by Bharat Biotech and assessment of interim efficacy and safety data by SEC of CDSCO, the condition of administration of COVID-19 vaccine in ‘clinical trial mode’ was removed on March 11, 2021, the Ministry said.

Authorisation to COVID-19 vaccines including Covaxin for restricted use in emergency situation with various conditions and restrictions were granted by the national regulator only on the recommendations of the Subject Expert Committee of CDSCO.

The Subject Expert Committee consists of domain knowledge experts from the fields of pulmonology, immunology, microbiology, pharmacology, paediatrics, internal medicine, etc.

Meanwhile, COVID-19 vaccine Covaxin maker Bharat Biotech said there was no external pressure on the firm to speed up its development.

In a press release, the vaccine maker said with several hundred million doses administered worldwide, COVID-19 vaccine Covaxin has demonstrated an excellent safety record with minimal adverse events and no vaccine associated cases detected for myocarditis or thrombocytopenia.

Refuting some media reports around the approvals for Covaxin, the vaccine maker said it condemns the “targeted narrative” against the vaccine put forth by a select few individuals and groups who have no expertise in vaccines or vaccinology, the firm said.

“There was no external pressure to accelerate development of Covaxin,” it said, adding the pressure was all internal to develop a safe and effective vaccine for the COVID-19 pandemic, to save lives and livelihoods in India and globally.

Covaxin is one of the most highly studied COVID-19 vaccines worldwide and was evaluated in approximately 20 pre-clinical studies, including three challenge trials and nine human clinical studies, more than any other Indian COVID-19 vaccine even as these trials have clearly demonstrated safety and efficacy of the vaccine, the company said.

The entire product development and clinical studies were executed as per global guidelines and submitted worldwide and the data from Covaxin has resulted in more than 20 publications, documenting every aspect of its development, Bharat Biotech further said.

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