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Experts question DCGI approval for COVID-19 vaccines usage

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Members of the All India Drug Action Network (AIDAN) have expressed disbelief over the approval of Bharat Biotech's vaccine COVAXIN

After the latest decision of DCGI to approve the vaccine jointly produced by UK-Swedish biopharmaceutical company AstraZeneca and Oxford University as well as by Bharat Biotech for emergency use in India to immunise people against the COVID-19 virus; many experts are questioning the foundation of these approvals.

There has been ambiguity over AstraZeneca vaccine, ever since the data was published in the Lancet journal in the month of November last year proving that two full shots were 62.1% effective. AstraZeneca later announced plans to collaborate with Sputnik V whose efficacy showed to be 91.4% based on analysis of the data of the final control point of clinical trials.

Should not there be more consideration and time given here?

"According to The Lancet- 'In participants who received two standard doses, vaccine efficacy was 62.1% and in participants

who received a low dose followed by a standard dose, efficacy was 90.0%. Overall vaccine efficacy across both groups was 70.4%.' As India will possibly go by 2 full doses regimen, efficacy should have been quoted at 62.1%. The mention of the "overall" efficacy at 70% in this case is misleading. Moreover, AstraZeneca uses one and the same component for both inoculations, the Russian vaccine uses two different ones in two separate inoculations. Using the latter approach could prove more efficient in achieving a longer-lasting immune response", said Dr. Debkishore Gupta, Consultant Clinical Microbiologist and Head of Infection Control, CK Birla Hospitals, Kolkata.

"India has approved a full two-dose regimen with no dosing schedule specified. However, when the UK approved the same vaccine last week it was recommended that people get one dose followed by a second four to 12 weeks later in a bid to speed up the vaccination programme with officials claiming efficacy could be as high as 80 percent with three months between doses", he added.

On the other hand, members of the All India Drug Action Network (AIDAN) have expressed disbelief over the approval of Bharat Biotech's vaccine COVAXIN.

"It appears that no efficacy data for the vaccine candidate were submitted from the Phase 3 trials that are ongoing and being conducted by Bharat Biotech and ICMR.The only data for humans, available through publication pre-prints, are for safety and immunoogenicity from Phase 1 and Phase 2 trials, across a total of 755 participants. In the interest of transparency it will be in the fitness of things that the trial data on the basis of which decisions have been taken by the SEC are immediately made public", as stated by AIDAN.

In particular, the member of AIDAN have urged the DCGI to reconsider the recommendations of the SEC in granting the restricted emergency use (REU) approval to COVAXIN.

Adding to this debate is an observation by Dr Gagandeep Kang, Professor of Microbiology, at the Wellcome Trust Research Laboratory, Division of Gastrointestinal Sciences at the Christian Medical College (CMC) in Vellore, that there is not much awareness of any data on efficacy of the Bharat Biotech vaccine. She has openly expressed her confusion on this recent development by the government.

In response to these uncertainities, Dr Krishna Ella, Chairman & Managing Director, Bharat Biotech stated in a press conference that people should have the patience to read on the internet the published articles by the company. "Many people say that I am not transparent in my data. Our articles have been published in various international journals. Many people are gossiping, it's just a backlash against Indian companies", he added.

These recent approvals have also brought the focus on other vaccine candidates such as Sputnik V and Pfizer that might have been currently neglected by the regulatory body.

"The approval of the Bharat Biotech and AstraZeneca vaccines on the primary basis will kickstart the vaccination campaign. However, in the longer run keeping in mind the demand of the largely populated country like India and India's promises to other countries, approval of other vaccines such as Pfizer and Sputnik V which are in the queue, would also be very critical. Other players are equally important and in order to cater to the domestic and global demand, mass vaccination is the key," says Dr. Gajendra Singh, Public Health Expert.

"It is interesting to note that what may have pushed AstraZeneca virologists to start work on combining their vaccine's vector with that from Russia's Sputnik V to see if that could help boost its vaccine's efficacy. Unlike AstraZeneca, which uses one and the same component for both shots, the Russian vaccine uses two different ones for two separate inoculations and has much higher efficacy shown in Phase III clinical trials – 91.4 percent", he added.

With these questions and recommendations by the experts, we hope that the government takes an informed decision for the benefit of the entire population.