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Claims and counterclaims over alleged adverse reaction in covid-19 vaccine in India

The Indian manufacturer of the Oxford-AstraZeneca candidate vaccine against covid-19 (the Serum Institute of India) has threatened to claim Rs1bn (£10m; €11.2m; \$13m) in damages from a clinical trial volunteer who alleges he developed a neurological illness after receiving the vaccine and has claimed Rs50m compensation.

The Serum Institute of India, which is also conducting a clinical trial to assess the vaccine's safety and immunogenicity in India, has said that the volunteer's claim is "malicious and misconceived" because he was specifically informed by the medical team that the complications he suffered were independent of the trial. Indian health officials said on 1 December—over six weeks after the volunteer reported the illness—that probes by the institutional ethics committee, the data safety monitoring board, and India's drug regulatory authority had found no correlation between the serious adverse event and the vaccine.

Balram Bhargava, India's department of health research secretary and director general of the Indian Council of Medical Research, said: "The initial causality assessment findings did not necessitate the stoppage of the trial."

The Serum Institute plans to seek emergency use authorisation for the vaccine from the Central Drugs Standard Control Organisation (CDSCO), India's regulatory authority, submitting safety and immunogenicity data from the Indian trial and efficacy data from the Oxford trial in the UK and Brazil.

The volunteer, who developed a neurological illness on 11 October, 10 days after he had received the first dose of the vaccine in the southern Indian city of Chennai, was among 1600 healthy adults recruited at 17 hospitals across India for the trial—an observer-blind randomised controlled study. Health officials said that the volunteer was discharged after treatment in the trial hospital and that investigations by the institutional ethics committee, the data safety monitoring board, and CDSCO did not find any correlation with the vaccine trial.

But the volunteer has sent a legal notice to the Serum Institute, the Indian Council of Medical Research, CDSCO, and the Oxford Vaccine Trial claiming a connection between his illness and the vaccine and seeking compensation. The Serum Institute has said that it is "sympathetic with the volunteer's medical condition" but has accused him of trying to lay false blame for his medical problem on the trial. A Serum Institute spokesperson said: "It is evident the intention behind the spread of such malicious information is an oblique pecuniary motive. The

Serum Institute will seek damages in excess of Rs1bn."

Doctors who are familiar with protocols for clinical trials but were not associated with the Serum Institute trial say that the dispute—which has triggered angry reactions from health rights advocates—has exposed the opacity of India's regulatory system that oversees clinical trials. Satyajit Rath, a medical immunologist and visiting professor at the Indian Institute of Science Education and Research, Pune, told *The BMJ*: "It is possible the data safety monitoring board and regulatory authorities did not see any reason for even an interim trial halt. But not saying this clearly and authoritatively with laid out reasoning contributes to major erosion of trust."

The All India Drug Action Network, a non-government organisation of physicians and healthcare activists has described Serum Institute's statement as a "blatant attempt at intimidation of a clinical trial participant."

The volunteer's lawyer Ramasamy Rajaram told *The BMJ* on 3 December that the volunteer had not received any communication so far about the regulatory probe into the serious adverse event. Rajaram said: "We have consulted independent neurologists—he is determined to go ahead. We see a long legal battle ahead."