

**GOVERNMENT OF INDIA
MINISTRY OF HEALTH AND FAMILY WELFARE
DEPARTMENT OF HEALTH AND FAMILY WELFARE**

**LOK SABHA
UNSTARRED QUESTION NO. 3426
TO BE ANSWERED ON 17th DECEMBER, 2021**

COVAXIN CLINICAL TRIAL

3426: SHRI THOMAS CHAZHIKADAN:

Will the Minister of **HEALTH AND FAMILY WELFARE** be pleased to state:

- (a) whether the Government is aware that several participants in the Covaxin clinical trial in Bhopal reported that the possible side-effects of the trial were not explained to them;
- (b) if so, the details thereof and the reasons therefor;
- (c) whether the Government has ordered any inquiry to see if such trial was in compliance with New Drugs and Clinical Trials Rules, 2019; and
- (d) if so, the details thereof?

**ANSWER
THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND
FAMILY WELFARE
(DR. BHARATI PRAVIN PAWAR)**

(a) to (d): As per the provision under New Drugs and Clinical Trials Rules, 2019, in all trials, a freely given, informed, written consent is required to be obtained from subjects of each study before their inclusion in clinical trial. CDSCO has informed that as per available information, none of the participants in the Covaxin clinical trial have been enrolled without taking an informed consent.

The Central Drugs Standard Control Organization (CDSCO) had received complaint regarding violations in the conduct of clinical trial of COVAXIN leading to death of trial participant in one of the clinical trial site at People's Hospital, Bhopal.

CDSCO has evaluated the case in consultation with expert committee & the committee after detailed deliberation opined that Serious Adverse Events (SAE) death is not related to the study vaccine and is not trial related.
