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

RAJYA SABHA
UNSTARRED QUESTION NO.914
TO BE ANSWERED ON 9TH FEBRUARY, 2021

TRANSPARENCY IN COVID-19 VACCINE TRIALS

914 SHRI NEERAJ DANGI:
SMT. PHULO DEVI NETAM:
SMT. AMBIKA SONI:

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

(a) whether Government is aware of reports that citizens are being used to test COVID-19 vaccine candidates without their consent;

(b) whether Government is aware of reports that companies have misrepresented the trial of vaccine candidates and failed to disclose potential side-effects of vaccine candidates;

(c) whether Government intends to investigate the companies involved for misconduct during COVID-19 vaccine trails; and

(d) if so, the details thereof and, if not, the reasons therefor?

ANSWER

THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE
(SHRI ASHWINI KUMAR CHOUBEY)

(a): As per the provisions 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.

As per the Rules, clinical trial shall be conducted in compliance with the approved protocols, requirements of New Drugs and Clinical Trials Rules, 2019; Good Clinical Practice Guidelines for conduct of clinical trials in India and other applicable regulations, to ensure conduct of scientific and ethical clinical trials with protection of rights, safety and well-being of the trial subjects.

Any non-compliance is subject to regulatory action as per the provisions of the Drugs and Cosmetics Act 1940 & Rules made there under.

There are no reports that citizens are being used to test COVID-19 vaccine candidates without their consent.

(b) to (d): Mechanisms for timely review and reporting of adverse events occurring during clinical trials has been laid down in the New Drugs and Clinical Trial Rules, 2019. Each serious adverse event (SAE) occurring during the vaccine trial is reported to the Institutional Ethics Committee, Head of the Institution and the CDSCO within 24 hours of occurrence.

CDSCO has not received any reports in this regard.