

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

**LOK SABHA
STARRED QUESTION NO. 71
TO BE ANSWERED ON THE 5TH FEBRUARY, 2021
ADVERSE EFFECTS OF COVID-19 VACCINES**

***71. SHRI VINCENT H. PALA:
SHRIMATI SAJDA AHMED:**

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

(a) whether adverse effects on health have been reported in relation to any COVID-19 vaccines currently being administered/developed in the country, if so, the details of such events reported and the corrective measures being taken;

(b) whether the Government had taken inputs from technical experts and State Governments while drawing up its COVID-19 Vaccine strategy, if so, the details thereof;

(c) whether COVID-19 vaccine was allegedly tested on citizens/candidates without their consent, if so, the details thereof including the details of companies which have misguided the candidates about the trial of vaccine on them and the potential side-effects of vaccine;

(d) whether the Government intends to investigate such incidents, if so, the details thereof along with the compensation proposed to be paid to the victims; and

(e) whether the Government has finalized the next phase of vaccination, if so, the details thereof?

**ANSWER
THE MINISTER OF HEALTH AND FAMILY WELFARE
(DR. HARSH VARDHAN)**

(a) to (e) A Statement is laid on the Table of the House.

**STATEMENT REFERRED TO IN REPLY TO LOK SABHA
STARRED QUESTION NO.71* FOR 5TH FEBRUARY, 2021**

(a) to (e) Adverse Event Following Immunization (AEFI) are monitored through a well-structured & robust AEFI surveillance system. AEFI is any untoward medical occurrence which follows immunization and may not necessarily have a causal relationship with the vaccine. Causality assessment by the designated AEFI committee helps in determining if AEFI is related to vaccine or vaccination process or otherwise.

For COVID19 vaccinations, same process is being followed. A total of 7,580 AEFIs i.e. 0.2% AEFIs cases have been reported out of total number vaccinated till 31st January 2021 under COVID-19 vaccination roll-out across the country. Most of these are minor AEFIs like Anxiety, vertigo, giddiness, dizziness, fever, pain, rashes, and headache which are self-limiting and all people have recovered. 14 hospitalizations i.e. 0.000372% hospitalization cases have been reported out of total number vaccinated till 31st January 2021. 12 deaths i.e. 0.000319% death cases out of total number vaccinated till 31st January 2021 not causally related to vaccination presently, have also been reported. These deaths were investigated and examined by the experts and as per current evidence none of these deaths have causal relationship with the COVID-19 vaccination. In addition, measures have been put in place like availability of anaphylaxis kits at each vaccination site, immediate referral to AEFI management center and observation of vaccine recipients for 30 minutes at session site for any adverse events so as to take timely corrective measure.

A National Expert Group on Vaccine Administration for COVID-19 (NEGVAC) has been established, which provides guidance on all aspects of COVID-19 vaccination including prioritization of population groups, procurement and inventory management, vaccine selection, vaccine delivery and tracking mechanism etc. NEGVAC is chaired by Member (Health), NITI Aayog and co-chaired by Secretary (H&FW). NEGVAC has representation of Secretaries from Ministry of External Affairs, Department of Expenditure, Dept. of Biotechnology, Dept. of Health Research, Dept. of Pharmaceuticals, Ministry of Electronics and Information Technology, representative from five State Governments i.e. Tamil Nadu (South), Assam (East), Maharashtra (West), Uttar Pradesh (North) and Madhya Pradesh (Central) and technical experts.

It is not a fact that the COVID-19 vaccine was allegedly tested on citizens/candidates without their consent. During clinical trials, all vaccines were tested only after obtaining consent of the clinical trial participants under a prescribed procedure. The New Drugs & Clinical Trials Rules 2019, clearly prescribe the modalities of payment of compensation in specific instances.

AEFI system of the country has been put in place so as to capture all the AEFIs to analyze for any causal relationship with COVID-19 vaccination. Clinical trials of vaccines are required to be conducted in human subjects in compliance with the provisions prescribed in New Drugs and Clinical Trial Rules, 2019 and Good Clinical Practices (GCP) guidelines.

NEGVAC has also recommended the prioritization of population groups for COVID-19 vaccination. The prioritized groups comprise Health Care Workers, Front Line Workers, persons above the age of 50 years and persons below 50 years with associated comorbidities.
