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

RAJYA SABHA
UNSTARRED QUESTION NO.908
TO BE ANSWERED ON 9TH FEBRUARY, 2021

ADVERSE EFFECTS FOLLOWING IMMUNISATION

908 SHRI PARTAP SINGH BAJWA:

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

(a) whether the Ministry has observed any Adverse Effects Following Immunisation (AEFI) arising from the use of COVAXIN and, if so, the details thereof;

(b) whether the Ministry has observed any AEFI arising from the use of COVISHIELD and if so, the details thereof;

(c) whether any COVID-19 vaccine currently under clinical trials in the country have led to any AEFI, if so, the details thereof; and

(d) the details of the common side effects of all vaccines currently being used or undergoing clinical trials in India?

ANSWER

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

(a) & (b): As on 4th February 2021, a total of 81 Adverse Event Following Immunisation (AEFIs) i.e. 0.096% AEFIs cases have been reported out of total beneficiaries vaccinated with Covaxin vaccine. For Covishield vaccine, a total of 8,402 AEFIs, i.e. 0.192% AEFI cases have been reported out of total beneficiaries vaccinated.

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.

(c): As per New Drugs and Clinical Trials Rules, 2019 under Drugs and Cosmetics Act,1940 and in light of urgent need due to COVID pandemic in the country, Central Drugs Standard Control Organization (CDSCO) headed by the Drug Controller General of India (DCGI) has granted permission to manufacture two COVID-19 vaccines based on the prescribed procedure and due evaluation of pre-clinical and clinical trial data. The details of the AEFI reported after introduction of these two vaccines is given at reply at (a) & (b) above.

(d): The common side effects of vaccines under country's immunization programme include pain, swelling, redness at injection site, local abscess, fever, malaise etc.

The adverse events which have been reported from COVID-19 vaccines which are approved for restricted use in emergency situation includes headache, rash, chills, myalgia, fatigue, fever, dizziness, inflammation and pain, swelling or redness at the site of injection, vaccination site, erythema, pruritus etc.