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

RAJYA SABHA
UNSTARRED QUESTION NO.98
TO BE ANSWERED ON 2ND FEBRUARY, 2021

SIDE-EFFECTS OF COVID-19 VACCINES

98 SHRI DEREK O' BRIEN:

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

(a) the side-effects of COVID-19 vaccines; and

(b) the authority liable for any adversity faced by a patient administered with COVID-19 vaccines?

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

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

(b): Central Drugs Standard Control Organisation under the Ministry of Health & Family Welfare has granted permission to manufacture of COVID-19 vaccines in the country as under:

1. M/s Serum Institute of India Pvt., Ltd., for manufacture of the COVID-19 Vaccine for restricted use in emergency situation with various conditions/restrictions.

2. M/s Bharat Biotech International Limited, for manufacture of the COVID-19 Vaccine for restricted use in emergency situation in public interest as an abundant precaution in clinical trial mode with various conditions/restrictions.

The firms are required to submit safety data on Adverse Events Following Immunization (AEFI) and Adverse events of special interest (AESI) with due analysis every 15 days for first two months and monthly thereafter.

As per Rule 82 of New Drugs and Clinical Trials Rules, 2019, the manufacturers are responsible for reporting of serious unexpected adverse reactions related to the drugs including COVID-19 vaccine to the Central Licensing Authority i.e. Drugs Controller General (India).

CDSCO, in consultation with Subject Expert Committee, has approved the protocol for rolling out the Whole Virion Inactivated CoronaVirus Vaccine (BBV152) in clinical trial mode alongwith factsheet, informed consent form and adverse event form. As per the approval "In case of any serious adverse events, Vaccine recipients will be provided medically recognized standard of care in the government designated and authorized centres/hospitals. The compensation for serious adverse event will be paid by sponsor (BBIL) if the SAE is proven to be causally related to the vaccine. If any Vaccine recipient develops symptoms of COVID-19, Vaccine recipient will be provided medically recognized standard of care in the government designated and authorized centers/hospitals"