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

RAJYA SABHA
UNSTARRED QUESTION NO. 1684
TO BE ANSWERED ON 9TH March, 2021

CONSENT FORM FOR VACCINE RECIPIENTS

1684 **SHRI DIGVIJAYA SINGH:**
SMT. PHULO DEVI NETAM:
SMT. PRIYANKA CHATURVEDI:

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

(a) the reasons due to which vaccine recipients are required to sign a consent form when being administered the Covaxin and not for the Covishield Vaccine;

(b) whether this difference is due to the fact that Covaxin has not released its Phase 3 trials efficacy data;

(c) the specific additional protections that accrue to the manufacturer of Covaxin as a consequence of the consent form; and

(d) the implications of these additional protections for Covaxin's safety and efficacy?

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

(a): Covaxin manufactured by M/s Bharat Biotech International Limited has been granted permission for restricted use in emergency situation in public interest as an abundant precaution, in clinical trial mode by the National Regulator i.e. Drug Controller General of India [DCG(I)]. Hence, the recipients of Covaxin vaccine are required to sign a consent form.

(b): The Phase-3 efficacy data of Covaxin has been released now by the manufacturer wherein it is estimated to have efficacy of 81%.

(c): No specific additional protections are accrued by the manufacturer of Covaxin as a consequence of the consent form.

(d): There are no specific implications of these additional protections for Covaxin's safety and efficacy. Safety and efficacy for vaccine are established based on data generated in pre-clinical and clinical studies.