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

RAJYA SABHA
UNSTARRED QUESTION NO. 3614
TO BE ANSWERED ON 24TH MARCH, 2026

TRANSPARENCY AND PUBLIC TRUST IN THE VACCINE APPROVAL PROCESS

3614. SHRI A. D. SINGH:

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

(a) the criteria and process followed for the approval of COVID-19 vaccines used in the country;

(b) whether the approval involved emergency use authorization and;

(c) whether the scientific evidence were considered in this regard;

(d) if so, whether the post-approval safety and efficacy monitoring mechanisms are in place; and

(e) how Government ensures transparency and public trust in the vaccine approval process?

ANSWER
THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE
(SMT. ANUPRIYA PATEL)

(a) to (e): Central Drugs Standard Control Organization (CDSCO) regulates quality, safety and efficacy of vaccines as per the provisions of New Drugs and Clinical Trials (NDCT) Rules, 2019 under Drugs and Cosmetics Act, 1940. As per the said rule, vaccines including COVID-19 vaccine are considered as "new drugs".

All applications for manufacturing/import of vaccines for sale and distribution in the country are required to be submitted along with pre-clinical and clinical data, Chemistry, Manufacturing, Control (CMC) data as per provisions of NDCT Rules, 2019.

These applications are reviewed by CDSCO in consultation with Subject Expert Committees (SECs) for clinical trial dossier and Central Drugs Laboratory (CDL), Kasauli Himachal Pradesh for quality dossier. Based on review of submitted data and recommendations of Subject Expert Committee (SEC) and CDL, Kasauli, permissions are granted to manufacture or import vaccines in the country. All the manufacturers & importers of human vaccines are required to send the samples along with protocol of manufacturing & testing of each batch to CDL, Kasauli for the purpose of lot-release before the final release of vaccines for sale and distribution in the country. Further, all manufacturers & importers have to comply with Post Marketing requirements as prescribed under the NDCT Rules, 2019.

As per the provisions of NDCT Rules, 2019 and in light of urgent need due to COVID pandemic in the country and based on the recommendations of Subject Expert Committee (SEC COVID-19), COVID vaccines were granted permissions by CDSCO for prevention of COVID-19. For ensuring transparency and public trust, details of approved vaccine such as recommendations of Subject Expert Committee (SEC COVID-19) and summary of product characteristics (SmPC) containing quality, safety, immunogenicity and/or efficacy details are publically available on CDSCO website www.cdsco.gov.in.

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