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Government issues regulatory guidelines for COVID-19 vaccine

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This document will provide guidance to the vaccine developers



Central Drugs Standard Control Organization (CDSCO), Directorate General of Health Services, Ministry of Health and Family Welfare, Government of India has launched draft regulatory guidelines for development of vaccines with special consideration for COVID-19 vaccine.

This document will provide guidance to the vaccine developers to ensure that-

Vaccines are well-characterized and manufactured consistently.

Vaccines remain stable at the recommended storage conditions for the duration of clinical trial during clinical development stage and throughout its shelf life post approval.

Adequate toxicity data as well as immunogenicity in respect of humoral and/or cellmediated immune response are generated in nonclinical studies in relevant animal models.

Challenge studies in relevant animal species and non-human primates may be conducted concurrently with clinical trial.

Adequate clinical data to establish safety and protective immunity are generated.

Post Marketing Surveillance including assessment of Adverse Events Following Immunization (AEFI) and Adverse Events of Special Interest (AESI) is carried out to assess vaccine safety in post market scenario.

The document also states that for a COVID-19 vaccine candidate consisting of a novel product type and for which no prior nonclinical and clinical data are available, nonclinical safety studies will be required prior to proceeding to first in human (FIH) clinical trials.