Central Drugs Standard Control Organization

Directorate General of Health Services

Ministry of Health and Family Welfare

Government of India

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NOTICE

Information on draft regulatory guidelines for development of vaccines with special consideration for Covid -19 vaccines

Development of vaccine is a complex activity which involves multidisciplinary research and generation of adequate laboratory, nonclinical and clinical data to ensure their safety, efficacy and quality. India is one of the major producers of vaccines in the world which cater the major portion of requirements of many vaccines globally.

In light of the present pandemic situation in the country, a need was felt to develop comprehensive guidelines on vaccines developments which will provide clear understanding of regulatory requirements to the vaccine developers.

Accordingly, CDSCO has prepared draft Guidelines for Development of Vaccines with Special Consideration of COVID-19 Vaccines under Drugs and Cosmetics Rules,1940 and New Drugs and Clinical Trials Rules,2019 in consideration of WHO, USFDA, and EMA guidelines as well as other applicable guidelines of CDSCO to facilitate early development of safe, effective and quality vaccines especially COVID-19 vaccines in the country. The same is attached herewith for all concerned.

These guidelines reflect the current thinking of CDSCO and they may be followed for development and regulatory approval of vaccines in India.

These guidelines are dynamic and recommendatory in nature and not meant to override or replace statutory requirements. Comments , if any , may be forwarded till 12th oct 2020 on dci@nic.in and vgsjdci@gmail.com. Accordingly, it will be further updated and refined on need basis to address any challenges that may arise during its implementation as well as to incorporate scientifically and technologically advanced method, design, etc. for vaccine development as emerged from research in this area.

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