

X-11026/07/2020-PRO
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization
(Public Relation Office)

FDA Bhawan, Kotla Road
New Delhi-110002

Date: 19/3/2020

NOTICE

Novel Corona-virus Disease (COVID-19) has spread over 118 countries with now more than 191,127 cases and 7807 people have lost their lives as on 18.03.2020. World Health Organization (WHO) has declared it as pandemic. However, there is no current evidence from randomized clinical trials to recommend any specific treatment for suspected or confirmed patients with COVID-19.

In order to encourage research & development of in-vitro diagnostic kits for diagnosis of COVID-19, any application submitted to CDSCO will be processed on high priority. CDSCO will also provide guidance on regulatory pathway on such matter.

The details are as under -

1. Any firm having a In-vitro Diagnostic Kit under development for COVID-19 can directly approach DCG(I) through Public Relations Office for seeking guidance for regulatory pathway.
2. Any firm having In-vitro Diagnostic Kit already approved for COVID-19 in any other country can directly approach DCG(I) through Public Relations Office regarding expedited review/accelerated approval for marketing in India.
3. Data requirement for clinical performance evaluation etc. may be abbreviated, deferred, or waived on case to case basis depending on type & nature of diagnostic kit, existing data on the product and evidence of available clinical performance evaluation data of such kit.
4. Applications to manufacture or import In-vitro Diagnostic Kit for test, evaluation and further use in performance evaluation may be processed on priority within 7 days.
5. Application for conducting performance evaluation and applications to import or manufacture In-vitro Diagnostic Kit for sale and distribution would be processed on priority through expedited review/accelerated approval.

For any additional information contact Public Relations Office through toll free number **1800 11 1454** & write to startupinnov@cdsco.nic.in .


(Dr. V. G. Somani)
Drugs Controller General (India)

To,

All Stakeholders through CDSCO web site

Copy for Information,

PS to JS(R), Ministry of Health and Family Welfare, Nirman Bhawan, New Delhi