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

FDA Bhawan, Kotla Roac
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. At present 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 drug or vaccine for prevention or treatment 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 Drug/Vaccine under development for COVID-19 can directly approach DCG(I) through Public Relations Office for seeking guidance for regulatory pathway.
2. Any firm or research institute having protocol for repurposing of existing drugs/vaccines for treatment of COVID-19 will also be given priority for review and approval.
3. Applications for Clinical Trial permission and applications to import or manufacture Drug/Vaccine for sale and distribution would be processed on priority though expedited review/accelerated approval.
4. Any firm having Drug/Vaccine 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.
5. Data requirement for animal toxicity study, clinical study, stability study etc. may be abbreviated, deferred, or waived on case to case basis depending upon the type of vaccine, nature of drug, plant from which the drug is extracted & its experience in case of Phyto-pharmaceuticals.
6. Applications to manufacture or import Drug/Vaccine for test, analysis and further use BA/BE or Clinical Trial may be processed within 7 days.
7. In case of emergency, Import license (Form 10) would be granted without Registration Certificate (Form 41) subject to approval of Central Government.

For any additional information kindly 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