6th India-Japan
Medical Products Regulatory Symposium

(Through Zoom, 01st Feb 2023)

Lesson and learn from COVID Pandemic
Regulatory Agility in India

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Addressing the pandemic – Regulatory Agility

- Facilitating research, development and access to COVID-19 related medical products
- Facilitating manufacturing of essential Drugs & Medical devices (including oxygen, masks, PPE Kits etc.) and managing shortages during the COVID-19 pandemic period and related lockdowns.
- Ensuring Regulatory facilitation & flexibilities during COVID-19 restrictions(Lockdown etc.)

Snapshot of India's key regulatory Agilities in tackling the COVID pandemic

Supporting Product Innovation & Facilitating Submissions

- **Expedited evaluation** of CT Protocols, sites and Testing
- Conducted **consultations to provide early scientific and regulatory advice** for COVID-19 therapeutics, vaccines and medical devices

Covid-19 Pandemic
11 Vaccine- 07 Indigenous vaccine & 04 non Indigenous
544- In-Vitro Medical Devices
12 Drugs for Covid-19 for restricted use

Expediting Market Access

- **Accelerated Approval Process** in accordance with NDCTR 2019
- Published notification for **stockpiling of vaccines** under clinical trial
- **Guidelines published for development of vaccines** with special consideration to covid-19 vaccines

Published notification for **Door Step Delivery**

Facilitating Manufacturing & Distribution

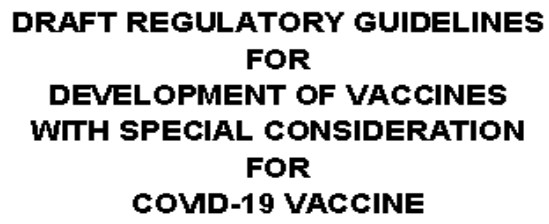
- **Day to Day intervention** for ensuring uninterrupted mfg. of the drugs, IVD kits, Medical Oxygen, hand sanitizers, PPEs etc during lockdowns
- **Ensuring availability of essential drugs at retail shelves during lockdowns to avoid stock-outs**
- Administrative orders to enable mfg., supply and sale of medicines including interventions in interstate transports for ease of doing

Regulatory Reliance

- Guidance issued for approval COVID-19 Vaccines in India **which are already approved for restricted use by US FDA, EMA, UK MHRA, PMDA Japan or which are listed in WHO Emergency Use Listing (EUL)**
- Marketing Authorisation of **Astrazeneca Vaccine (COVISHIELD), Sputnik V and Moderna vaccine** through regular interaction with concerned regulatory authorities.
- **Regular participation** in various international regulatory platform like ICMRA, WHO, R&D Blue Print, RVAG with international regulatory agencies to ensure regulatory agility and decision making to cope with the pandemic outbreak.

Regulatory Response in COVID-19 Pandemic

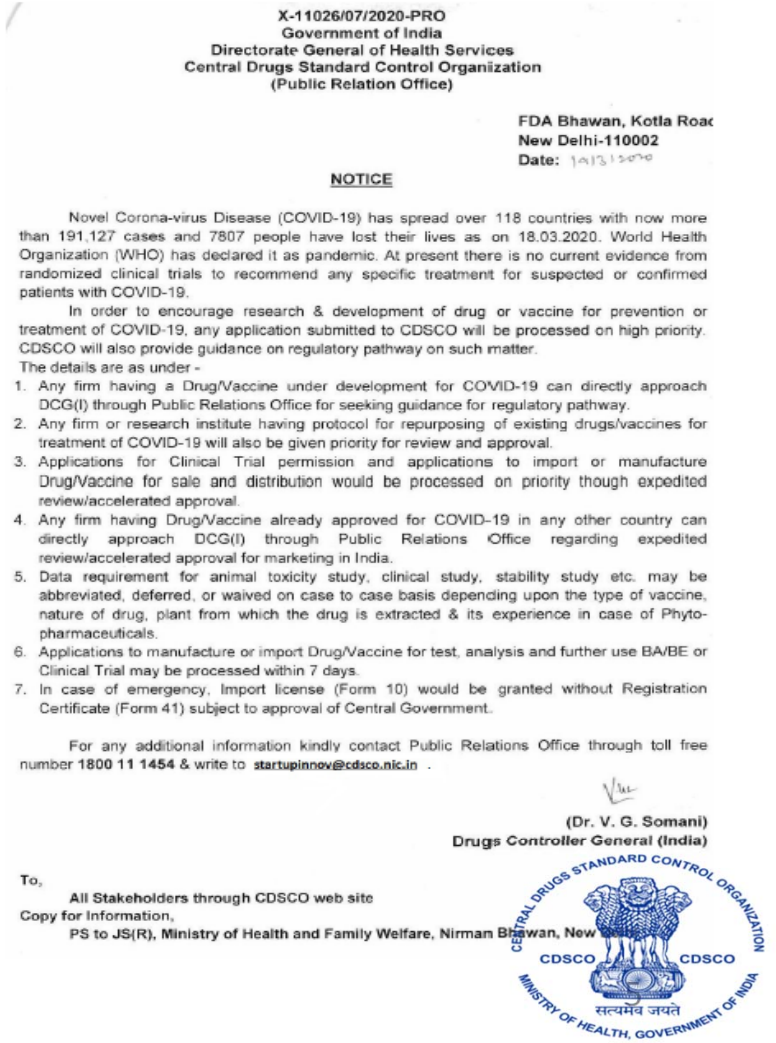
- Published Draft regulatory guidelines for development of vaccines with special consideration for COVID-19 vaccine on 21.09.2020.
- Expeditious review of applications for test licences, clinical trials, marketing authorization permissions & manufacturing licenses.
- Approvals of combined phases (I/II or Phase II/III) to reduce the timelines of Development.
- Rolling review during the conduct of clinical trials.
- Allowed parallel testing to reduce the testing time at Central Drugs Laboratory (CDL), Kasauli



Central Drugs Standard Control Organization
Directorate General of Health Services
Ministry of Health and Family Welfare
Government of India

Regulatory Response in COVID-19 Pandemic

- Special Subject Expert Committee (SEC) constituted to examine all proposals relating to Clinical Trial and Marketing Authorization of COVID-19 Vaccines. Meetings held through Web conference.
- Notice issued on 25.03.2020 providing the pathway for release of consignments of imported Vaccines from port offices during lockdown.
- To facilitate quick development, manufacturing site inspections were conducted during the clinical batches development instead of initial development.



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. 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

CENTRAL DRUGS STANDARD CONTROL ORGANIZATION
CDSCO CDSCO
सत्यमेव जयते
MINISTRY OF HEALTH, GOVERNMENT OF INDIA

Regulatory Reliance in COVID-19 Pandemic

- Regulatory pathway for approval of COVID-19 Vaccines in India for restricted use in emergency situation which are already approved for restricted use by US FDA, EMA, UK MHRA, PMDA Japan or which are listed in WHO Emergency Use Listing (EUL) on 15.04.2021 & 01.06.2021

- Approvals of COVID-19 vaccines are based on emerging science & knowledge on epidemiological situation

Other Regulatory flexibilities for pandemic situations

- **Regulation published for :**

❖ **Stockpiling of COVID-19 vaccines** while still under Clinical trial to make the vaccines available immediately after Marketing Authorization.

❖ **Doorstep Delivery** of medicines with provisions of prescription of e-mail.

- **Guidance was published :**

❖ **Extension of validity of Licences/Permissions/Certificates**

- WHO-GMP/COPP certificate
- BABE Centre Registration certificate
- Import Registration certificate
- Import Licence / Import Permission
- import of drug with residual shelf life less than 60 %.

❖ **Conduct of inspections during early development stages of COVID-19 vaccines & drugs**

Other Regulatory flexibilities for pandemic situations

In order to meet the emergency demands due to pandemic-

- CDSCO published the **notices on approval of vaccine** including the accelerated approval and expedited review process as per New Drugs and Clinical Trials Rules, 2019

- Priority licences for **Hand Sanitizers, Medicated Oxygen, Ventilators, PPE kits,** etc

- Regular **monitoring of production and availability** of essential medical products

CDSCO's International Cooperation

- **Agreements signed**
  1. Japan
  2. United States
  3. United Kingdom
  4. Sweden
  5. Brazil
  6. Russia
  7. Argentina
  8. Indonesia
  9. Saudi Arabia
  10. Afghanistan
  11. Myanmar
  12. Germany

- **MOUs in progress:** With almost 50+ other countries

- **Presence in Multilateral Fora:**
  - DCG(I) is the member of Board of Uppsala Monitoring Centre
  - India (CDSCO) is Observer in ICH and participating as experts in 05 Working Groups
  - Member of ICMRA (International Coalition of Medicine Regulatory Authorities)
  - Member of WHO SEARN (South-East Asia Regulatory Network,)
  - Was immediate past chair of MSM for falsified medicines and currently vice chair

Lessons Learnt from COVID Pandemic

- Regulatory Agilities, Accelerated, expedited and evidence based approvals
- Utility of Virtual Audit/Hybrid Audit
- Digitisation of regulatory processes – to meet the challenges of COVID-19 restrictions through processing of online applications as per urgency & emergency
- Virtual Subject Expert Committee Meetings – almost every day
- Regulatory Reliance
- Regular Market Survey for checking availability of drugs & devices (Covid & non- Covid essential drugs in entire country).
- Government initiatives like “ATMANIRBHAR Bharat” (self-reliant India)

Government of India Schemes for Development of Pharmaceutical Industry

- Umbrella scheme initiated by Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers, Government of India (DoP)
- Objective of the scheme
  - To enhance the efficiency and capabilities of domestic Indian pharma industry to effectively address the public needs
  - To enhance manufacturing capabilities by increasing investment and production of value added products
- Sub-schemes under the umbrella scheme
  - Production Linked Incentive (PLI) Scheme
  - Pharmaceutical Technology Upgradation Assistance Scheme (PTUAS); and
  - Assistance to Pharmaceutical Industry for Common Facilities (API-CF)
  - Assistance to Medical Device Industry for Common Facilities (MD-CF)

Production Linked Incentive (PLI) Scheme

- To attain self-reliance and reduce import dependence in critical APIs
- **Objective:**
  - To boost domestic manufacturing of identified KSMs, Drug Intermediates and APIs by attracting large investments in the sector and thereby reduce India's import dependence in critical APIs.

Pharmaceutical Technology Upgradation Assistance Scheme

Objective

- To facilitate Small and Medium Pharma Enterprises (SMEs) of proven track record to upgrade the facility to WHO-GMP norms
- Providing assistance as interest subvention against sanctioned loan

Assistance to Pharmaceutical Industry for Common Facilities

Objective

i. Strengthening the existing infrastructure facilities in order to make Indian Pharma Industry a global leader in Pharma Sector

ii. Easy access to standard testing facilities and value addition in the domestic Pharma Industry especially to SMEs through creation of common world class facilities for increased competitiveness

iii. To help industry meet the requirements of standards of environment at a reduced cost through innovative methods of common Waste Management System

iv. Exploit the benefits arising due to optimization of resources and economies of scale

Future Considerations and way forward

1. Accelerating research and innovation by maintaining progressive regulatory approaches, augmenting industry- academia partnership for research and exploring new models for encouraging R&D activities.
2. Strengthening manufacturing and supply base in domestic and global market for self-reliance, by developing and manufacturing more identified and value-based products to reduce Import dependency.
3. Improving access to affordable and quality Medical products by creating competitive eco-system.
4. Simplification and digitalization of processes.

Thank You