# The Central Drugs Standard Control Organization (CDSCO)

| Notification/Circular Date | Notification/ Circular No. | Title (Link) of Notification/Circular and Description |
|---|---|---|
| **Clarification on Regularization of Absence During COVID-19 Epidemic Lockdown Period** | | |
| 08.10.2020 | Z-29021/01/2020-D | *CDSCO published a circular clarifying on regularization of absence of government officials during Covid-19 epidemic lockdown period*. |
| **Notice for Vaccine Guidelines** | | |
| 21.09.2020 | | *CDSCO published the notice providing information on the draft regulatory guidelines for development of vaccines.* |
| **Regulatory Guidelines for Development of Vaccine 21.09.2020** | | |
| 21.09.2020 | | *CDSCO published the guidelines to provide guidance to the vaccine developers to ensure that: (a) vaccines are well-characterized and manufactured consistently; (b) 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; (c) adequate toxicity data as well as immunogenicity in respect of humoral and/or cell-mediated immune response are generated in nonclinical studies in relevant animal models; (d) challenge studies in relevant animal species and non-human primates may be conducted concurrently with clinical trial; (e) adequate clinical data to establish safety and protective immunity are generated; and (f) 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* |
| **Requirement of Fees for Change in Address of Authorized Agent Without Change in Constitution as Post Approval Change Under MDR 2017** | | |
| 31.08.2020 | No. 29/Misc/03/2020-DC (124) | *CDSCO made a decision that the fees may not be required for change of address of authorized agent without change i constitution under MDR, 2017.* |
| **Submission of Notarized/Apostilled Documents for Import of Medical Device and In-Vitro Diagnostic Kits in View of Covid-19** | | |
| 31.08.2020 | No. 29/Misc/03/2019-DC (134) | *CDSCO has informed the applicants vide notice that they can submit the notarized/ apostilled documents required while submitting the application for procurement of import license under Medical Devices Rules, 2017 after normalization of situation in light of COVIID-19 or within 4 months, whichever is earlier.* |
| **Submission of Notarized/ Apostilled Documents for Import and Registration of Cosmetics in View of Covid-19** | | |
| 19.08.2020 | File No. COS/ Misc./31/20 | *CDSCO has informed the applicants vide notice that they can submit the notarized/ apostilled documents required while submitting the application for procurement of import license for cosmetics under the Drugs and Cosmetics Act, 1940 and rules framed thereunder after* |

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| | | *normalization of situation in light of COVIID-19 or within 4 months, whichever is earlier.* |
| **Circular Regarding Special Condition Under which the Permission for Import of Drug with Residual Shelf Life Less than 60% is Allowed** | | |
| 10.07.2020 | File No. DCGI/Misc/2020(110) | *CDSCO vide this circular extended the validity of circular dated April 17, 2020 in relation to special condition under which the permission for import of drug with residual shelf life less than 60% is allowed.* |
| **Information on Convalescent Plasma in COVID-19** | | |
| 01.07.2020 | File No. X/11026/179/2020-BD | *CDSCO published the revised information on convalescent plasma in COVID-19 cases.* |
| **Clarification Regarding Import of Diagnostic Kits/ Reagents for Research Use Only ROU for Academic Research Purpose** | | |
| 19.06.2020 | 29/Misc/03/2020-DC(89) | *CDSCO clarified that the products meant for 'research use only' shall only be used in the academic research institute and not for any diagnostic or therapeutic purposes, as provided under the Drugs and Cosmetics Act, 1940, the Medical Devices Rules, 2017 and the rules framed thereunder.* |
| **Circular Regarding Criteria for Consideration for COVID-19 Testing Kit Approval in Pandemic Situation for Emergency Use Licensing** | | |
| 01.06.2020 | IVD/Misc./094/2020 | *CDSCO suggested that US-FDA approved, including emergency use authorization and CE approved COVID-19 test kits by regulators of country origin will be considered for approval for emergency use licensing as per Medical Devices Rules, 2017 and use in India by CDSCO.* |
| **Rapid Response Regulatory Framework for COVID-19 Vaccine Development** | | |
| 26.05.2020 | BT/03/27/2020-PID | *CDSCO in order to deal with applications for development of vaccines, diagnostics, prophylactics and therapeutics under 'Rapid Response Framework for COVID-19' for fast track processing of applications relating to recombinant vaccines for COVID-19 has been developed.* |
| **Advisory Notice Regarding Voluntary Registration of Personal Protection Equipment Coveralls at CDSCO and ITES Testing at Labs Recognised by Ministry of Textiles** | | |
| 22.05.2020 | DCGI/Misc/2020(119) | *CDSCO has issued an advisory to all the personal protection equipment coveralls manufacturers to consider themselves registered voluntarily on the CDSCO medical devices portal i.e. cdscomdonline.gov.in to secure a registration number from CDSCO, which will be a benchmark of their quality management system.* |
| **Extension of Validity of WHO GMP/Certificate of Pharmaceutical Product (COPP)** | | |

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| 01.05.2020 | 7-5/2020/Misc.070 | *CDSCO has informed all the State / UT drug controller that the validity of WHO GMP/ COPP expiring from March to August 2020may be extended by 6 months from the date of expiry of the certificate.* |
| **Submission of Notarized/Apostilled Document for Import and Registration of Medical Devices in View of COVID-19** | | |
| 23.04.2020 | 29/Misc./03/ 2020-DC(60 | *CDSCO has informed the applicants vide notice that they can submit the notarized/ apostilled documents required while submitting the application for procurement of import license under Medical Devices Rules, 2017 after normalization of situation in light of COVIID-19 or within 4 months, whichever is earlier.* |
| **Amended Clinical Trial Protocol (Version 1.4) Convalescent Plasma Protocol** | | |
| 22.04.2020 | Convalescent Plasma in COVID-19 Version 1.4 | *CDSCO has amended the protocol for randomized controlled trial to assess the safety and efficacy of convalescent plasma to limit COVID-19 associated complications in moderate disease.* |
| **Submission of Notarized/Apostilled Document for Import and Registration of Cosmetics in View of COVID-19** | | |
| 20.04.2020 | Cos/Misc./31/20 | *CDSCO has informed the applicants vide notice that they can submit the notarized/ apostilled documents required while submitting the application for procurement of import license for cosmetics under the Drugs and Cosmetics Act, 1940 and rules framed thereunder after normalization of situation in light of COVIID-19 or within 4 months, whichever is earlier.* |
| **Clinical Trial of Convalescent Plasma in COVID-19 Patients** | | |
| 17.04.2020 | X-11026/78/2020-BD | *CDSCO has formulated the protocol for all the persons/ institute/ organization interested in conducting the trail of convalescent plasma in COVID-19 patients.* |
| **Functionality of Autonomous / Subordinate Office** | | |
| 16.04.2020 | A.3209/02/2020-D | *CDSCO has issued an office memorandum regarding functionality of CDSCO and field offices including laboratories to function without restrictions with 100% attendance of Deputy Securities and level above and remaining officers and staff to attend up to 33% as per requirement.* |
| **Submission of Notarized/Apostilled Document for Import and Registration of Drugs in View of COVID-19** | | |
| 15.04.2020 | Import/Misc./101/ 2020-DC | *CDSCO has informed the applicants vide notice that they can submit the notarized/ apostilled documents required while submitting the application for procurement of import license for drugs under the Drugs and Cosmetics Act, 1940 and rules framed thereunder after normalization of situation in light of COVIID-19i* |
| **Granting Permission to Manufacturers of Industrial Oxygen to Manufacture Oxygen for Medical use in the Light of COVID-19** | | |

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| 07.04.2020 | DCGI/Misc./2020(96) | *CDSCO has granted permission to the manufactures having facility to manufacture industrial oxygen to initiate the production within 24 hours of receipt of manufacturing license*. |
| **Circular Regarding Procedure for Lot Release of Human Vaccine in View of Prevailing COVID-19 Pandemic** | | |
| 03.04.2020 | X-11026/65/2020-BD | *CDSCO has issued a circular regarding procedure for lot release of human vaccine in view of prevailing COVID-19 pandemic.* |
| **Release of Consignments of Vaccine and Critical IVDs-Certain Instructions Issued** | | |
| 25.03.2020 | --- | *CDSCO has directed to release the consignments of vaccines and critical IVDs and blood products by all the port offices based on the review of documents, protocol, certificate and satisfactory history of product*. |
| **Notice Regarding COVID-19 Outbreak** | | |
| 23.03.2020 | DCGI/MISC/2020(99) | *CDSCO clarified that all the communication amidst this coronavirus shall be done over e-mail by CDSCO.* |
| **Office Memorandum on Rapid Response Regulatory Framework for COVID-19** | | |
| 20.03.2020 | BT/03/27/2020-PID | *CDSCO has issued and office memorandum regarding fast track regulatory approval in relation to development of vaccine, diagnostics, prophylactics and therapeutics for COVID-19*. |
| **Notice Regarding Measures to Contain Spread of COVID-19** | | |
| 19.03.2020 | X-11026/06/2020-PRO | *CDSCO has issued notice in relation to: (a) social gathering; (b) setting up of toll-free number; (c) hygiene and sanitization, etc.* |
| **Notice Regarding Regulatory Pathway for R&D of Drug or Vaccine for COVID-19** | | |
| 19.03.2020 | X-11026/07/2020-PRO | *CDSCO has issued a notice regarding regulatory pathway and process the application on a high priority basis.* |
| **Monitoring of the Quality Standards of Hand Sanitizer** | | |
| 18.03.2020 | DCGI/Misc./2020(96) | *CDSCO has issued a notice in relation to monitoring of the quality standards of hand sanitizer as per Drugs and Cosmetics Act, 1940 and Rules made thereunder and expediting the licensing of manufacturers of such products*. |