The Central Drugs Standard Control Organization (CDSCO)

Notification/Circular Date	Notification/ Circular No.	Title (Link) of Notification/Circular and Description
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 in 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 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		

Notification/Circular Date	Notification/ Circular No.	Title (Link) of Notification/Circular and Description
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)		
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		

Notification/Circular Date	Notification/ Circular No.	Title (Link) of Notification/Circular and Description
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

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.*

Notification/Circular Date	Notification/ Circular No.	Title (Link) of Notification/Circular and Description
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*.