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A quarterly update on the Pharma Industry

Volume IV | Issue II | September 2020

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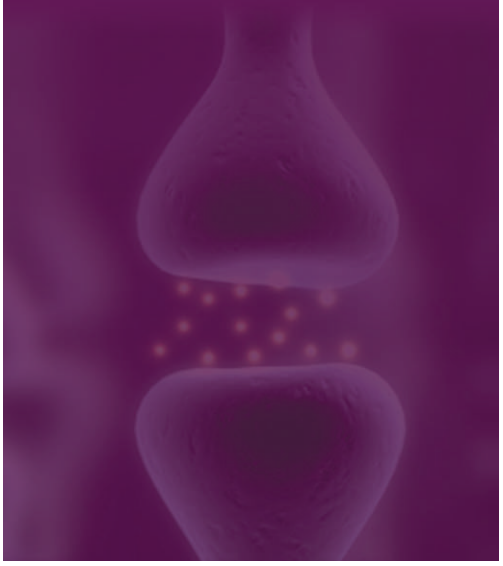


Dear Readers,

We hope that all of you and your families are safe and healthy during these unprecedented, difficult and stressful times. With lockdowns in place, life has moved to a *new normal* and we are all hoping and praying for these difficult times to pass.

The world is going through a widespread healthcare crisis. The Covid-19 pandemic has wreaked havoc on a global level with increasing fatalities putting tremendous strain on global healthcare infrastructure, testing it to its absolute limits. To combat this, Governments all over the world have been putting testing, isolation, and treatment protocols in place. Nations have gone through lockdowns to curb the spread and give healthcare systems an opportunity to scale up to meet demands. Our doctors, nurses, EMTs, and other medical personnel have been forced to the brink of exhaustion and some have even succumbed to this dreaded disease in the line of duty. The world owes them its gratitude and is in their debt. We salute our healthcare professionals.

While our healthcare professionals are doing their bit, scores of scientists are engaged in efforts to develop testing kits and are working relentlessly to find a cure for this dreaded virus. We have multiple testing kits in the market today. Multiple vaccine candidates are in various stages of trials as we speak. Our scientists also deserve our deep gratitude.

India, like the rest of the world, has also been caught in the midst of the virus. Our substantial populace coupled with a lack of adequate healthcare infrastructure has created its own set of problems. The rapid rise in infection and fatality rates has brought to the fore an emergent need to control the spread of the disease, ramp up healthcare infrastructure, and also expedite the search for a possible cure. The Indian Government has invoked provisions of a century old legislation to deal with the situation today and has also passed a slew of advisories and regulatory guidelines/ directives in this regard. All of these are featured in this issue of *Synapse*.

Due to the prevailing Covid-19 pandemic, most of the regulatory developments that took place during the April - July period in the pharmaceutical sector were focused on its detection, prevention and mitigation. In this regard, various regulatory bodies such as the Ministry of Health and Family Welfare (**MoHFW**), the Indian Council of Medical Research, the Central Drugs Standard Control Organisation and the National Pharmaceuticals Pricing Authority (**NPPA**) have come up with multiple notifications and guidelines. Some important notifications in this regard have been summarised in this newsletter.

To reduce dependence on foreign countries for the supply of Active Pharmaceutical Ingredients (**API**) and raw materials, India has started ramping up its domestic production. Alongside, special attention is given to boost healthcare infrastructure. The inward focus has enabled India to emerge as an investment

destination for development in the pharma and healthcare sector. We have witnessed some major investments in the pharmaceutical sector. A series of agreements were signed between various companies and institutions for the manufacturing and marketing of drugs, especially those drugs and vaccines which may be used to combat Covid-19.

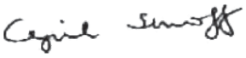
Cyril Amarchand Mangaldas, India's premier full-service law firm has an industry leading and dedicated Pharmaceutical, Healthcare and Life Sciences practice. Our class-leading practice specialists are always on top of the latest developments in the sector.

In our endeavor to keep you abreast of the latest developments in this dynamic sector, we present to you Volume IV Issue II of Synapse. We hope you find this issue of interest. As always, your feedback makes us improve our efforts. Please feel free to send your comments, feedback and suggestions to cam.publications@cyrilshroff.com. We also encourage you to visit our blog at https://corporate.cyrilamarchandblogs.com for more articles on matters of interest in the Indian pharmaceutical and healthcare sector.

We have created a dedicated section on our website that provides up-to-date information in relation to Covid-19 related notifications across different legal sectors. We encourage our readers to visit our Covid-19 resource page at http://www.cyrilshroff.com/covid-19-know-how-cyril-amarchand-mangaldas/.

Take care and stay safe.

Regards,
CYRIL SHROFF



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Regulatory Updates

A. Regulatory Response to the Covid-19 Pandemic

In view of the Covid-19 pandemic, the Government of India and various regulatory and research bodies have issued numerous advisories and directives in relation to steps taken/ to be taken to combat the pandemic. These cover aspects such as prevention, detection, and treatment in relation to the pandemic.

1. Fast Track Processing of Applications for Recombinant Vaccines

The Department of Biotechnology, Ministry of Science and Technology, *vide* Office Memorandum (**OM**) dated May 26, 2020[1], published a rapid regulatory framework for fast-track processing of applications relating to recombinant vaccines for Covid-19.

In terms of this OM, a checklist for the application to conduct pre-clinical toxicity studies of such vaccines was issued. It was also clarified that pre-clinical studies conducted outside India and any other data generated outside India may also be submitted by the applicants as part of the regulatory submissions. The regulatory authorities will examine and consider such data and an abbreviated pathway may be considered for Covid-19 vaccines based on scientific rationale, completeness of data in human trials and satisfactory pre-clinical data.

It has been clarified that these guidelines are recommendatory and dynamic in nature. Individual applications will be examined based on the type of the vaccines and their data requirements.

2. Procedure for Release of Human Vaccines

The Central Drugs Standard Control Organisation (**CDSCO**), *vide* Circular no. X-11026/65/2020-BD dated April 3, 2020[2], eased the process for release of human vaccines (manufactured domestically) in the market. As part of this relaxed process, instead of sending samples from each batch, a manufacturer is required to forward the summary lot protocol of each batch to the Central Drugs Laboratory (**CDL**), Kasauli through an e-mail along with a certificate of analysis and an undertaking that the human vaccine released in the market shall be recalled in case of quality failures. Once logistics are restored, the manufacturers will be required to send samples for evaluation to CDL, Kasauli as per usual procedures.

3. Extension of Validity of Registration of BA/ BE Study Centres

The CDSCO, *vide* Circular no. 7-5/2020/Misc/070 dated April 30, 2020[3], clarified that in accordance with the New Drugs and Clinical trials Rules, 2019 (**NDCT Rules**), if an application for renewal of bioavailability/ bioequivalence (**BA/ BE**) study centre in Form CT-08 is received by the CDSCO 90 (ninety) days prior to the date of expiry, the registration shall continue to be in force until orders to the contrary are passed on such an application.

4. Extension of Validity of WHO GMP Certificates and Certificates of Pharmaceutical Products

The CDSCO, *vide* letter dated May 1, 2020[4], communicated its decision to extend the validity period of WHO GMP certificates and Certificates of Pharmaceutical Products expiring between March 2020 and August 2020, by 6 (six) months. This was done in order to maintain continuity of essential activities by the pharmaceutical industry in light of the current pandemic situation.

5. Submission of Notarized/ Apostilled Documents for Import of Drugs, Cosmetics and Medical Devices

The CDSCO, *vide* Notice File No. Import/Misc./101/2020-DC dated April 15, 2020[5], Notice File No. COS/Misc./31/20 dated April 20, 2020[6], and Notice No. 29/Misc/03/2020-DC(60) dated April 23, 2020[7], communicated its decision that for registration and import of drugs, cosmetics and medical devices respectively, the applicant may submit the documents required under the Drugs and Cosmetics Act, 1940 (**D&C Act**), the Drugs and Cosmetics Rules, 1945 (**D&C Rules**) and the Medical Device Rules, 2017 (**MD Rules**) along with self-attested documents and an undertaking that they will submit the notarized/ apostilled documents after normalisation of the Covid-19 situation. The documents with respect to cosmetics and medical devices are required to be submitted after normalisation of the Covid-19 situation or within 4 (four) months, whichever is earlier.

6. N95 Masks: Price Control and Measures by NPPA

The NPPA *vide* OM File No. 37007/2020/Div.III/NPPA dated May 21, 2020[8], noted that there was a mismatch between the demand and supply of N-95 masks in the country and that non-government entities which were procuring these masks were getting these at differential prices. Therefore, in order to ensure the availability of N-95

1 http://dbtindia.gov.in/sites/default/files/Checklist_Recombinant%20Vaccine%20_COVID%2019.pdf
2 https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=NTgxNg==
3 https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=NTgxNg==
4 https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=NTg5OA==
5 https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=NTg1MQ==
6 https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=NTg2OA==
7 https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=NTg4NQ==
8 http://www.nppaindia.nic.in/wp-content/uploads/2020/06/N95-OM-on-price-reduction-03.06.20.pdf

masks at affordable prices, the NPPA directed the manufacturers, importers and sellers of N-95 masks to maintain parity in prices for the government and non-government entities and to make the same available at reasonable prices.

In this regard, *vide* OM dated June 3, 2020[9], a list of revised maximum retail price reported by manufacturers of N-95 masks was also shared with all States' Drug Controllers and FDAs for the purpose of ensuring availability of the masks at such revised maximum retail prices. Further, in terms of an OM dated June 23, 2020[10], the NPPA directed all the manufacturers and importers of N-95 masks to submit pricing information in the prescribed format under Paragraph 20 of the Drugs (Price Control) Order, 2013 (**DPCO**) within 10 (ten) days of the OM being issued. We note that the NPPA has, however, not fixed any prices in this regard.

It may be noted that the inclusion of masks and hand sanitizers under the EC Act was valid till June 30, 2020.

7. **Modification in Medicine List in Telemedicine Practice Guidelines**

The Telemedicine Practice Guidelines were issued by the MoHFW on March 25, 2020[11] to provide registered medical practitioners with guidance on how to treat patients remotely by using the telemedicine tools at their disposal. In this regard, the Medical Council of India *vide* its Public Notice dated April 11, 2020[12], modified the 'Medicine List' which forms part of the Telemedicine Practice Guidelines by adding 'drugs used in psychiatry practice such as Phenobarbitone, Clobazam and Clonazepam as first consult as well as follow up' to the list. **For a detailed analysis of the Telemedicine Practice Guidelines, you may refer to our blog, which can be accessed here.**

8. **Pulse Oximeters and Oxygen Concentrators: NPPA Monitoring Prices**

The NPPA, *vide* OM dated June 29, 2020[13], directed all manufacturers and importers of (i) Pulse Oximeters; and (ii) Oxygen Concentrators, to submit details of the maximum retail prices of their products according to the provisions of the DPCO within a period of 10 (ten) days. This was done with a view to monitor the prices of critical medical equipment required in clinical management of Covid-19. It may be noted that in terms of Paragraph 20 of the DPCO, the NPPA is empowered to monitor the prices of non-scheduled formulations.

9. **Covid-19 Testing Kits: Approval Based on US FDA/ CE Approval**

The CDSCO, *vide* Circular File No. IVD/Misc./094/2020 dated June 1, 2020[14], communicated its decision that United States Food and Drug Administration (**USFDA**)-approved (including emergency use authorization) and CE-approved Covid-19 kits will be considered for approval for emergency use licensing in terms of the MD Rules, and for use in India. There will be parallel testing of these kits, post approval, to monitor quality. Based on historical data and risk assessment of specific kits, some of the kits that have CE approval may require testing prior to approval.

Further, the Indian Council of Medical Research (**ICMR**), *vide* its notification dated June 4, 2020[15], issued revised guidelines for validation and batch testing of Covid-19 diagnostic kits. In terms of the guidelines, United States Food and Drugs Administration (**USFDA**) approved RT-PCR, RNA Extraction and VTM kits, and Rapid Antibody Test, ELISA and CLIA Kits will not require validation. Further, an ICMR identified validation centre will undertake random sample testing of batches of kits for quality assurance.

10. **Standard Operating Procedures to be Followed in Public Places**

The MoHFW issued various standard operating procedures (**SOP**) on preventive measures to be followed to contain spread of Covid-19 in various public places. Some of the important SOPs which were notified by the MoHFW are:

9 *Ibid.*
10 http://www.nppaindia.nic.in/wp-content/uploads/2020/06/OM-on-N95-Monitoring-dt.-23.06.2020.pdf
11 https://www.mohfw.gov.in/pdf/Telemedicine.pdf
12 https://www.mohfw.gov.in/pdf/ModificationinMedicineListinTelemedicinePracticeGuidelines.pdf
13 http://www.nppaindia.nic.in/wp-content/uploads/2020/06/OM-on-Pulse-Oximeter-and-Oxygen-Concentrator-29.06.2020.pdf
14 https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=NTk2MA==
15 https://www.icmr.gov.in/pdf/covid/kits/Guidelines_Validation_Batch_testing_04062020.pdf

i. SOP on Preventive Measures to Contain Spread of Covid-19 in Offices, dated June 4, 2020[16];

ii. SOP on Preventive Measures to Contain Spread of Covid-19 in Religious Places/ Places of Worship, dated June 4, 2020[17];

iii. SOP on Preventive Measures in Restaurants to Contain Spread of Covid-19, dated June 4, 2020[18];

iv. SOP on Preventive Measures in Shopping Malls to Contain Spread of Covid-19, dated June 4, 2020[19]; and

v. SOP on Preventive Measures in Hotels and Other Hospitality Units to Contain Spread of Covid-19, dated June 4, 2020[20].

11. Deviation from BA/ BE Study Protocols

The CDSCO, *vide* Notice F.No.12-09/BA-BE/2020/MISC-18/DC dated June 9, 2020[21], clarified that while in the prevailing Covid-19 situation, it may be difficult to maintain complete adherence to approved protocol and regulatory provisions for conducting BA/ BE studies, the protection of rights, safety and well-being of trial subjects continue to remain of utmost importance. Therefore, in some cases where protocol amendments and procedural modifications become necessary, the sponsor and the BA/ BE study centre should assess the impact and take appropriate decision in consultation with the investigator and the ethics committee to ensure rights, safety and well-being of trial subjects. It is also important to preserve the integrity of study data and maintain complete record of the same, including reasons for any amendments/ deviations etc.

12. Industrial Oxygen for Medical Use: 24 Hour Timeline for Grant of Manufacturing Licenses

The CDSCO, *vide* its letter to all States and Union Territories' Drugs Controllers dated April 7, 2020[22], directed them to grant licenses to manufacture oxygen for medical use (at premises which have facility to manufacture industrial oxygen) within 24 (twenty four) hours of receiving an application under the D&C Act and D&C Rules.

13. Immunization Services During and Post Covid-19 Outbreak

The MoHFW issued a guidance document[23] on immunization services during and post the Covid-19 outbreak. In terms of this document, immunization services have been sub classified into (i) Immunization in Containment & Buffer Zone; and (ii) Immunization in areas beyond Buffer Zone and Green Zone. In the Containment & Buffer Zone, only birth dose vaccination will be allowed and vaccination by way of 'Health facility Based Session' and 'Outreach Session' will be discontinued. Further, practices of social distancing, hand washing, and respiratory hygiene would be required to be maintained at all immunization sessions irrespective of zones/ district categorization by all persons (i.e. beneficiaries and service providers) in all sessions. Any area exiting a 'containment/ buffer zone' can start facility based and outreach immunization activities after a minimum gap of 14 (fourteen) days following delisting of that area as Containment & Buffer Zone.

14. Advisory on Use of Rapid Antigen Detection Test

The ICMR, *vide* its notification dated June 14, 2020[24], issued an advisory on the use of rapid antigen detection test for Covid-19. In terms of this document, despite not having a reliable antigen detection tests worldwide, such tests would help in proper implementation of the strategy to test, track and treat. In view of this, an independent 2 (two) site evaluation of the only available or standalone antigen detection assay: 'Standard Q Covid-19 Ag detection kit', was conducted. This kit was found to have a very high specificity (i.e. ability to detect true negatives) and the sensitivity of the test (i.e. ability to detect true positives) ranged from 50.6% (fifty point six percent) to 84% (eighty four percent). Accordingly, the ICMR recommended the use of 'Standard Q Covid-19 Ag' detection assay for testing in combination with the gold standard RT-PCR test. Such tests may be carried out in circumstances and in terms of the conditions laid out in the guidance document. The ICMR further issued newer additional strategies for Covid-19 testing dated June 23, 2020[25], to provide further guidance on the same and also with respect to conducting sero-surveys to know who has been infected in the past and has now recovered.

15. Plasma Therapy: Approval for Conduct of Clinical Trials

The CDSCO, *vide* Notice File No. X-11026/78/2020-BD dated April 17, 2020[26], granted its 'no-objection' to ICMR's proposal for conducting clinical trials of convalescent plasma in Covid-19 patients. In view of this, any institution interested to conduct clinical trial as per the protocol developed by the ICMR and approved by the CDSCO, may do so in consultation with the ICMR.

16 https://www.mohfw.gov.in/pdf/1SoPstobefollowedinOffices.pdf
17 https://www.mohfw.gov.in/pdf/2SoPstobefollowedinReligiousPlaces.pdf
18 https://www.mohfw.gov.in/pdf/3SoPstobefollowedinRestaurants.pdf
19 https://www.mohfw.gov.in/pdf/4SoPstobefollowedinShoppingMalls.pdf
20 https://www.mohfw.gov.in/pdf/5SoPstobefollowedinHotelsandotherunits.pdf
21 https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=NTk4Nw==
22 https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=NTgzNQ==
23 https://www.mohfw.gov.in/pdf/3ImmunizationServicesduringCOVIDOutbreakSummary150520202.pdf
24 https://www.icmr.gov.in/pdf/covid/strategy/Advisory_for_rapid_antigen_test14062020.pdf
25 https://www.icmr.gov.in/pdf/covid/strategy/New_additional_Advisory_23062020_2.pdf
26 https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=NTg2Mw==

16. Clinical Management Protocol for Covid-19

The MoHFW, *vide* its notification dated July 3, 2020[27], issued a consolidated and amended clinical management protocol for Covid-19. This protocol contains *inter alia* guidance on case definition, risk factors, infection prevention and control practices, management of Covid-19 (mild, moderate and severe cases) and prevention of complications.

17. Revised Testing Guidelines

The ICMR, *vide* its notification dated May 18, 2020[28], issued a revised strategy for testing of Covid-19. In terms of this revised strategy, symptomatic frontline workers involved in containment and mitigation of Covid-19, hospitalised patients who develop influenza like illness (**ILI**) symptoms, asymptomatic direct and high risk contacts of a confirmed case between day 5 (five) and day 10 (ten) of coming into contact, and all symptomatic ILI among returnees and migrants within 7 (seven) days of illness, have been included in list of cases which will be eligible for testing. Further, in terms of this strategy document, no emergency procedures (including deliveries) should be delayed for lack of tests.

18. ENT Practice During Covid-19: Guidelines

The MoHFW, *vide* its notification dated June 3, 2020[29], issued guidelines for safe ENT practice during Covid-19. These guidelines are aimed to minimise the spread of Covid-19 infection among ENT doctors, nursing staff, support staff, patients and their attendants and comprise (i) Protocols and SOPs for ENT OPD; (ii) Protocol for ENT and Head & Neck Surgery Ward; and (iii) Guidelines for Operation Theatre for ENT surgeries. In terms of these guidelines, *inter alia* teleconsultations should be preferred, walk in patients without appointment should be discouraged, and patients entering the ENT OPD should be screened.

19. Dental Practice: Guidelines for Dental Professionals

The MoHFW, *vide* a notification dated May 19, 2020[30], issued guidelines for dental professionals in Covid-19 pandemic situation. In terms of these guidelines, dental procedures require close contact with the patient's oral cavity, saliva, blood, and respiratory tract secretions and therefore, all patients visiting a dental office must be treated with due precautions. These guidelines *inter alia* provide for dental clinics to remain closed in containment zones (they can continue to provide tele triage), to perform only emergency procedures in red zones, and to provide dental consults in orange and green zone (here too dental operations should be restricted to emergency and urgent treatment procedures only). Further, all routine and elective dental procedures should be deferred for a later review until new policy/guidelines are issued.

27 https://www.icmr.gov.in/pdf/covid/strategy/New_additional_Advisory_23062020_2.pdf
28 https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=NTg2Mw==
29 https://www.mohfw.gov.in/pdf/ENTCOVID0306.pdf
30 https://www.mohfw.gov.in/pdf/DentalAdvisoryF.pdf

20. New Molecules/ AYUSH Regimens/ Products/ Technologies/ Diagnostic Kits, etc.: ICMR Guidance for Evaluation of Novel Applications for Covid-19 and Detailed List of Partner Institutions

The ICMR issued a guidance document for evaluation of novel applications for Covid-19[31]. In terms of this document, since the start of the Covid-19 pandemic the ICMR had received over 190 (one hundred and ninety) requests for evaluation of molecules/ AYUSH regimens/ products/ technologies/ diagnostic kits, etc. In view of ICMR's involvement in diagnosis, research, surveillance, clinical trials and validation of diagnostic kits for Covid-19, the ICMR was directed to partner with various departments like Department of Science and Technology, Department of Biotechnology and Council of Scientific and Industrial Research for evaluating the antiviral properties of investigational products/ repurposed drugs/ devices/ technologies, etc. Accordingly, the detailed list of identified institutions from each department along with the contact details of the nodal person has been provided under this guidance document.

21. Establishment of Network of Biorepositories in India

The ICMR, vide its notification dated July 23, 2020[32], identified the processes and operational mechanisms for establishment of a Covid-19 biorepositories in India. Currently, there is no structured mechanism for collecting and storing these valuable clinical samples. Thus, it was deemed important to create designated biorepositories for collecting, storing and maintaining clinical samples (oropharyngeal/ nasopharyngeal swabs, bronchoalveolar lavage, sputum, blood, urine and stool) of Covid-19 patients. Such samples will be used to develop validated diagnostics, therapeutics, vaccines etc.

It is proposed to establish 17 (seventeen) national Covid-19 biorepositories, identified by ICMR and other science ministries and Council of Scientific & Industrial Research (**CSIR**). The list of the 17 (seventeen) biorepositories has also been identified. The designated biorepositories will be responsible for earmarking/ arranging dedicated space, storage facilities, staff etc. for establishing and maintaining the facility.

22. Use of Hydroxychloroquine: Revised Advisory Issued

The MoHFW issued a revised advisory on the use of 'Hydroxychloroquine' as a prophylaxis for Covid-19 infection[33]. In terms of these revised guidelines, the prophylactic use of 'Hydroxychloroquine' has been recommended in the following cases:

i. All asymptomatic healthcare workers involved in containment and treatment of Covid-19 and all asymptomatic healthcare workers working in non-Covid-19 hospitals/ non-Covid-19 areas of Covid-19 hospitals/ blocks;

ii. Asymptomatic frontline workers, such as surveillance workers deployed in containment zones and paramilitary/ police personnel involved in Covid-19 related activities; and

iii. Asymptomatic household contacts of laboratory confirmed cases.

This advisory replaces the previous advisory issued on March 23, 2020[34] which provided for placing only asymptomatic healthcare workers involved in care of suspected or confirmed cases of Covid-19, and asymptomatic household contacts of laboratory confirmed cases, under chemoprophylaxis with 'Hydroxychloroquine'.

23. Revised Guidelines for Home Isolation of Very Mild/ Pre-Symptomatic Covid-19 Cases

The MoHFW, *vide* its notification dated April 27, 2020[35], issued 'Guidelines for Home Isolation of Very Mild/ Pre-Symptomatic COVID-19 Cases'. Thereafter, on May 10, 2020[36], the MoHFW issued revised guidelines for home isolation of very mild/ pre-symptomatic Covid-19 cases. In terms of these guidelines, very mild/pre-symptomatic patients having the requisite facility at his/her residence for self-isolation will have the option for home isolation. To be eligible for home isolation, the patient must *inter alia* be clinically assigned as a very mild case/ pre-symptomatic case by the treating medical officer and such cases should have the requisite facility at their residence for self-isolation and also for quarantining the family contacts.

These guidelines were further revised vide notification dated July 2, 2020[37], whereby 'asymptomatic positive cases' were added to the list of patients who can avail of home isolation. Patients suffering from immune compromised status (HIV, transplant recipients, cancer therapy etc.) were specifically excluded from the list of eligible patients.

24. Covid-19 Diagnostic Kits/ Reagents: Clarifications Regarding Import for R&D Purposes

The CDSCO, *vide* its letter to all zonal, sub zonal and port offices of the CDSCO dated June 19, 2020[38], clarified that products meant for 'research use only' are to be used in

31 https://dst.gov.in/sites/default/files/Guidance%20for%20Evaluation%20COVID%20ICMR.pdf
32 https://www.icmr.gov.in/cbiorn.html
33 https://www.mohfw.gov.in/pdf/RevisedadvisoryontheuseofhydroxychloroquineasprophylaxisforSARSCOVID19infection.pdf
34 https://www.mohfw.gov.in/pdf/AdvisoryontheuseofHydroxychloroquinasprophylaxisforSARSCoV2infection.pdf
35 https://www.mohfw.gov.in/pdf/GuidelinesforHomeIsolationofverymildpresymptomaticCOVID19cases.pdf
36 https://www.mohfw.gov.in/pdf/RevisedguidelinesforHomeIsolationofverymildpresymptomaticCOVID19cases10May2020.pdf
37 https://www.mohfw.gov.in/pdf/RevisedHomeIsolationGuidelines.pdf
38 https://cdsco.gov.in/opencms/resources/UploadCDSCOWeb/2018/UploadPublic_NoticesFiles/clarificationmd.pdf

academic research institutions and are not meant for any diagnostic or therapeutic use as they are not regulated under the D&C Act and the MD Rules. However, the applicants are required to submit an undertaking at the concerned port offices stating that the imported products shall be used by the research institution for academic research only and shall not be used for any in-vitro diagnostic or therapeutic purpose.

25. Covid-19 Deaths: Guidance for Mortality Surveillance and Record Keeping

The ICMR, vide its notification dated May 10, 2020[39], published a guidance document for appropriate recording of Covid-19 deaths in India. In terms of this guidance document, mortality surveillance is a very important public health tool to assess the impact of the viral infection. Accordingly, the ICMR has provided guidance on the manner of recording death due to Covid-19 and the information required to be captured on the medical certificate of cause of death. The MoHFW had earlies published detailed guidelines for dead body management[40] for Covid-19 cases.

26. National Guidelines for Ethics Committees Reviewing Biomedical and Health Research During Covid-19

The ICMR, *vide* its notification dated May 8, 2020, issued the 'National Guidelines for Ethics Committees Reviewing Biomedical and Health Research During Covid-19'[41]. In terms of these guidelines, research has to take the centre stage in order to tackle the novel challenges that have come to the forefront during Covid-19 and that the role of Ethics Committees has become very important in reviewing protocols prepared for such emergency situations. Responsiveness to the situation includes expediting or fast tracking of processes, ensuring robust ethics review and monitoring research. Accordingly, the guidelines contain provisions to facilitate and guide the Ethics Committees on the same.

The guidelines say that while conducting Biomedical and Health Research, four basic principles namely; respect for persons (autonomy), beneficence, non-maleficence and justice must be maintained to protect the dignity, rights, safety and well-being of participants. The Ethics Committees must decide about the type of review required (exempted, expedited, full committee) based on the type of risk involved in each study and must ensure a thorough scientific and ethical review of research as per national guidelines and regulations.

27. Guidelines for Liver Transplantation

The ICMR, *vide* its notification dated April 13, 2020[42], issued the 'Guidelines for Liver Transplantation and Covid-19 Infection'. In terms of these guidelines, immunocompromised patients were at a greater risk and hence, there was an immediate need for liver transplantation guidelines in India, both in deceased donor liver transplant and living donor liver transplant centres.

These guidelines provide for *inter alia* testing of all donors and recipients for Covid-19 and the circumstances under which liver transplants can take place. These guidelines further specify that doctors should avoid minimally invasive surgery and opt for open surgeries during the pandemic and that all transplant recipients should be sent an advisory from the respective transplant centre regarding various do's and don'ts for prevention of Covid-19 infection.

28. Guidance for Management of Pregnant Women

The ICMR, *vide* its notification dated April 12, 2020[43], issued 'Guidance for Management of Pregnant Women in Covid-19 Pandemic'. In terms of these guidelines, obstetric units should *inter alia* take into consideration appropriate isolation of pregnant patients who are Covid-19 positive or are under investigations, and processes to protect new-borns from the risk of Covid-19. This document further contains detailed guidance on management of Covid-19 during a pregnancy, including guidance on antenatal care, care in labour, postnatal management, and hospital discharge.

29. Advisory for Sample Collection Sites

The ICMR, *vide* its notification dated April 7, 2020[44], issued an advisory for sample collection sites. In terms of this advisory, the ICMR has no objection on establishing convenient sample collection sites (drive through centres for sample collection) by the respective State Governments, subject to the following conditions:

i. The sample collection should be done using the recommended personal protective equipment (**PPE**);

ii. These sites should be disinfected regularly as per recommended procedures;

iii. All recommended biosafety and biosecurity precautions should be implemented; and

iv. Sample transport to the nearest Covid-19 testing laboratory should be ensured under proper cold-chain conditions and with triple layered packing.

30. Advisory for Managing Health Care Workers

The MoHFW, *vide* its notification dated June 18, 2020[45], issued an advisory for managing health care workers in

39 https://www.icmr.gov.in/pdf/covid/techdoc/Guidance_appropriate_recording_of_related_deaths_India.pdf
40 https://www.mohfw.gov.in/pdf/1584423700568_COVID19GuidelinesonDeadbodymanagement.pdf
41 https://main.icmr.nic.in/sites/default/files/guidelines/EC_Guidance_COVID19_06_05_2020.pdf
42 https://www.icmr.gov.in/pdf/covid/techdoc/Guidelines_for_Liver_Transplantation_and_COVID_13042020.pdf
43 https://www.icmr.gov.in/pdf/covid/techdoc/Guidance_for_Management_of_Pregnant_Women_in_COVID19_Pandemic_12042020.pdf
44 https://www.icmr.gov.in/pdf/covid/techdoc/Guidance_for_Management_of_Pregnant_Women_in_COVID19_Pandemic_12042020.pdf
45 https://www.mohfw.gov.in/pdf/updatedAdvisoryformanagingHealthcareworkersworkinginCOVIDandNonCOVIDareasofthehospital.pdf

Covid and non-Covid areas of the hospital. In terms of these guidelines, the health care personnel working in hospitals are at increased risk of acquiring the Covid-19 disease, if there is a breach in the personal protection while managing patients. Accordingly, this advisory provides guidance on preventive measures, isolation and quarantine of health care functionaries. This advisory *inter alia* contains guidance on institutional mechanisms for preventing healthcare-associated infections among health care workers and lays down instructions for appropriate use of PPEs. It also asks to follow the prescribed SOP in case a healthcare worker reports exposure/ breach of PPE or symptoms suggestive of Covid-19.

31. Eye Protection Goggles: Advisory on Reuse

The MoHFW, *vide* its notification dated May 27, 2020[46], issued an advisory on reprocessing and reuse of eye protection goggles. In terms of this advisory, goggles are a crucial component of PPE, which need not be discarded after their use. Usually, all components of PPE are discarded as bio-medical waste, but goggles conforming to prescribed EN/ BIS specifications can be reused after proper disinfection. The advisory further contains an SOP to be followed for disinfection and reuse of such goggles.

32. Voluntary Registration of Personal Protective Equipment

The CDSCO, *vide* its Advisory Notice File No. DCGI/Misc/2020(119) dated May 22, 2020[47], clarified that PPE coveralls are 'medical devices' and hence it was important that all manufacturers of such coveralls were aware of the latest rules governing medical devices, which enable these manufacturers to take advantage of the voluntary registration scheme with the CDSCO and secure a registration number which will act as an assurance for their quality management system.

33. Guidance Note on Provision of Reproductive, Maternal, New-born, Child, Adolescent Health Plus Nutrition (RMNCAH+N) Services

The MoHFW, *vide* its notification dated May 27, 2020[48], issued a Guidance Note on Provision of RMNCAH+N services. In terms of this guidance note, owing to the large number of pregnancies each year in the country, it is important to ensure the availability of services during this period. Any denial of services can have an impact on maternal and new-born mortalities, morbidities as well as add to the health care costs. Accordingly, the guidance note elaborates the various RMNCAH+N services to be provided at different levels in accordance with the categorisation of Containment Zones, Buffer Zones and beyond these zones.

34. Exemption of Hand Sanitizers From Sale License

The MoHFW, vide Gazette Notification no. SO 2451(E) dated July 27, 2020[49], in exercise of the powers conferred by Section 26B of the D&C Act directed that 'hand sanitizers' shall be exempted from the requirement of sale licence for their stocking or selling under the provisions of the D&C Act and D&C Rules. This exemption is subject to the condition that provisions Rule 65(17) of the D&C Rules *(i.e. prohibition on sale/ stocking after the date of expiration of potency recorded on its container, label or wrapper, or in violation of any statement or direction recorded on such container, label or wrapper)* are complied with by the person stocking or selling such hand sanitizers.

35. Deemed Validity of Registration Certificates for Import of Drugs

The MoHFW, vide Gazette Notification no. SO 2450(E) dated July 27, 2020[50], in view of the Covid-19 pandemic and to ensure that the supply of drugs does not get interrupted, directed that if an existing Registration Certificate (for import of drugs for sale/ distribution) holder makes an application for a fresh Registration Certificate (for import of drugs for sale/ distribution) before the expiry of such existing certificate, then such existing Registration Certificate shall be deemed to be valid until orders are passed on the application and shall be deemed to be valid for all purposes.

36. Guidance on Covid-19 and Tobacco Use

The MoHFW has recently issued a guidance note[51] on the 'Covid-19 Pandemic and Tobacco use in India'. In terms of this note, the MoHFW highlighted the fact that the use of tobacco is a risk factor for many respiratory infections and increases the severity of respiratory diseases. Further, the guidance note suggests that the smokers are likely to be more vulnerable to Covid-19 as the act of smoking means that fingers (and possibly contaminated cigarettes) are in contact with lips which increases the possibility of transmission of virus from hand to mouth. Smokers are also more likely to develop severe symptoms or die from Covid-19, as it primarily attacks the lungs. Further, it states that smoking products such as water pipes or hookah often involve the sharing of mouth-pieces and hoses, which could facilitate the transmission of Covid-19 in communal and social settings. Accordingly, the MoHFW has warned against the use of any tobacco products.

37. Empowering Citizens for Covid-19 Testing

The MoHFW and the ICMR, in a letter to Chief Secretaries/ Administrators/ Advisors to Governors/ Advisors to Lt.

46 https://www.mohfw.gov.in/pdf/Advisoryonreprocessingandreuseofeyeprotectiongoggles.pdf
47 https://cdsco.gov.in/opencms/resources/UploadCDSCOWeb/2018/UploadPublic_NoticesFiles/advisorynotice22.pdf
48 https://www.mohfw.gov.in/pdf/GuidanceNoteonProvisionofessentialRMNCAHNServices24052020.pdf
49 https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=NjMzMA==
50 https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=NjMyOQ==
51 https://www.mohfw.gov.in/pdf/COVID19PandemicandTobaccoUseinIndia.pdf

Governors dated July 1, 2020[52], observed that in some States and Union Territories, the capacity utilization of testing labs is grossly sub-optimal. In some States and Union Territories, a prescription from a Government doctor was also required to enable a person to get tested for Covid-19. However, this might create unnecessary delays and at the present juncture, it was necessary to facilitate testing at the earliest. Therefore, the ICMR recommended that laboratories should be free to test any individual who fulfilled the criteria set out by the ICMR and that authorities must not restrict such persons from getting tested.

38. Expedited Approval of TrueNat/ CBNAAT for Covid-19 Testing Labs

The ICMR, vide letter dated July 3, 2020, bearing reference number D.O.No.ECD/COVIdI 9/Misc./2020, issued to all Chief Secretaries (Sates)/ Addl. Chief Secretaries/ Secretaries/ Commissioners/ Principal Secretaries (health & family Welfare)[53], emphasized that the National Accreditation Board for Testing & Calibration Laboratories (**NABL**) has established expedited approval mechanisms with fast track approvals being granted within 7 (seven) days. Further, with a view to support all States in ramping up testing, all private laboratories who intend to initiate TrueNat/ CBNAAT based testing for Covid-19 should be encouraged to immediately apply for NABL accreditation. All the labs who have applied, can reach out to the ICMR (at aggarwal.n@icmr.gov.in) with a copy of their NABL application, and based on the same the ICMR will provide expedited approval for TrueNat/ CBNAAT, subject to NABL approval, which can be submitted within a maximum time span of 4 (four) weeks from the date of approval. The ICMR requested the concerned authorities to direct the private labs and hospitals in their states to adopt the abovementioned mechanism for expedited approvals.

39. Fixation of Rate for RT- PCR Test for Covid-19 in Relation to Central Services (Medical Attendance) Beneficiaries

The MoHFW *vide* its OM dated July 13, 2020[54], directed that the rate of RT-PCR test for Covid-19 prescribed by the ICMR, or the concerned Government or actual, whichever is lower, shall be admissible for reimbursement to beneficiaries of Central Services (Medical Attendance) (**CS(MA)**) who have undergone the said test.

40. Guidelines and Advisory for Gated Residential Complexes

The MoHFW vide its guidance document[55] dated July 17, 2020, issued detailed guidelines to help and guide Resident Welfare Associations/ Residential Societies/ Non-Governmental Organizations, who want to establish a small Covid-19 care facility within the premises of the said gated communities. The said document provides guiding principles, infrastructural requirements, human resource, inspection facility etc. needed by such Covid-19 care facilities. Further, through its advisory[56] dated July 17, 2020, the MoHFW, issued advice and guidelines for such gate residential complexes to prevent the transmission of Covid-19 within their premises.

41. Guidelines for International Arrival

The MoHFW vide its guidance document[57] dated August 2, 2020, (which is in supersession of the guidance document dated May 24, 2020) gave a detailed set of guidelines to be followed by an international traveller arriving in India. The same is applicable from August 8, 2020.

42. Circular Regarding Special Condition Under which the Permission for Import of Drug with Residual Shelf Life Less than 60% (sixty percent) is allowed – Extended

The DCGI, *vide* its circular[58] dated July 10, 2020, extended the application of circular dated April 17, 2020 in relation to "Circular Regarding Special Condition Under which the Permission for Import of Drug with Residual Shelf Life Less than 60% is allowed", to October 31, 2020 or till further order is issued by the DCGI regarding the same, whichever is earlier.

43. Enhancement of Testing Capacity

The ICMR, *vide* a letter dated July 17, 2020[59], to the Additional Chief Secretary/ Principal Secretary (Health &

52 https://www.icmr.gov.in/pdf/covid/strategy/Joint_Letter_Test_Track_Treat.pdf
53 https://www.icmr.gov.in/pdf/covid/labs/Letter_regarding_expedited_TrueNat_CBNAAT.pdf
54 https://www.mohfw.gov.in/pdf/OMregfixationofCOVIDtestorCSMAbeneficiaries.pdf
55 https://www.mohfw.gov.in/pdf/CovidCareFacilityinGatedcomplexes.pdf
56 https://www.mohfw.gov.in/pdf/AdvisoryforRWAsonCOVID19.pdf
57 https://www.mohfw.gov.in/pdf/RevisedguidelinesforInternationalArrivals02082020.pdf
58 https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=NjEzMw==
59 https://www.icmr.gov.in/pdf/covid/labs/Joint_Lettter_for_Enhancement_of_Testing_Capacity_Reg.pdf

Family Welfare) of all States and Union Territories, addressed the concern surrounding the increasing number of Covid-19 positive cases in the country and the urgent necessity to increase/ enhance the testing capacity in the country. It was stated that the same can be done by increasing the number of labs having testing facility or by increasing the capacity of the labs which are currently testing and laid out short term and medium term measures to enhance testing capacity.

44. Electronic Vaccine Intelligence Network

The MoHFW through the Press Information Bureau on August 3, 2020, has informed that the Electronic Vaccine Intelligence Network (**eVIN**), an innovative technological solution aimed at strengthening immunization supply chain systems across the country, has been used with the requisite customization during the Covid-19 pandemic for ensuring continuation of the essential immunization services and protecting children and pregnant mothers against vaccine preventable diseases[60]. It has also been emphasized that this strong platform has the potential to be leveraged for any new vaccine including Covid-19 vaccine, as and when available.

45. DCGI approves Phase II+III trials of Oxford University vaccine by Serum Institute

The MoHFW, through the Press Information Bureau[61], on August 3, 2020 has informed that the DCGI has given the requisite approval to Serum Institute of India for conducting Phase II and Phase III clinical trials of Oxford University-Astra Zeneca Covid-19 vaccine in India. This will ensure the fast development of the Covid-19 vaccine.

46. Guidance on Mental Health Support for Health Care Warriors During COVID-19

The Department of Health and Family welfare, Government of Karnataka, in association with the National Institute of Mental Health and Neurosciences, Bengaluru, issued a guidance document on "Caring for Health Care Warriors- Mental Health Support During Covid-19"[62]. This documents notes that due to the spread of Covid-19 healthcare workers in the frontline have become particularly vulnerable to mental stress. Worries about risk of infection to self and their families, adequacy of protection, long working hours, being in quarantine/ isolation, and separation from families can lead to severe psychological distress among health professionals. If not effectively recognised and treated, such stress can transform into more persistent illness, even leading to suicidal thoughts and feelings.

Therefore, it has become necessary for all non-psychiatric health care professionals to be trained to provide initial mental health care to the extent possible. Accordingly, this guidance document defines the framework for administrators and health care supervisors to address the mental health needs of healthcare personnel in Covid-19 treatment settings. It also provides technical input to guide health care personnel to help themselves and their colleagues in distress. It has been further stated that although this document has been primarily prepared for addressing mental health needs of healthcare workers in Covid-19 treatment setting in Karnataka, the framework is adaptable across the country and other countries with constrained resources.

B. Amendment of Epidemic Diseases Act, 1897

As the country faces the ravages of the Covid-19 pandemic, we saw the invocation of the provisions of the Epidemic Diseases Act, 1897 (**ED Act**). The act is over a century old and many have considered its provisions inadequate in terms of its effective application in today's times. With a view towards updating the provisions of this century plus old legislation, the Ministry of Law and Justice, *vide* Gazette Notification no. 25 dated April 22, 2020[63], promulgated the Epidemic Diseases (Amendment) Ordinance, 2020. The salient features of this ordinance are as follows:

i. 'Act of violence' has been defined to include any act committed by any person against any healthcare service personnel serving during an epidemic, which causes or may cause (i) harassment which impacts the living or working conditions of such personnel; (ii) harm, injury, hurt, or danger to the life of such personnel; (iii) obstruction or hindrance to such personnel in discharge of his/ her duties; or (iv) loss or damage to the property (or documents) in custody of such healthcare service personnel. 'Healthcare Service Personnel' has also been defined to mean a person who while carrying out his duties, may come in contact with affected patients and is thereby at a risk of being impacted by the disease, and includes (i) public and clinical healthcare providers such as doctors, nurses, paramedical worker, and community health worker; (ii) any person empowered under the ED Act to take measures to prevent the outbreak/ spread of the disease; and (iii) any persons designated as such by the State Government by notification in the Official Gazette;

ii. Insertion of a new Section 2A in the ED Act which provides that no person shall indulge in any act of violence against a healthcare service personnel or cause any damage or loss to any property during an epidemic; and

iii. Whoever commits/ abets an act of violence against a healthcare service personnel or abets/ causes any damage or loss to any property shall be liable to a term of

60 https://pib.gov.in/PressReleseDetailm.aspx?PRID=1643172
61 https://pib.gov.in/PressReleasePage.aspx?PRID=1643136
62 https://www.mohfw.gov.in/pdf/HCWMentalHealthSupportGuidanceJuly20201.pdf
63 http://egazette.nic.in/WriteReadData/2020/219108.pdf

between 3 (three) months and 5 (five) years and with fine of between INR 50,000 (Indian Rupees Fifty Thousand) and INR 2,00,000 (Indian Rupees Two Lakh). Additionally, the person convicted of such an offence will also be liable to pay compensation of such amount as may be determined by the Court.

These amendments were made ostensibly to ensure the protection of our front line healthcare personnel in light of increasing incidents of aggression and violence towards these professionals as the country battled with the consequences of the nationwide lockdown and quarantine protocols that were enforced in communities with high numbers of Covid-19 positive persons.

C. Use of Unapproved Drugs: Draft Rules on Compassionate Use

The MoHFW, *vide* Gazette Notification no. GSR 354(E) dated June 5, 2020[64], notified the draft of amendments to the NDCT Rules. The draft amendment contemplates insertion of new Rules 96A, 96B, 96C, 96CA, 96D, 96E, 96F, 96G, 96H and 96I in the NDCT Rules which would allow a medical officer of a hospital or medical institution to import, or apply for manufacture of an unapproved 'new drug' in limited quantities for compassionate use in treatment of patients suffering from life threatening disease or disease causing serious permanent disability or disease requiring therapy for unmet medical need, subject to the conditions specified therein.

The application for import of such a drug would be required to be accompanied by *inter alia* the rationale behind the compassionate use of new drug over the available therapeutic options. It also requires to state information such as- the criteria for patient selection, method of administration of the drug, description of manufacturing facility, description of clinical procedures, drug information such as pharmacology and toxicology information, and chemistry, manufacturing and controls information adequate to ensure the proper identification, quality, purity, and strength of the drug.

A time period of 15 (fifteen) days was granted for submission of any objections and suggestions on the proposed amendment to the MoHFW.

D. Drug Price Control. Discontinuation of Scheduled Formulations. Draft Guidelines for Procedure

The NPPA, *vide* its Notice F.No.31(67)/2016/Div.III/NPPA dated June 1, 2020[65], published a draft of the guidelines for dealing with cases of discontinuation of Scheduled Formulations in terms of Paragraph 21 of the DPCO, and invited comments and suggestions of the stakeholders on the same by June 15, 2020.

In terms of these draft guidelines, *inter alia* if a company intending to discontinue a scheduled formulation has not issued a public notice, it will be directed to do so in at least 2 (two) national newspapers (1 (one) each in Hindi and English) and the date of discontinuation shall be treated as being 6 (six) months from the public notice, subject to further conditions specified therein. Depending upon the Moving Annual Turnover (in units) (**MAT**) of the company in relation to the total MAT value of a formulation (in units), the company may be directed to continue production, import and sale of the formulation for a period ranging from 6 (six) to 12 (twelve) months from the date of issue of the public notice and to ensure that there are no shortages of the formulation during this period. If the MAT (in units) of the company is more than 40% (forty percent), the case will also be put up for discussion on whether or not there is any emergency or urgency requiring invocation of Paragraph 3 of the DPCO. The NPPA may also consider upward price revision of the formulation if the proposal for discontinuation is on account of non-remunerative pricing, a ground which will be required to be established by the manufacturer.

Further, whenever a formulation is found to be critical for public health, and where it is established that the company is intending to discontinue the formulation to evade price control, exercise of powers under Paragraph 3 of the DPCO to ensure supply of the formulation for such period as may be considered necessary may be considered.

64 https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=NTk3Mw==
65 http://www.nppaindia.nic.in/wp-content/uploads/2020/06/Guidelines-reg-discontinuation.pdf

News Updates

1. **DCGI Permits Human Clinical Trials for Covid-19 Vaccine of Zydus Cadila**

   On July 2, 2020, the Drugs Controller General of India (**DCGI**) granted approval to Cadila Healthcare Ltd. (**Zydus Cadila**) to conduct Phase I and Phase II human clinical trials for its Covid-19 vaccine. The said approval was given soon after the recommendation of the subject expert committee (approved by the DCGI) to the said drug[66].

   Zydus Cadila had submitted the results/ observations of their animal trials to the authorities and after a thorough inspection of the same the permission/ approval to conduct trials on human subjects was given by the DCGI.

2. **Bharat Biotech's Covid-19 Vaccine Candidate Covaxin Gets Regulatory Nod**

   'Covaxin', a Covid-19 vaccine candidate, developed by the Hyderabad-based Bharat Biotech International Limited (**BBIL**) in collaboration with the ICMR and the National Institute of Virology (**NIV**) received approval from the DCGI for conducting human clinical trials, on June 30, 2020.

   We understand that 'Covaxin' uses the virus isolated from an Indian patient by the NIV to develop the inactivated virus vaccine.[67]

3. **Dexamethasone: First Drug Proves Able to Improve Survival from Covid-19**

   On June 16, 2020, researchers and scientists from England announced that they had found evidence that 'Dexamethasone' a widely available and cheap steroid, had a positive impact in the treatment of patients who had contracted Covid-19 and who were severely unwell and required ventilator/ oxygen support.

   The drug is given either orally or through an intravenous mechanism. After 28 (twenty eight) days, it had reduced deaths by 35% (thirty five percent) in patients who needed treatment with breathing machines and by 20% (twenty percent) in those only needing supplemental oxygen. It did not appear to help slightly ill patients[68].

   We understand that though the World Health Organisation has advised against the usage of steroids, the same is used by the doctors to treat the inflammation that is caused due to aggressive overreaction of the immune system while fighting the virus.

   In a statement released by the University of Oxford, it has been stated that the survival benefit is clear upon usage of 'Dexamethasone' in those patients who are sick enough to require oxygen treatment, and therefore, 'Dexamethasone' should now become standard of care in these patients. 'Dexamethasone' is inexpensive, on the shelf, and can be used immediately to save lives worldwide.[69]

66 https://health.economictimes.indiatimes.com/news/pharma/dcgi-permits-human-clinical-trials-for-covid-19-vaccine-of-zydus-cadila/76761602
67 https://health.economictimes.indiatimes.com/news/pharma/covid-vaccine-nod-for-human-trials-marks-beginning-of-end-says-centre/76805242
68 https://health.economictimes.indiatimes.com/news/pharma/first-drug-proves-able-to-improve-survival-from-covid-19/76415539
69 https://indianexpress.com/article/world/first-drug-proves-able-to-improve-survival-from-covid-19-6462007/

4. **Covid treatment. Remdesivir. India's Drug Regulator Grants Gilead Sciences Inc. Marketing Authorisation for Remdesivir**

   DCGI has granted marketing authorisation to Gilead Sciences, Inc. for its anti-viral drug 'Remdesivir' for "*restricted emergency use*" on hospitalised Covid-19 patients.

   The approval process for the said anti-viral drug was accelerated in view of the unforeseen emergency situation and the unmet need for medicines in the midst of the ongoing pandemic.

   We note that the NDCT Rules provide for such expedited approval mechanism upon satisfaction of certain conditions, provided there exists a health emergency which needs to be remedied. We also note that the said drug has been issued an 'Emergency Use Authorisation' by the USFDA to treat hospitalised Covid-19 positive patients. This is an important precondition that is to be satisfied and noted by the DCGI for expedited approval under the NDCT Rules.

   'Remedesivir'[70] has been allowed for restricted emergency use for treating suspected or laboratory-confirmed cases of Covid-19 in adults and children hospitalised with severe symptoms, subject to several safeguarding conditions.[71]

5. **Sun Pharma Gets DCGI Approval for Clinical Trial with Nafamostat in Covid-19 Patients**

   On May 29, 2020, Sun Pharmaceutical Industries received an approval from the DCGI which enables the said company to initiate clinical trial with 'Nafamostat Mesilate' in relation to Covid-19 patients. It is pertinent to note that the said drug has been approved in Japan for improvement of acute symptoms of pancreatitis and treatment of disseminated intravascular coagulation.[72]

   Further, a group of scientists from the University of Tokyo in Japan and Leibniz Institute for Primate Research in Germany have found that that 'Nafamostat', at very low concentrations, suppresses a protein (i.e. TMPRSS2) that the Covid-19 virus uses to enter human lung cells. Additionally, a group from Institut Pasteur in South Korea also published data comparing antiviral efficacy of 24 (twenty four) drugs and 'Nafamostat' against SARSCoV-2 in in-vitro studies in human lung epithelial derived cells.[73]

6. **Biocon Gets DCGI Nod for Device to Treat Critical Covid-19 Patients**

   Biocon Biologics, a subsidiary of Biocon Limited, received an approval from the DCGI for its blood purification device 'CytoSorb' meant for Covid-19 patients. The said device is to be used for extracorporeal blood purification to reduce pro-inflammatory cytokines levels in confirmed Covid-19 patients who have been admitted to the intensive care unit with confirmed or imminent respiratory failure.[74]

   It is pertinent to note that 'CytoSorb' has received an approval from the USFDA in April for emergency use in Covid-19 patients. This is an important pre-condition to be satisfied by any drug that applies for an approval when there is a prevailing health emergency in the country.

   Biocon Biologics has been granted licence for emergency use of 'CytoSorb' in public interest by the DCGI to treat Covid-19 patients who are 18 (eighteen) years of age or older. The validity of the license is until the control of the Covid-19 outbreak in the country.

7. **Natco Pharma Joins Columbia University Trials Using Chloroquine Phosphate to Prevent Covid-19 Infections**

   A global network named CROWN (Covid-19 Research Outcomes Worldwide Network) is conducting a collaborative trial using Choloroquine Phosphate at the Washington University School of Medicine in St Louis. Subsequent to being a part of the global clinical trial using Chloroquine Phosphate, Natco Pharma Ltd. has collaborated with a study by New York's Columbia University to carry out Phase-II clinical trials using 'Chloroquine Phosphate' to prevent symptomatic SARS-CoV-2 infections.[75]

   Natco Pharma Ltd. is donating the 'Chloroquine Phosphate' tablets for the said trials through its marketing partner in the United States, Rising Pharmaceuticals. Natco Pharma Ltd. has been supplying the USFDA-approved drug through its marketing partner to the United States since 2011.

8. **Johnson and Johnson (J&J) to Stop Selling Talc-Based Baby Powder in US, Canada**

   J&J has decided to discontinue its iconic talc powder amidst the row of multiple lawsuits and alleged claims that the usage of the said product causes cancer. In the recent years, the company has noticed a dwindling in the demand for its talc powder in North America.

70 We note that Gilead Sciences, Inc. has signed non-exclusive voluntary licensing agreements with generic pharmaceutical manufacturers based in Egypt, India and Pakistan to further expand supply of Remdesivir. The agreements allow the companies – Cipla Ltd.; Dr. Reddy's Laboratories Ltd.; Eva Pharma; Ferozsons Laboratories; Hetero Labs Ltd.; Jubilant Lifesciences; Mylan; Syngene, a Biocon company; and Zydus Cadila Healthcare Ltd. – to manufacture Remdesivir for distribution in 127 countries. (https://www.gilead.com/purpose/advancing-global-health/covid-19/voluntary-licensing-agreements-for-remdesivir)

71 https://health.economictimes.indiatimes.com/news/pharma/indias-drug-regulator-grants-gilead-sciences-marketing-authorisation-for-remdesivir/76147160

72 https://health.economictimes.indiatimes.com/news/pharma/sun-pharma-gets-dcgi-approval-for-clinical-trial-with-nafamostat-in-covid-19-patients/76091219

73 Ibid.

74 https://health.economictimes.indiatimes.com/news/pharma/biocon-gets-dcgi-nod-for-device-to-treat-critical-covid-19-patients/76032686

75 https://health.economictimes.indiatimes.com/news/pharma/natco-pharma-joins-columbia-university-trials-using-chloroquine-phosphate-to-prevent-covid-19-infections/75916044

We note that J&J has contended and consistently maintained that the overwhelming majority of medical research on talc indicates that the talc baby powder is safe and doesn't cause cancer.

9. Government Taking Measures to Ramp up Drug Production

In an effort to accelerate the production of essential drugs and to avoid any circumstances of drug crisis, the Ministry of Environment, Forest and Climate Change has amended the Environmental Impact Assessment Notification, 2006, following which all projects of drugs manufactured for the treatment of all diseases have been re-classified from the existing 'A' category to 'B2' category.

10. Bharat Bio Consortium Gets Grant for Chikungunya Vaccine

The Coalition for Epidemic Preparedness Innovations (**CEPI**) has partnered with Bharat Biotech's consortium to advance the development of a vaccine for Chikungunya and has agreed to provide with funding of up to USD 14.1 (fourteen point one) million (which is around INR 106,00,00,000 (Indian Rupees One Hundred and Six Crores)).

The Bharat Biotech consortium will also receive the support of a grant of USD 2 (two) million (which is around INR 14,96,55,000 (Indian Rupees Fourteen Crore Ninety Six Thousand Fifty Five Thousand)) from the Indian Government's Ind-CEPI initiative. The said initiative will fund the setting up of GMP manufacturing facilities for the proposed vaccine and the subsequent manufacture of clinical trial materials[76].

The partnering agreement, in addition to manufacturing, will finance a multi-centre Phase-2/3 adaptive clinical trial to be conducted by Bharat Biotech's consortium partner International Vaccine Institute in Colombia, Panama and Thailand[77].

11. ICMR Selects 12 (twelve) Institutes for Clinical Trial of Covid-19 Vaccine

The ICMR has selected 12 (twelve) institutes, for clinical trial of the country's first indigenous Covid-19 vaccine. ICMR has developed the indigenous Covid-19 vaccine (BBV152 COVID vaccine) in partnership with Bharat Biotech International Limited.

The said 12 (twelve) institutes have been asked by the ICMR to fast track clinical trials of the vaccine as it is being considered as one of the top priority projects which are being monitored at the topmost level of the government[78].

76 https://health.economictimes.indiatimes.com/news/pharma/bharat-bio-consortium-gets-14m-grant-for-chikungunya-vaccine/76191068
77 Ibid.
78 https://health.economictimes.indiatimes.com/news/pharma/icmr-selects-12-institutes-for-clinical-trial-of-covid-19-vaccine/76760506

As on August 06, 2020, the said vaccine has completed its Phase I study in 11 (eleven) sites and has started its Phase II study.[79]

12. Mylan Gets DCGI Nod for Remdesivir in India, to Launch at INR 4,800 (Indian Rupees Four Thousand Eight Hundred only) Per Vial

Mylan NV, received an approval from DCGI to manufacture and market its Remdesivir for restricted emergency use in the country for the treatment of Covid-19[80].

The drug will be priced at INR 4,800 (Indian Rupees Four Thousand Eight Hundred only) per 100 (hundred) mg vial and would be available to the patients in July. The DCGI has approved the company's Remdesivir 100 (hundred) mg per vial for restricted emergency use in India as part of the regulator's accelerated approval process to address urgent, unmet needs amid the evolving Covid-19 pandemic.

13. Mylab Launches Machine to Automate Molecular Diagnostic Tests Including Those for Covid- 19

Mylab Discovery Solutions has launched a machine to automate the manual processes of molecular diagnostic tests including RT-PCR tests for Covid-19. The machine will be available for pre-ordering starting July 13, 2020. The machine to automate molecular diagnostic tests is a compact bench-top machine that will automate lab processes from sample handling to preparing RT-PCR (reverse transcription-polymerase chain reaction) ready tubes. It is a cartridge-based machine and can test multiple samples at the same time. The machine can be used for a wide range of RNA and DNA-based tests including Covid-19 RT-PCR tests.[81]

14. Coronavirus Treatment: DCGI Approves Psoriasis Injection for Limited Use

DCGI has approved Itolizumab, a drug used to cure skin ailment psoriasis for "restricted emergency use" to treat Covid-19 patients with moderate to severe acute respiratory distress. Intolizumab is a monoclonal antibody injection developed by Biocon Limited. The approval was given after its clinical trials on Covid-19 patients in India was found satisfactory by the expert committee comprising pulmonologists, pharmacologists and medicine experts from AIIMS[82].

15. Kerala Institute Develops Bridge Device for Patients Needing Ventilator Support

Sree Chitra Tirunal Institute for Medical Sciences & Technology, a Kerala-based central government institute, has developed an emergency breathing assist device that can provide respiratory assistance to patients for 3-4 (three-four) hours which is extremely crucial given that there is an acute shortage of oxygen and ventilator beds, across the country due to increasing Covid-19 cases.[83]

The institute is of the opinion that the device would be useful even beyond Covid-19 pandemic situation. In case of mass casualties due to accidents, natural disasters like fire, floods, earthquake, the said device can provide crucial support before mechanical ventilation takes place. It can be stationed in public places like malls, airports, etc. for emergencies like cardio-respiratory arrest.

16. Special Investigation Team (SIT) to Look Into Covid-19 Drug Racket

On August 2, 2020, the Gurugram Police formed a five member SIT to investigate the international drug smuggling racket, which also included drugs for treating patients who were Covid-19 positive, which operated out of Gurugram.[84] The drugs were smuggled to Iraq from India.

The SIT will investigate the involvement of people associated with the said drug smuggling racket and how the same was working to smuggle the drugs outside India. A Delhi pharmacist is also accused of supplying drugs (including Remdesevir) to the drug smuggling racket.

79 https://timesofindia.indiatimes.com/life-style/health-fitness/health-news/coronavirus-vaccine-india-covaxin-zycov-d-move-to-phase-ii-clinical-trials/articleshow/77367413.cms
80 https://health.economictimes.indiatimes.com/news/pharma/mylan-gets-dcgi-nod-for-remdesivir-in-india-to-launch-at-rs-4800-per-vial/76815420
81 https://indianpharma.in/industry/Mylab-launches-machine-to-automate-molecular-diagnostic-tests-including-those-for-COVID-19
82 https://www.businesstoday.in/sectors/pharma/coronavirus-treatment-drug-controller-approves-psoriasis-injection-for-limited-use/story/409564.html
83 https://indianpharma.in/industry/Kerala-Institute-develops-bridge-device-for-patients-needing-ventilator-support
84 https://timesofindia.indiatimes.com/city/gurgaon/five-member-sit-to-probe-drug-racket/articleshow/77309203.cms

Major Transactions / Corporate Arrangements

1. **AstraZeneca & Serum Institute of India Sign Licensing Deal for 1 Billion Doses of Oxford University's Covid-19 Vaccine**

   AstraZeneca and Serum Institute of India have entered into a licensing agreement dated June 4, 2020, through which one billion doses of vaccine against Covid-19, being developed in Oxford University (which is in Phase-II/ III of its clinical trial), will be supplied to middle and low income countries including India[85].

   The 'ChAdOx1 nCoV-19' vaccine, now known as 'AZD1222', was developed by Oxford University's Jenner Institute, working with the Oxford Vaccine Group. It uses a replication-deficient viral vector derived from a chimpanzee. Such vector is based on a weakened version of a common cold (adenovirus) virus that causes infections in chimpanzees and it contains the genetic material of the SARS-CoV-2 spike protein. The vaccine contains the Covid-19 surface spike protein that induces the immune system to develop antibodies against the virus.[86]

   AstraZeneca is a global biopharmaceutical company that focuses on the discovery, development and commercialisation of prescription medicines, primarily for the treatment of diseases in three therapy areas- Oncology, Cardiovascular, Renal & Metabolism, and Respiratory & Immunology.

   AstraZeneca has entered into several other agreements to supply the vaccine to United States and countries in Europe. By the end of this year, the said parties to the aforementioned licensing agreement have agreed to provide 400 (four hundred) million doses of the aforementioned vaccine[87].

2. **Carlyle Picks Up 20 Percent Stake in Piramal Enterprises Limited (PEL) Pharma Business for USD 490 Million**

   The Carlyle Group has taken a significant 20% (twenty percent) minority share in the pharma business of PEL. The sale will be conducted through the issuance of fresh equity. The estimated equity capital investment for the Carlyle group's 20% (twenty percent) stake in PEL's pharma business would amount to INR 3700 crore (Indian Rupees Three Thousand Seven Hundred Crore).

   The 20% (twenty percent) stake sale at Carlyle group's offer would value PEL's pharma business business at around INR 20,000 crore (Indian Rupees Twenty Thousand Crore).

85 https://www.astrazeneca.com/media-centre/press-releases/2020/astrazeneca-takes-next-steps-towards-broad-and-equitable-access-to-oxford-universitys-covid-19-vaccine.html.
86 Ibid.
87 https://health.economictimes.indiatimes.com/news/pharma/astrazeneca-serum-institute-of-india-sign-licensing-deal-for-1-billion-doses-of-oxford-vaccine/76204373

The proceeds gathered by PEL from the deal will be utilised by the company as growth capital for the pharma businesses to expand existing capacities as well as to tap attractive acquisition opportunities within and outside India.

The stock has appreciated 48% (forty eight percent) in June in anticipation of this transaction even as PEL posted a net loss in the March quarter[88].

3. Cipla, Boehringer Ingelheim Join Hands to Co-Market Three Oral Anti-Diabetic Drugs in India

On June 29, 2020 Cipla Limited and Boehringer Ingelheim India announced that the said companies are entering into a partnership to co-market three new oral anti-diabetic drugs in India. The companies have partnered to co-market three new oral anti-diabetics drugs: (a) Oboravo (Empagliflozin); (b) Oboravo Met (Empagliflozin+Metformin); and (c) Tiptengio (Empagliflozin+Linagliptin).[89]

4. Cipla Expands Partnership with Roche Pharma to Improve Access for Oncology Medicine

On June 18, 2020, Cipla Limited and Roche Products India Pvt. Ltd. (**Roche**) announced that the companies have entered into an agreement to provide better access to innovative cancer medicines for patients in India.

Under the said agreement, Cipla Limited will be responsible for the marketing and distribution of Roche's key trademark oncology drugs 'Trastuzumab', 'Bevacizumab' and 'Rituximab'.

5. KKR & Co. Inc. (KKR) to Buy 54% (fifty four percent) Stake in JB Chemicals

United States private equity fund KKR to acquire about 54 (fifty four) per cent stake in drug manufacturer JB Chemicals & Pharmaceuticals, for INR 3,100 crore (Indian Rupees Three Thousand One Hundred Crores only). This investment comes after KKR, in the month of May, bought 2.32 (two point three two) per cent stake in Reliance Industries Limited's digital assets subsidiary Jio Platforms.

KKR has agreed to acquire 41.7 (forty one point seven) million shares of JB Chemicals & Pharmaceuticals from the promoters at INR 745 (Indian Rupees Seven Hundred and Forty Five only) each. Further, the deal will trigger an open offer for an additional 26 (twenty six) per cent stake, the company said in a statement. If fully subscribed, KKR will end up paying INR 4,600 crore (Indian Rupees Four Thousand Six Hundred crores only) for 80 (eighty) per cent of the company, making it arguably the largest private equity buyout in Indian pharma sector[90]. KKR will make the investment through its subsidiaries, Tau Investments Holdings Pte. Ltd., Tau Holdco Pte. Ltd., and KKR Asia III Fund Investments Pte.[91]

However, we note that KKR does not wish to own more than 65 (sixty five) per cent of the company and will accordingly adjust the stake from the promoters depending on the success of the open offer, which would then translate to a INR 3,750 crore (Indian Rupees Three Thousand Seven Hundred Fifty only) payout for KKR.

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88 https://health.economictimes.indiatimes.com/news/pharma/carlyle-picks-up-20-stake-in-piramal-pharma-biz-for-490-mn/76661033
89 https://health.economictimes.indiatimes.com/news/pharma/cipla-boehringer-ingelheim-join-hands-to-co-market-3-oral-anti-diabetic-drugs-in-india/76691137
90 https://health.economictimes.indiatimes.com/news/pharma/kkr-to-buy-54-stake-in-jb-chemicals-for-rs-3100-crore/76782791
91 https://www.financialexpress.com/industry/jb-chemicals-and-pharmaceuticals-kkr-to-buy-controlling-stake-in-company-open-offer-to-be-launched/2011916

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