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A quarterly update on the Pharma Industry

Volume IV | Issue III | February 2021

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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. The Covid pandemic has changed our lives in more ways than one.

The pharmaceuticals and healthcare sector has been in focus for the past year. We have witnessed a slew of regulatory developments in the latter half of 2020 as well. The authorities, in addition to managing and combating the Covid-19 pandemic, are back to focusing on regular policy and regulatory matters. This can be witnessed in the developments, which this sector saw in the past few months, many of the which will have far reaching consequences. For instance, regulation of cosmetics has now been delinked from the Drugs and Cosmetics Rules, 1945, and instead, it will now be regulated as a dedicated code, much like medical devices and clinical trials.

Approval of Covid vaccines has taken center stage. Approvals across countries have taken place. Many countries have already started to deploy Covid-19 vaccines and have begun mass immunisation programmes. The Indian regulatory authorities are also a part of this. With two vaccine approvals in hand, India too is seeing a mass vaccination drive, with healthcare workers being given first preference in vaccination. To this end, various guidance documents and advisories have been issued.

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 keep abreast of the latest developments in this dynamic sector, we present to you the latest issue 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 https://www.cyrilshroff.com/covid-19-know-how-cyril-amarchand-mangaldas/.

Please stay safe.

Regards,

CYRIL SHROFF

Managing Partner
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Regulatory Updates

1. 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 that cover aspects such as prevention, detection, and treatment in relation to the pandemic.

i. Approval of Covid-19 Vaccines and Roll-Out of Vaccination Programme in India

The Central Drugs Standard Control Organisation's ("**CDSCO**") Subject Expert Committee recommended the grant of permission for restricted emergency use of the Covid-19 vaccines developed by M/s Serum Institute of India Private Limited ("**SII**").[1] and M/s Bharat Biotech International Limited ("**Bharat Biotech**")[2], in its meetings held on January 1, 2021, and January 2, 2021, respectively. Accordingly, formal regulatory approvals in this regard were granted by the CDSCO on January 3, 2021[3].

To answer questions that have been raised as regards the above approvals, the Ministry of Health and Family Welfare ("**MoHFW**") *vide* a letter dated January 14, 2021[4], requested the Additional Chief Secretaries, Principal Secretaries, and Secretaries (Health and Family Welfare) of all States and Union Territories, to disseminate a comparative factsheet of the 2 (two) approved vaccines to all programme managers, cold chain handlers and vaccinators for their ready reference. This comparative factsheet includes information on the vaccine platform, physical specifications, dosage, cold chain storage requirements, contraindications and special precautions, and adverse events following immunisation.

The vaccination drive was rolled out on January 16, 2021[5]. This vaccination drive is the world's largest vaccination programme[6]. On the first day of the vaccination drive, a total of 3,352 (three thousand three hundred and fifty-two) sessions were held and 1,91,181 (one lakh ninety-one thousand one hundred and eight one) people were vaccinated[7]. Further, 3,429 (three thousand four hundred and twenty-nine) beneficiaries were vaccinated in defence institutions. As with other countries, frontline healthcare workers remain a priority for vaccination.

ii. Price Capping and Prevention of Hoarding of Oxygen

The National Pharmaceutical Pricing Authority ("**NPPA**"), *vide* a letter dated September 18, 2020[8], instructed all State Drug Controllers to ensure strict vigil and take strong actions under the Drug and Cosmetics Act, 1940 ("**D&C Act**"), and the Essential Commodities Act, 1955 ("**ECA**"), to ensure uninterrupted supply of medical oxygen. This was done in light of instances of black marketing and hoarding of medical oxygen coming to light. In this regard, *vide* Order (F.No. 12(41)/2020/Div II/NPPA), dated September 24, 2020[9], the NPPA instructed all manufacturers and re-fillers of medical oxygen to submit information (in the prescribed format) on capacity, stocks, production and sales of oxygen, to the control room set up by the Central Government to monitor availability, distribution and demand of medical oxygen. This information is required to be submitted on a daily basis till further orders.

Thereafter, *vide* Gazette Notification no. SO 3322(E), dated September 25, 2020[10], the price of liquid medical oxygen and oxygen inhalation (medicinal gas) in cylinder was fixed at INR 15.22 (Indian Rupees Fifteen and Twenty-Two Paise)/ cubic meter and INR 25.71 (Indian Rupees Twenty Five and Seventy one Paise)/ cubic meter, respectively. On September 26, 2020[11], the NPPA also issued a letter to the Chief Secretaries of all States and Union Territories in relation to ensuring the prices of liquid medical oxygen and oxygen inhalation (medicinal gas).

iii. Submission of Notarised/ Apostilled Documents for Import and Registration of Cosmetics and Medical Devices

CDSCO *vide* Notice (File No. COS/ Misc./31/20), dated August 19, 2020[12], informed applicants that the applications for import registration of cosmetics may be submitted in terms of the D&C Act and the Drugs and Cosmetics Rules, 1945 ("**D&C Rules**"), along with documents that are self-attested and an undertaking to submit notarised/ apostilled documents after normalisation of situation in light of Covid-19 or within 4 (four) months, whichever is earlier. The terms of this relaxation were extended for another 4 (four) months, *vide* Notice (File No. COS/Misc./31/20), dated December

1 https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/common_download.jsp?num_id_pk=MTMwMQ==
2 https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/common_download.jsp?num_id_pk=MTMwMA==
3 https://www.thehindu.com/news/national/drug-controller-general-approves-covishield-and-covaxin-in-india-for-emergency-use/article33485539.ece
4 https://www.mohfw.gov.in/pdf/LetterfromAddlSecyMoHFWregContraindicationsandFactsheetforCOVID19vaccines.PDF
5 https://pib.gov.in/PressReleasePage.aspx?PRID=1689112
6 https://pib.gov.in/PressReleaseIframePage.aspx?PRID=1689034
7 https://pib.gov.in/PressReleasePage.aspx?PRID=1689167
8 http://www.nppaindia.nic.in/wp-content/uploads/2020/09/Letter-to-SDCs-regarding-blackmarketing-of-Oxygen.pdf
9 http://www.nppaindia.nic.in/wp-content/uploads/2020/09/Oxygen_1-1.pdf
10 http://www.nppaindia.nic.in/wp-content/uploads/2020/09/222006-1.pdf
11 http://www.nppaindia.nic.in/wp-content/uploads/2020/09/Letter-to-all-CS-for-Oxygen-Price-Cap-26.09.2020.pdf
12 https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=NjQyMA==

18, 2020[13]. Further, the CDSCO *vide* Notice (No. 29/Misc/03/2019-DC (134)), dated August 31, 2020[14], extended similar relaxations granted for medical devices and in-vitro diagnostic ("**IVD**") kits till normalisation of situation in light of Covid-19 or within 4 (four) months (i.e., by December 31, 2020), whichever is earlier.

iv. Draft Regulatory Guidelines for Development of Covid-19 Vaccine

The CDSCO issued a draft of the *"Regulatory Guidelines for Development of Vaccines with Special Consideration for Covid-19 Vaccine"* on September 21, 2020[15]. These guidelines will be applicable in relation to nonclinical and clinical development of any vaccine, including Covid-19 vaccines, and aim to ensure that: (a) vaccines are well-characterised and manufactured consistently; (b) vaccines remain stable at the recommended storage conditions for the duration of clinical trial during the clinical development stage and throughout their 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 immunisation and adverse events of special interest is carried out to assess vaccine safety.

In this regard, the CDSCO *vide* a Notice dated September 21, 2020[16], clarified that these guidelines are dynamic and only recommendatory in nature. They are not meant to override any statutory requirements. The CDSCO invited comments, if any, on these draft guidelines by October 12, 2020.

v. Guidance Notes, Standard Operating Procedures and Guidelines

The MoHFW and the Indian Council of Medical Research ("**ICMR**") issued various guidance notes, standard operating procedures ("**SOP**") and guidelines for the general public, as well as healthcare professionals to provide advice and guidance on the best practices to combat Covid-19. Some of the important guidance notes, SOPs and guidelines issued during this period were:

(a) **Guidelines for International Arrivals (issued on November 5, 2020)[17]:** These guidelines were issued in supersession of the earlier guidelines dated August 2, 2020, on the same subject. They lay down procedures to be followed (a) before planning for travel; (b) before boarding; (c) during travel; and (d) on arrival.

(b) **Guidelines on Preventive Measures to Contain Spread of Covid-19 in Yoga Institutes & Gymnasiums *(issued on August 3, 2020)*[18]:** These guidelines lay down various generic precautionary measures to be adopted, in addition to specific measures to be taken at yoga institutes and gymnasiums to prevent the spread of Covid-19.

(c) **Guidelines on Safe Ophthalmology Practices in Covid-19 Scenario *(issued on December 28, 2020)*[19]:** These guidelines are aimed at minimising the spread of Covid-19 infection among ophthalmologist, ophthalmic assistants/ technicians, nurses, support staff, patients and their attendants.

(d) **Clinical Guidance on Diabetes Management at Covid-19 Patient Management Facility *(issued on August 26, 2020)*[20]:** This clinical guidance note is meant for healthcare professionals to ensure proper medical care of diabetic Covid-19 patients.

(e) **Guidance Note on Bi-directional TB-Covid screening and screening of tuberculosis among ILI/ SARI cases *(issued on August 26, 2020)*[21]:** This guidance note is

13 https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=Njc3OQ==
14 https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=NjQyOQ==
15 https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=NjUwMA==
16 https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=NjQ5OQ==
17 https://www.mohfw.gov.in/pdf/05112020Guidelinesforinternationalarrivals.pdf
18 https://www.mohfw.gov.in/pdf/Guidelinesonyogainstitutesandgymnasiums03082020.pdf
19 https://www.mohfw.gov.in/pdf/GuidelinesonSafeOphthalmologyPracticesinCovid19Scenario.pdf#_blank
20 https://www.mohfw.gov.in/pdf/ClinicalGuidanceonDiabetesManagementatCOVID19PatientManagementFacility.pdf#_blank
21 https://www.mohfw.gov.in/pdf/1TBCOVIDscreeningguidancenote.pdf#_blank

intended to tackle dual morbidity of tuberculosis ("**TB**") and Covid-19, and suggests to undertake (a) Bi-directional TB-Covid screening; (b) TB screening for ILI cases; and (c) TB screening for SARI cases, to address the same.

(f) **Containment and Surveillance Manual for Supervisors in Containment Zones[22]:** This manual lists out the duties and responsibilities of supervisors in Covid-19 containment zones, and also includes a self-assessment checklist of field actions to be taken by such supervisors.

(g) **Manual for Surveillance Teams for Containment Zones[23]:** This manual lists out the roles and responsibilities of surveillance teams in Covid-19 containment zones and also provides guidance and information on self-protection actions for surveillance teams, while visiting suspect cases and contacts and conducting community activities.

(h) **SOP on Preventive Measures to Contain the Spread of Covid-19 in Skill or Entrepreneurship Training Institutions, Higher Educational Institutions Conducting Doctoral Courses and Post Graduate Studies in Technical & Professional Programmes Requiring Laboratory/ Experimental Work *(Issued on September 8, 2020)*[24]:** This SOP aims to enable safe resumption of teaching/ training activities in skill or entrepreneurship training institutions, higher educational institutions conducting doctoral courses and post graduate studies in technical & professional programmes, requiring laboratory/ experimental work, and specifies detailed preventive measures to be taken to ensure the same.

(i) **SOP for Partial Reopening of Schools for Students of 9th to 12th Classes on a Voluntary Basis, for Taking Guidance from Their Teachers: In the Context of Covid-19 *(issued on September 8, 2020)*[25]:** This SOP specifies precautionary measures to be adopted, in addition to specific measures to be taken when schools are permitting students to physically attend classes. In terms of this SOP, students from class 9th to 12th will have the option of attending classes remotely/ virtually or physically, only on a voluntary basis, for guidance from their teachers, subject to written permission of parent/ guardian.

(j) **Revised SOP on Preventive Measures to be Followed While Conducting Examinations to Contain Spread of Covid-19 *(issued on September 10, 2020)*[26]:** This SOP specifies generic measures and simple public health measures that are to be followed to reduce the risk of Covid-19 at examination centres.

(k) **Post Covid Management Protocol *(issued on September 13, 2020)*[27]:** This protocol provides an integrated holistic approach for managing patients who have recovered enough from Covid for care at home.

(l) **Advisory for use of Cartridge Based Nucleic Acid Amplification Test ("CBNAAT") *(issued on October 15, 2020)*[28]:** This advisory lays down the minimum requirements for a laboratory to initiate testing using CBNAAT platforms.

(m) **Advisory on Clustered Regularly Interspaced Short Palindromic Repeats ("CRISPR") technology-based SARS-COV-2 test *(issued on October 22, 2020)*[29]:** This advisory lays down the standards and requirements for a laboratory to use the new CRISPS test.

(n) **Evidence Based Advisory to Address Inappropriate Use of Convalescent Plasma in Covid-19 Patients *(issued on November 17, 2020)*[30]:** This advisory lays down the requirements that must be met before Convalescent plasma therapy is used on Covid-19 patients.

(o) **Advisory on use of Dry Swab RNA Extraction Free RT-PCR Method *(issued on November 26, 2020)*[31]:** This advisory states that considering its lesser cost and quick turn-around, the dry swab variant method can be used as a screening tool only in settings where automated RNA extraction is not available.

(p) **SOP on Preventive Measures to Contain Spread of Covid-19 During Festivities *(issued on October 6, 2020)*[32]:** This SOP specifies various generic precautionary measures to be adopted, in addition to specific measures to be taken at locations to prevent spread of Covid-19 during the festive season.

22 https://www.mohfw.gov.in/pdf/ContainmentandSurveillanceManualforSupervisorsincontainmentzones.pdf#_blank
23 https://www.mohfw.gov.in/pdf/ManualforSurveillanceTeamsforcontainmentzones.pdf#_blank
24 https://www.mohfw.gov.in/pdf/FinalSOPonSkillinstitutions&PGinstitutes08092020.pdf#_blank
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26 https://www.mohfw.gov.in/pdf/RevisedSOPonpreventivemeasurestobefollowedwhileconductingexaminationstocontainspreadofCOVID19.pdf#_blank
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31 https://www.icmr.gov.in/pdf/covid/techdoc/Advisory_Dry_Swab_RNAExtraction_26112020.pdf
32 https://www.mohfw.gov.in/pdf/StandardOperatingProceduresonpreventivemeasurestocontainspreadofCOVID19duringfestivities.pdf

(q) **SOP on Preventive Measures to be Followed in Entertainment Parks and Similar Places to Contain Spread of Covid-19 *(issued on October 8, 2020)*[33]:** This SOP specifies various generic precautionary measures to be adopted, in addition to specific measures to be ensured at entertainment parks and similar places to prevent the spread of Covid-19.

(r) **Guidelines for Management of Co-Infection of Covid-19 with Other Seasonal Epidemic Prone Diseases *(issued on October 13, 2020)*[34]:** These guidelines lay down steps for prevention and treatment of co-infections of Covid-19, with diseases like dengue, malaria, seasonal influenza (H1N1), leptospirosis, chikungunya, etc.

(s) **Guidelines on Managing Mental Illness in Hospital Settings during Covid-19 *(issued on November 1, 2020)*[35]:** These guidelines lay down the procedures and guidelines for management of patients, protecting persons with mental illness in mental health establishments from Covid-19 infection and clinical management of persons with mental illness or mental disability who test positive for Covid-19.

(t) **SOP on Preventive Measures in Markets to Contain Spread of Covid-19 *(issued on November 30, 2020)*[36]:** This SOP specifies various generic precautionary measures to be adopted, in addition to specific measures to be ensured at marketplaces to prevent the spread of Covid-19.

(u) **Frequently Asked Questions on Covid-19 Vaccine *(issued on December 17, 2020)*[37]:** These FAQs are meant for the general public and provide clarity with regards to the Covid-19 vaccine.

(v) **SOP for Epidemiological Surveillance and Response in the Context of New Variant of SARS-CoV-2 Virus Detected in the United Kingdom *(issued on December 22, 2020)*[38]:** This SOP specifies the activities to be undertaken at the point of entry and in the community for all international passengers, who have travelled from or transited through the United Kingdom, in light of the new variant of the Covid-19 virus.

(w) **Covid-19 Vaccines Operational Guidelines *(issued on December 28, 2020)*[39]:** These guidelines have been prepared in anticipation of a vaccine for Covid-19, and lay down various aspects of the vaccination programme such as training, administration, logistics, monitoring, etc.

vi. Import of Covid-19 Vaccines Though Courier

The Central Board of Indirect Taxes and Customs, *vide* Circular no. 56/2020-Customs, dated December 30, 2020[40], informed the concerned authorities that the Courier Imports and Exports (Electronic Declaration and Processing) Amendment Regulations, 2020, had been notified to facilitate the import/ export of Covid-19 vaccines.

These regulations *inter alia* provide for import and export of Covid-19 vaccines without any value limitation. Concerned authorities were also directed to form task forces at international courier terminals for efficient clearance of such vaccines.

vii. Advisory on Strategy for Covid-19 Testing in India

The ICMR, on September 4, 2020, issued an advisory on the strategy for Covid-19 testing in India[41]. In terms of this advisory, choices of tests (in order of priority) have been specified for (a) routine surveillance in containment zones and screening at points of entry; (b) routine surveillance in non-containment areas; (c) in hospital setting; and (d) testing on demand, respectively.

33 https://www.mohfw.gov.in/pdf/SOPonpreventivemeasurestobefollowedinEntertainmentParksandsimilarplacestocontainspreadofCOVID19.pdf
34 https://cdnbbsr.s3waas.gov.in/s3850af92f8d9903e7a4e0559a98ecc857/uploads/2020/10/2020101310.pdf
35 https://www.mohfw.gov.in/pdf/GuidelinesforDeliveryofMentalMentalHealthcareServicesduringtheCOVID19.pdf
36 https://www.mohfw.gov.in/pdf/30NovSOPonpreventivemeasuresinmarketstocontainspreadofCOVID19.pdf
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39 https://www.mohfw.gov.in/pdf/COVID19VaccineOG111Chapter16.pdf#_blank
40 https://www.cbic.gov.in/resources//htdocs-cbec/customs/cs-circulars/cs-circulars-2020/Circular-No-56-2020-updated.pdf
41 https://www.mohfw.gov.in/pdf/AdvisoryonstrategyforCOVID19TestinginIndia.pdf

viii. Extension of Validity of Import Licences

The MoHFW, *vide* Gazette Notification no. SO 4244(E), dated November 26, 2020[42], in exercise of its powers under Section 26B of the D&C Act, directed that notwithstanding anything contained in the D&C Rules, for import of drugs for sale or distribution, if an existing valid import licence holder under the said rules, makes an application for a fresh import licence before the expiry of the existing licence, the existing import licence shall be valid until orders are passed on the application and shall be deemed to be valid for all purposes. This direction will remain in force for a period of 6 (six) months, i.e. up till May 26, 2021.

ix. Covid-19 Vaccine Communication Strategy

The MoHFW, on December 30, 2020, issued a 'Covid-19 Vaccine Communication Strategy'[43] document. This strategy document is intended for dissemination of timely, accurate and transparent information about the vaccines, with the aim of alleviating apprehensions about the vaccine, ensuring its acceptance and encouraging uptake. The strategy is also supposed to guide national, state and district-level communication activities, so that information on the Covid-19 vaccine and vaccination process reaches all people across the country.

2. Notification of Cosmetics Rules, 2020

The MoHFW, *vide* Gazette Notification no. GSR 763(E), dated December 15, 2020[44], notified the Cosmetics Rules, 2020 ("**CR 2020**"). The CR 2020 replaces the provisions of the D&C Rules, which relates to cosmetics, and will act as a dedicated code for regulation of cosmetics in India. Some of the salient features of the CR 2020 are as follows:

(a) **Definition of 'New Cosmetics':** Rule 3 defines 'new cosmetics' as cosmetics containing a novel ingredient, which has not been used anywhere in the world or is not recognised for its use in cosmetics in any national or international literature. In terms of Rule 13 and 23 of the CR 2020, prior approval from the Central Licensing Authority ("**CLA**") is required for import and manufacture of such cosmetics. Further, in terms of Rule 32 of the CR 2020, the applicant for import and manufacture is required to submit data on safety and effectiveness of the cosmetics for obtaining approval.

(b) **Introduction of Change in Constitution Concept:** The D&C Rules were silent on the aspect of change in constitution. However, with the promulgation of CR 2020, the provisions of change in constitution, as provided under the Medical Device Rules, 2017 (MD Rules), now have also been incorporated under the CR 2020.

(c) **Increased Scrutiny and Compliance:** In terms of Rule 39 of CR 2020, it is prohibited to import or manufacture any cosmetics, unless it complies with the standards of quality and safety, applicable to it under the provisions of CR 2020.

(d) **Declaration by the Manufacturers:** In terms of Rule 23 of the CR 2020, the manufacturer of a cosmetic is required to provide a self-declaration, conforming compliance with 'good manufacturing practices', requirements of premises, plants and equipment for manufacture of cosmetics as specified in the seventh schedule to the CR 2020.

(e) **Inspection for Verification of Compliance:** In terms of Rule 57 of the CR 2020, the State Licensing Authority ("**SLA**"), along with inspector appointed by the Central Government and the State Government under Section 21 of the D&C Act, are required to carry out inspection of the manufacturing premises and equipment used for testing of cosmetics and the professional qualification of the expert staff, prior to the approval. Further, in terms of Rule 31 of the CR 2020, manufacturing premises under licence are required to be inspected by inspectors appointed by the Central Government and the State Government for ensuring compliance with the conditions of licence and provisions of the D&C Act and CR 2020. The inspection is required to be carried out once in 3 (three) years.

Ahead of the publication of CR 2020, the CDSCO, in order to streamline the process of import registration of cosmetics and for ease of doing business, *vide* its notice dated January 19, 2021, bearing file number COS/MISC/12/18[45], notified the document titled 'frequently asked questions on registration and import of cosmetics into India'[46].

3. Regulation of Blood Glucose Monitors, Blood Pressure Monitors, Nebulizers and Thermometers

Nebulizers, Blood Pressure Monitoring Devices, Digital Thermometers and Glucometers became the subject matter

42 https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=NjcyMQ==
43 https://www.mohfw.gov.in/pdf/Covid19CommunicationStrategy2020.pdf#_blank
44 https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=Njc3NA==
45 https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=NjkxOQ==
46 https://cdsco.gov.in/opencms/export/sites/CDSCO_WEB/Pdf-documents/cosmetics/Frequently-Asked-Questions-FAQcosmeticia.pdf

of regulation as 'drugs', with effect from January 1, 2021. In this regard, the CDSCO, *vide* an Order (F. No. 29/Misc/03/2020-DC(297)) dated December 28, 2020[47], clarified that in case an existing importer/ manufacturer, who is already importing/ manufacturing any of these devices, has already submitted an application for grant of an import/ manufacturing license under the MD Rules, the said application shall be deemed to be valid and the importer/ manufacturer can continue to import/ manufacture the devices up to 6 (six) months from the date of this order, or till the licensing authority takes a decision on the said application, whichever is earlier.

4. Fee for Change in Address of Authorised Agent Without Change in Constitution

The CDSCO, *vide* Notice (No. 29/Misc/03/2020-DC (124)) dated August 31, 2020[48], observed that there is no need for submission any fee under the MD Rules in cases of post approval change in address of authorised agent, without change in constitution.

5. Regularisation of Fixed Dose Combinations

The CDSCO, *vide* a letter (F. No. 04-146/2007-DC(Part-I)) to all State and Union Territories' Drug Controllers, dated September 8, 2020[49], declared 3 (three) more fixed dose combination ("**FDC**") drugs as rational. These FDCs are (a) Atenolol + Losartan + Hydrochlorothiazide; (b) Duloxetine + Mecobalamin; and (c) Mecobalamin + Vit. B6 + Folic Acid. In terms of this letter, the date for submission of applications for approval of FDCs (by manufacturers holding licenses issued by the SLA) has also been extended up to March 31, 2021.

6. Pathway for Regularisation of FDCs Relating to Vitamins, Minerals, and Micronutrients

The CDSCO, *vide* a letter (File No. 4-01/2013-DC (Misc. 13-PSC) (Pt.III)) to all States and Union Territories' Drugs Controllers, dated August 3, 2020[50], notified the procedure/ pathway for grant of product licenses by the SLAs to the 471 (four hundred seventy one) FDCs, relating to vitamins, minerals and micronutrients, etc., which have been declared as rational by the Prof. Kokate Committee, and accepted by the MoHFW.

As per the notified pathway, applicants are required to submit the requisite fee to the CDSCO. The application for grant of manufacturing license is required to be submitted to the SLAs in terms of the D&C Rules, along with details of the FDC, serial no. of the FDC in the list, stability studies data (6 (six) months accelerated), test specification of the FDC, along with method of analysis, as well as label and other documents specified in the D&C Rules. The SLAs shall verify the quality of the concerned FDC and grant licenses for the same, without seeking any further no objection certificate from the Drugs Controller General of India ("**DCGI**"), if all other conditions of the licence are satisfied. Thereafter,

47 https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=Njc5Mg==
48 https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=NjQzMA==
49 https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=NjQ2Ng==
50 https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=NjM0NA==

every manufacturer who has been permitted to manufacture such FDCs will be required to submit periodic safety update reports to the CLA.

7. Classification of Newly Notified Medical Devices

The CDSCO, *vide* Notice (IVD/Misc/196/2020) dated September 3, 2020[51], issued a draft risk-based classification of medical devices, which were notified *vide* Gazette Notification nos. SO 648(E) and GSR 102(E) on February 11, 2020. This draft classification covers all IVD medical devices, which have been sub divided into (a) IVD Analyzer; (b) IVD Instrument; and (c) IVD Software.

The draft classification for the remaining newly classified medical devices was also issued by the CDSCO *vide* Notice (File. No. 29/Misc./03/2020-DC(200)), dated September 3, 2020[52]. In terms of this draft classification, the new medical devices have been sub divided into 24 (twenty-four) categories.

The CDSCO invited comments on these draft classifications by October 3, 2020.

8. Undertaking for Import of Drugs and Cosmetics

The CDSCO, *vide* Notice (File No. import/Misc./89/2015-DC) dated September 17, 2020[53], published the format of an undertaking to be submitted by importers of drugs and cosmetics at the time of importing such drugs and cosmetics. The undertaking is to the effect that the packaging of the drug/ cosmetic is not damaged or broken or destroyed and that the contents of the drug/ cosmetic have not deteriorated. This step has been taken to reduce human interface and promote online clearance of imported drugs and cosmetics.

9. Online Application for Free Sale Certificate, Market Standing Certificate and Non-Conviction Certificate of Medical Devices

The CDSCO, *vide* Notice (F. No. 29/Misc/03/2020-DC(205)) dated September 3, 2020[54], informed that the online portal for submission of applications and issuance of free sale certificate, market standing certificate and non-conviction certificate of medical devices has been operationalised. In this regard, it has been clarified that offline (hard copy) applications for these certificates will not be accepted after September 30, 2020.

10. Operationalisation of the National Medical Commission Act, 2019

The MoHFW, *vide* Gazette Notification no. SO 3262(E) dated September 24, 2020[55], has brought all provisions of the National Medical Commission Act, 2019 ("**NMC Act**"), into force, with effect from September 25, 2020.

The NMC Act was notified *vide* Gazette Notification No. 49 dated August 8, 2019[56]. The NMC Act repeals the Indian Medical Council Act, 1956 ("**IMC Act**"), and constitutes the National Medical Commission in place of the Medical Council of India ("MCI"). The Board of Governors appointed under the IMC Act in supersession of the MCI thus stands dissolved.

11. Drafts of Amendments to Rules and Regulations under the Food Safety and Standards Act, 2006 (FSS Act)

The MoHFW issued the following drafts of certain amendments to the Rules and Regulations formulated under the FSS Act, for comments from the relevant stakeholders:

(a) Food Safety and Standards (Amendment) Rules, 2020 *(issued vide Gazette Notification no. GSR 535(E) dated August 27, 2020[57])*;

(b) Food Safety and Standards (Packaging and Labelling) Amendment Regulations, 2020 *(issued vide Gazette notification no. F. No. 1/Stds/Notification/Sweeteners-labelling/FSSAI-2019, dated September 16, 2020[58])*;

(c) Food Safety and Standards (Contaminants, Toxins and Residues) Amendment Regulations, 2020 *(issued vide gazette Notification no. F. No. 01-SP (PAR) Notification-Pesticides /Stds-FSSAI/2017, dated August 20, 2020[59])*;

(d) Food Safety and Standards (Organic Foods) Amendment Regulations, 2020 *(issued vide Gazette Notification no. F.No. Stds/Organic/Notification-01/FSSAI-2019, dated August 27, 2020[60])*;

51 https://www.mohfw.gov.in/pdf/GuidelineforEyeCare.pdf
52 https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=NjQ1MA==
53 https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=NjQ5Ng==
54 https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=NjQ0OA==
55 http://www.egazette.nic.in/WriteReadData/2020/221939.pdf
56 http://egazette.nic.in/WriteReadData/2019/210357.pdf
57 https://www.fssai.gov.in/upload/uploadfiles/files/Draft_Notification_FSS_Rule_Amendment_04_09_2020.pdf
58 https://www.fssai.gov.in/upload/uploadfiles/files/Draft_Notification_Label_Sweetener_18_09_2020.pdf
59 https://taxguru.in/wp-content/uploads/2020/08/F.-No.-01-SP-PAR-Notification-PesticidesStds-FSSAI2017.pdf
60 https://www.fssai.gov.in/upload/uploadfiles/files/Draft_Notification_Organic_03_09_2020.pdf

(e) Food Safety and Standards (Prohibition and Restriction on Sales) Amendment Regulations, 2020 *(issued vide Gazette Notification no. F. No. 1-116/Scientific Committee/Notif.28.4/2010-FSSAI(2), dated August 27, 2020*[61]*);*

(f) Food Safety and Standards Authority of India (Transaction of Business and Procedures for the Scientific Committee and Scientific Panels) Regulation, 2016, Amendment Regulations, 2020 *(issued vide Gazette Notification no. F. No. F. 2-63/FSSAI/Tr. Business SC and SP/Reg/2020, dated August 27, 2020*[62]*);*

(g) Food Safety and Standards (Food Products Standards and Food Additives) Amendment Regulations, 2020 (issued *vide* Gazette Notification no. F. No. 1-116/Scientific Committee/Notif.28.4/2010-FSSAI(1) dated August 27, 2020[63]);

(h) Food Safety and Standards (Fortification of Foods) Amendment Regulations, 2020 (issued *vide* Gazette Notification no. F. No. Stds/Fortification/Misc-03/FSSAI-2018, dated December 4, 2020[64]);

(i) Food Safety and Standards (Licensing and Registration of Food Businesses) Amendment Regulations, 2020 (issued *vide* Gazette Notification no. F. No. 15(6)2017/ FLRS/ RCD/ FSSAI dated November 17, 2020[65]);

(j) Food Safety and Standards (Prohibition and Restrictions on Sales) Amendment Regulations, 2020 (issued *vide* Gazette Notification no. No. Stds/SP-15/T(T(IMST) dated November 10, 2020[66]);

(k) Food Safety and Standards (Packaging and Labelling) Amendment Regulations, 2020 (issued *vide* Gazette Notification no. F. No. Std/SP-08/A-1.2019/N-02 dated November 10, 2020[67]);

(l) Food Safety and Standards (Import) Amendment Regulations, 2020 (issued *vide* Gazette Notification no. F. No. 4067/MOC-Trade/Reg-FSSAI/2017(part-1) dated November 10, 2020[68]); and

(m) Food Safety and Standards (Fortification of Foods) Amendment Regulations, 2020 (issued *vide* Gazette Notification no. F. No. Stds/SP-18/A-1.12/N-1 dated November 10, 2020[69]).

12. Amendments to Rules and Regulations under the FSS Act

The MoHFW issued the following amendments to the Rules and Regulations formulated under the FSS Act:

(a) **Food Safety and Standards (Contaminants, toxins and Residues) First Amendment Regulations, 2020 *(issued vide Gazette Notification no. F. No. Stds/SP/(Contaminants)/Notification-1/FSSAI-2018, dated August 7, 2020*[70]*):*** This amendment modifies the permissible limits of metal contaminants, crop contaminants and naturally occurring toxic substances in food products.

(b) **Food Safety and Standards (Food Products Standards and Food Additives) Sixth Amendment Regulations, 2020 *(issued vide Gazette Notification no. F. No. Stds./M&MP/Notification(04)/FSSAI-2019, dated September 2, 2020*[71]*):*** This amendment lays down the standards for low lactose and lactose free milk, and mozzarella cheese.

(c) **Food Safety and Standards (Packaging and Labelling) First Amendment Regulations, 2020 *(issued vide Gazette Notification no. F. No. REG-18/Menu Labelling/FSSAI-2018, dated August 21, 2020*[72]*):*** This amendment prescribes the information that a food

61 https://www.fssai.gov.in/upload/uploadfiles/files/Draft_Notification_Prohibition_03_09_2020.pdf
62 https://www.fssai.gov.in/upload/uploadfiles/files/Draft_Notification_TR_Business_03_09_2020.pdf
63 https://www.fssai.gov.in/upload/uploadfiles/files/Draft_Notification_Walnuts_03_09_2020.pdf
64 https://fssai.gov.in/upload/uploadfiles/files/Draft_Notification_Fortification_Oil_Milk_14_12_2020.pdf
65 https://fssai.gov.in/upload/uploadfiles/files/Draft_Notification_FSS_Licensing_25_11_2020.pdf
66 https://fssai.gov.in/upload/uploadfiles/files/Draft_Notification_Prohibit_Mustard_Oil_18_11_2020.pdf
67 https://fssai.gov.in/upload/uploadfiles/files/Draft_Notification_Vegetable_Oil_18_11_2020.pdf
68 https://fssai.gov.in/upload/uploadfiles/files/Draft_Notification_FSS_Import_16_11_2020.pdf
69 https://fssai.gov.in/upload/uploadfiles/files/Draft_Notification_Fortified_Milk_Powder_13_11_2020.pdf
70 https://www.fssai.gov.in/upload/notifications/2020/08/5f3d09f97b78aGazette_Notification_Limit_Metal_19_08_2020.pdf
71 https://www.fssai.gov.in/upload/notifications/2020/09/5f50bca66e5bdGazette_Notification_Standards_Milk_Cheese_03_09_2020.pdf
72 https://www.fssai.gov.in/upload/notifications/2020/08/5f4611c4eca96Gazette_Notification_Information_Display_Food_26_08_2020.pdf

service establishment shall display on the menu cards or boards or booklets, such as calorific value and information relating to allergens.

(d) **Food Safety and Standards (Food Products Standards and Food Additives) Seventh Amendment Regulations, 2020 *(issued vide Gazette notification no. F. No. Stds/Additives-1/Notification/FSSAI/2018, dated September 16, 2020*[73]):** This amendment has included "4,5 epoxydec-2(trans)-enal" as a restricted flavouring agent, in addition to various amendments to Appendix-A (List of Food Additives) of the principal regulations.

(e) **Food Safety and Standards (Food Products Standards and Food Additives) Tenth Amendment Regulations, 2020 *(issued vide Gazette Notification no. F. No. 1-116/Scientific Committee/Notif./2010-FSSAI dated December 29, 2020*[74]):** This amendment lays down a definition for 'refined vegetable oil' and standards for the same.

(f) **Food Safety and Standards (Alcoholic Beverages) First Amendment Regulations, 2020 *(issued vide Gazette Notification no. F. No. Stds/SP(water and Beverages)/Notification(1)/FSSAI-2019, dated December 18, 2020*[75]):** This amendment modifies the standards for various alcoholic beverages, including *inter alia* 'low alcoholic beverage', 'fortified wine', and 'sherry'.

(g) **Food Safety and Standards (Fortification of Foods) First Amendment Regulations, 2020 *(issued vide Gazette Notification no. F. No. REG/Fortification Amendment (1)/Notification/FSSAI-2018 dated December 18, 2020*[76]):** This amendment includes a definition for 'fortified processed foods' and standards for the same.

(h) **Food Safety and Standards (Prohibition and Restrictions on Sales) Third Amendment Regulations, 2020 *(issued vide Gazette Notification no. Stds/O&F/Notification(12)/FSSAI-2019 dated October 26, 2020*[77]):** This amendment specifies that 'total polar compounds' in unused or fresh vegetable oil or fat shall not be more than 15% (fifteen percent) and used vegetable oil or fat having developed Total Polar Compounds more than 25% (twenty five percent) shall not be used.

(i) **Food Safety and Standards (Import) First Amendment Regulations, 2020 *(issued vide Gazette Notification no. F. No. 1-1275/FSSAI/Import/2015, dated October 20, 2020*[78]):** This amendment relates to modification of the procedure for clearance of imported food by the food authorities.

(j) **Food Safety and Standards (Prohibition and Restriction on Sales) Second Amendment Regulations, 2020 *(issued vide Gazette Notification no. F. No. Stds/Agmark-BIS/02/FSSAI-2018, dated October 20, 2020*[79]):** This amendment relates to deletion of regulations 2.3.2, 2.3.9 and 2.3.10 from the principal regulations.

(k) **Food Safety and Standards (Laboratory and Sample Analysis) Second Amendment Regulations, 2020 *(issued vide Gazette Notification no. F.No. 11023/24/2017-QA dated October 15, 2020*[80]):** This amendment prescribes *inter alia* that the sample of any imported article will be sent by the Authorised Officer for analysis to the food analyst of any of the laboratories notified under the FSS Act.

(l) **Food Safety and Standards (Food Products Standards and Food Additives) Ninth Amendment Regulations, 2020 *(issued vide Gazette Notification no. F. No. Stds/Processing aids/Notification/FSSAI/2018, dated October 9, 2020*[81]):** This amendment lays down the conditions and requirements for use of processing aids in food products.

(m) **Food Safety and Standards (Food Products Standards and Food Additives) Eight Amendment Regulations, 2020 *(issued vide Gazette Notification no. F. No. 1/Additional Additives-III/ Stds/ Notification/ FSSAI/2017, dated October 9, 2020*[82]):** This amendment amends the standards and requirements for additives used in various food products. This amendment *inter alia* inserts standards in relation to use of 'sorbitan esters of fatty acids', 'nisin' and 'sorbitan monostearate' in various food products.

73 https://www.fssai.gov.in/upload/notifications/2020/09/5f6443d153fc8Gazette_Notification_FPS_FA_Amendment_AppendixA_18_09_2020.pdf
74 https://fssai.gov.in/upload/notifications/2020/12/5fedb66ac1b15Gazette_Notification_FPS_Tenth_amendment_31_12_2020.pdf
75 https://fssai.gov.in/upload/notifications/2020/12/5fe0894d618cfGazette_Notification_Alcoholic_Beverages_21_12_2020.pdf
76 https://fssai.gov.in/upload/notifications/2020/12/5fe0896c5a160Gazette_Notification_Fortification_Foods_21_12_2020.pdf
77 https://fssai.gov.in/upload/notifications/2020/10/5f97f560d39aeGazette_Notification_Limit_Polar_Compound_27_10_2020.pdf
78 https://fssai.gov.in/upload/notifications/2020/10/5f9288da67acbGazette_Notification_FSS_Import_23_10_2020.pdf
79 https://fssai.gov.in/upload/notifications/2020/10/5f92abc8af09aGazette_Notification_Agmark_23_10_2020.pdf
80 https://fssai.gov.in/upload/notifications/2020/10/5f8d5d1b7ac6dGazette_Notification_Labs_19_10_2020.pdf
81 https://fssai.gov.in/upload/notifications/2020/10/5f8d5a959fdedGazette_Notification_Processing_Aids_15_10_2020.pdf
82 https://fssai.gov.in/upload/notifications/2020/10/5f86e028b231eGazette_Notification_Spices_14_10_2020.pdf

(n) **Food Safety and Standards (Advertising and Claims) First Amendment Regulations, 2020 *(issued vide Gazette Notification no. F. No. Stds/ SP(L&C/A)/ Oil Claims/FSSAI-2018, dated October 9, 2020*[83]):** This amendment provides a schedule of claims, which may be used in advertising or on labels of edible vegetable oils.

13. Food Safety and Standards (Foods for Infant Nutrition) Regulations, 2020

The MoHFW, *vide* Gazette Notification no. F. No. Stds/03/Notification (IFR)/ FSSAI-2017, dated December 4, 2020[84], notified the Food Safety and Standards (Foods for Infant Nutrition) Regulations, 2020. These regulations *inter alia* define 'infant food', 'infant formula' and 'food for infants based on traditional food ingredients' and lay down the general requirements and compositions of such food products.

14. Food Safety and Standards (Labelling and Display) Regulations, 2020

The MoHFW, *vide* Gazette Notification no. F. No. 1-94/FSSAI/SP(Labelling)/2014(Pt-2) dated November 17, 2020[85], notified the Food Safety and Standards (Labelling and Display) Regulations, 2020. These regulations *inter alia* prescribe the labelling requirements of pre-packaged foods and display of essential information on premises where food is manufactured, processed, served and stored.

15. Food Safety and Standards (Safe food and Balanced Diets for Children in School) Regulations, 2020

The MoHFW, *vide* Gazette Notification no. F. No. 15(1)2016/School Children Regulation/Enf/FSSAI, dated September 4, 2020[86], notified the Food Safety and Standards (Safe food and Balanced Diets for Children in School) Regulations, 2020. These regulations *inter alia* require school authorities, selling or catering meals by themselves in the school campus, to get registered as food business operators and to ensure that the food is safe and balanced. The school authorities are also required to encourage and promote consumption of safe and balanced diet in school canteens or messes or kitchens in terms of these regulations.

16. Draft for Inclusion of 'Tapentadol' in Schedule H1 of the D&C Rules

The CDSCO, *vide* Gazette Notification no. GSR 656(E), dated October 20, 2020[87], issued draft amendments to the D&C Rules for inclusion of 'Tapentadol' in Schedule H1 of the D&C Rules. Objections and comments were invited on the same from various stakeholders within a period of 30 (thirty) days of the publication of the draft amendment.

17. Extension in Regulation of 'Ultrasound Equipment'

The MoHFW, *vide* Gazette Notification no. GSR 3721(E) dated October 16, 2019[88], had notified 'ultrasound equipment' as medical devices, with effect from November 1, 2020. However, *vide* Gazette Notification no. GSR 3722(E), dated October 21, 2020[89], this has been extended to November 1, 2021.

83 https://fssai.gov.in/upload/notifications/2020/10/5f86e06ba342fGazette_Notification_Claims_Edible_Oil_14_10_2020.pdf
84 https://fssai.gov.in/upload/notifications/2020/12/5fd719575c4d5Gazette_Notification_Food_Infant_14_12_2020.pdf
85 https://fssai.gov.in/upload/notifications/2020/12/5fd87c6a0f6adGazette_Notification_Labelling_Display_14_12_2020.pdf
86 https://www.fssai.gov.in/upload/notifications/2020/09/5f55ecdfd1cbaGazette_Notification_Safe_Food_Children_07_09_2020.pdf
87 https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=NjYwOA==
88 http://egazette.nic.in/WriteReadData/2019/213288.pdf
89 https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=NjU5OQ==

News Updates

1. **The Union Ministry of AYUSH approves clinical study to access medicinal herbs in Covid-19 patients**

   The Union Ministry of AYUSH has approved a proposal to carry out a clinical study to assess the role of Vasa Ghana, Guduchi Ghana and Vasa-Guduchi Ghana in therapeutic management of symptoms in Covid-19 patients.[90]

   The study aims to look into the efficacy of mono-herbal formulations of whole extracts of vasa and guduchi, respectively, and polyherbal formulation of vasa-guduchi whole extract on therapeutic management of SARS-CoV2 positive asymptomatic and, or, mild Covid-19 symptomatic cases, along with the impact of the said formulations on the speed of viral replication.[91]

2. **SII Seeks India Trial of a Second Covid Vaccine**

   SII has applied to authorities to conduct a small domestic trial of Novavax Inc's Covid-19 vaccine, which was found to be 89.3% (eighty-nine point three per cent) effective in a UK trial, wherein 15,000 (fifteen thousand) people aged 18 (eighteen) to 84 (eighty-four) were enrolled.[92]

3. **SII looking for a USD 1 Billion funding to fight Covid-19, talks on with Blackstone, Kohlberg Kravis Roberts & Co. (KKR) and others**

   In order to facilitate the development of Covid-19 vaccine, SII, the world's largest vaccine manufacturer, is in discussion with private equity investors, including top tier private equity investors such as Blackstone and KKR, as well as philanthropists and social venture funds to raise up to USD 1,000,000,000 (United Stated Dollar One Billion only).

   For the fundraising process, a special purpose vehicle ("**SPV**") will be formed. The funds raised in this fundraising process will go into this SPV and not SII. SII has already received USD 150,000,000 (United Stated Dollar One Hundred and Fifty Million only) from the Bill & Melinda Gates Foundation for the development and distribution of the AstraZeneca-Oxford University vaccine candidate, as well as that of the United States ("**US**") biotech firm Novavax for low- and middle-income countries. SII has plans to manufacture 100 (one hundred) million doses every month and 400 (four hundred) million doses of the Oxford vaccine by the end of this year.[93]

   The fundraising process will be managed by Goldman Sachs, Citigroup Inc. and Avendus Capital Private Limited. SII has invested close to USD 200 million (United Stated Dollar Two Hundred Million only) for the AstraZeneca-Oxford vaccine at 'personal risk', in the initial stages. This was done with the aim of getting the necessary approvals to conduct trials and start manufacturing the vaccine.

90 http://www.pharmabiz.com/ArticleDetails.aspx?aid=131467&sid=1
91 https://www.hindustantimes.com/india-news/ayush-ministry-okays-clinical-test-efficacy-of-medicinal-herbs-in-covid-management/story-uPtySAyjPujHmtCiL8v6OK.html
92 https://www.ndtv.com/india-news/serum-institute-seeks-approval-to-conduct-trial-for-novavax-vaccine-2359761
93 https://health.economictimes.indiatimes.com/news/pharma/serum-institute-looking-for-a-1-billion-shot-to-fight-covid-talks-on-with-blackstone-kkr-and-others/77605473

4. **India's first vaccine portal**

The ICMR vaccine portal has developed an online vaccine portal[94] that will work as a repository for all information related to vaccine development in India.

At the beginning, the ICMR vaccine portal will reflect the information on Covid-19 vaccine in India. However, with time, the web portal will be strengthened with data available for all the vaccines used to prevent various diseases.[95]

5. **Bharat Biotech initiates steps for developing Covaxin for US markets, signs letter of intent ("LOI") with Ocugen Inc.**

Hyderabad-based Bharat Biotech has started initiating steps for manufacturing Covaxin Covid-19 vaccine for US markets. As part of this, the company has recently signed a binding letter of intent with US based Ocugen Inc to co-develop the vaccine.[96]

Having achieved positive results during the first part of phase-3 clinical trials for Covaxin, the company has now embarked on enrolling the remaining clinical trial subjects and has already registered more than 13,000 (thirteen thousand) volunteers for the second part of phase-3 clinical trials, which is going to be concluded by January 2021-end.

6. **The DCGI has directed all SLAs to recall batches of rapid antigen IVD kits of Labcare Diagnostics and SD Biosensor for non-compliance**

The DCGI has directed all SLAs to recall batches of rapid antigen IVD kits of Gujarat-based manufacturer Labcare Diagnostics India Pvt. Ltd. and Haryana-based SD Biosensor Healthcare Pvt. Ltd. for non-compliance with minimum acceptance criteria of sensitivity and specificity as stipulated by ICMR[97].

The said rapid antigen IVD kits have been found to be non-conforming to the requirements, as prescribed under Rule 7 of MD Rules, 2017, especially in Covid -19 pandemic situations.

Therefore, in public interest, SLAs have been directed to inform everybody to whom the two manufacturers had distributed or supplied such kits to stop further use of it and also recall the same with immediate effect.

7. **India & South Africa's proposal to waive IP rights on COVID-19 products fails to reach consensus at World Trade Organisation ("WTO")**

India and South Africa's joint proposal to the WTO to temporarily suspend certain Intellectual Property ("IP") rights related to Covid-19 medicines and diagnostics made progress at the WTO, but failed to reach consensus due to opposition from WTO member countries such as the US, the European Union ("EU") and the United Kingdom ("UK").

The US, EU, UK and other developed countries are of the view that suspension of IP rights will stifle innovation, which is particularly required in times like these. They also contend that solutions to this issue, raised by India and South Africa, can be sought under existing flexibilities provided under Trade Related Aspects of Intellectual Property Rights ("TRIPS") for public health and through other alternative mechanisms. IP rights as stipulated under TRIPS provides flexibilities as per Article 31 and Article 31bis to member countries to use patented inventions without authorisation of the right holder, in cases of national emergency, extreme urgency, or public non-commercial use to safeguard public health at the national level by way of compulsory licencing[98].

8. **Biological E Limited ("BE") signs exclusive licence agreement for COVID-19 vaccine with US-based Ohio State Innovation Foundation ("OSIF")**

JThe Hyderabad-based BE and US-based OSIF have signed an exclusive agreement for sharing the necessary technology to develop a Covid-19 vaccine in the upcoming period.

OSIF has licenced novel live attenuation measles virus vectored vaccine candidate against SARS-Cov-2, which were developed by the Ohio State University College of Veterinary Medicine.[99] In continuation to this, the Hyderabad-based vaccine maker BE will be responsible for the evaluation and further development, including commercialisation of the said vaccine.[100]

9. **Generic Aadhaar to open eight hundred-plus retail outlets across the country by December 2020 to provide generic medicines to underprivileged people**

ITo cater to the medicinal needs of underprivileged people, Swasthya Lifescience Pvt Ltd. (registered trademark-Generic

94 vaccine.icmr.org.in
95 https://health.economictimes.indiatimes.com/news/health-it/soon-india-will-have-its-dedicated-vaccine-portal-icmr/77701212
96 http://www.pharmabiz.com/ArticleDetails.aspx?aid=134364&sid=1
97 http://www.pharmabiz.com/ArticleDetails.aspx?aid=134221&sid=1
98 http://www.pharmabiz.com/ArticleDetails.aspx?aid=134172&sid=1
99 https://techtransfercentral.com/2020/12/23/biological-e-to-commercialize-covid-19-vaccine-developed-at-ohio-state/
100 http://www.pharmabiz.com/ArticleDetails.aspx?aid=134040&sid=1

Aadhaar), which is a Mumbai-based pharmaceuticals company, intends on expanding its pan-India reach by opening more than 800 (eight hundred) plus retail outlets across India by December 2021. The company is currently operating 45 (forty-five) outlets in cities such as Mumbai and Pune.

Generic Aadhaar works on the same mission plan as laid out under the Pradhan Mantri Jan Aushadi Yojana. Under the mandate of Generic Aadhaar, the company provides medication directly from WHO-GMP facility and has tied up with drug retailers from Mumbai, Pune, Bengaluru and Odisha, following a profit-sharing model. It follows a pharmacy-aggregator business model, sourcing generic drugs directly from the manufacturer to the drug retailer, which delivers medicines to masses at a much lesser cost. Being a B2B2C model, it aims to provide Indians with affordable medication, by supporting single retail drug stores across the nation.[101]

10. Odisha Government accords in-principle approval for active pharmaceutical ingredient (API) Park in Ganjam district

In furtherance to the initiatives taken by the Government of India to incentivise bulk manufacturing of drugs here by drug manufacturers and to reduce the dependence on APIs being imported (primarily from countries like China), the State Government of Odisha has given its in-principle approval for the development of an API Park in Gopalpur in Ganjam district.

Furthermore, in order to hasten the process of setting up of the said API Park, the industry department of the State Government shall set up a special purpose vehicle and a detailed report to that effect will be prepared for the Government of India, for its approval.

We understand that the pharma park for the API will be set up in a 1,000 (one thousand) acre land area at the Tata Steel Special Economic Zone at Gopalpur, which is well connected with national highways and the airport. The park will be established with the financial assistances of both the Union Government and the State Government. The estimated infrastructure development cost for the park is INR 1,500,00,00,000 (Indian Rupees One Thousand Five Hundred crore only), out of which INR 1,000,00,00,000 (Indian Rupees One Thousand crore only) is expected from the Union Government.[102]

The project envisages all infrastructure facilities for the API park, which is expected to consist of a technology business incubator to support start-ups, advanced effluent treatment

101 http://www.pharmabiz.com/ArticleDetails.aspx?aid=131007&sid=1
102 http://www.pharmabiz.com/ArticleDetails.aspx?aid=130980&sid=1

plant, solid waste management facilities, warehousing, own power distribution system, common cooling system, state-of-the-art testing laboratory and IPR services. It is estimated that the API park can provide job opportunities for 5,000 (five thousand) people, especially pharmacy graduates and postgraduates.[103]

11. NPPA further extends price cap on knee implants by one year to September 16, 2021

The National Pharmaceutical Pricing Authority ("NPPA") has further extended price cap on knee implants by 1 (one) year to September 16, 2021, from the earlier date of September 15, 2020.

The NPPA had earlier extended the price cap on knee implants from August 15, 2020, to September 15, 2020, which was earlier applicable for a period of 1 (one) year from August 16, 2019, to August 15, 2020. This is in lieu of the notifications dated August 16, 2017, and August 13, 2018, issued by the NPPA, regarding the fixation of ceiling price of orthopaedic knee implants issued under paragraph 19 of DPCO-2013.[104]

The NPPA fixed the ceiling prices of orthopedic implants, used in knee surgeries, in order to prevent unethical profiteering and ensure affordable and quality healthcare for the public. The NPPA had imposed price ceiling on knee replacement systems and categorised knee implants into two major categories -- primary knee replacement systems and revision knee replacement systems.[105] As per the data available with the NPPA, it was found that there was a huge margin of unreasonable profits, which was added during the sale of these implants – thus the NPPA took the decision to set a price cap for the said implants.

12. Department of Pharmaceuticals ("DoP") to set up 10 (ten) pharma clusters to equip Micro, Small and Medium Enterprises ("MSMEs") to meet global regulatory standards

The DoP, in an effort to encourage pharma MSMEs to equip themselves in order to meet the regulatory requirements of Pharmaceutical Inspection Cooperation Scheme (PICS), has decided to set up 10 (ten) clusters in the country under its cluster development scheme, with a grant-in-aid of INR 20,00,00,000 (Indian Rupees Twenty Crores) for each cluster.

The aim of the scheme is to increase competitiveness, easy access to standard testing facilities and value addition in the domestic pharma industry, especially to small and medium enterprises, through the creation of common world class facilities, such as common testing facilities, training centre, research and development centres, effluent treatment plant, and common logistics centre.[106]

13. Government of Andhra Pradesh signs pact with IICT to set up bulk drug park to boost pharma manufacturing

The Andhra Pradesh Government has taken the decision to set up a bulk drug park in order to give impetus to the pharma manufacturing sector. Presently, the state has an industrial cluster at the Jawaharlal Nehru Pharma City at Parawada in Vishakhapatnam, which serves as a major pharma manufacturing centre of the state. However, to boost the API manufacturing sector, the state government has recently entered into an agreement with CSIR-IICT, Hyderabad, to establish a second major bulk drug hub in the state.

Moreover, as the central government, as part of its policy to establish more bulk drug parks to ensure the Indian pharma industry gains self-reliance, reducing its dependence on China for sourcing APIs and other key starting materials, and the Andhra Pradesh Government are trying to cash in on this opportunity and are planning to set up one among the 3 (three) major bulk drug clusters announced by the Central Government.

14. Centre steps up interventions for geriatric population as part of Draft National Policy for Senior Citizens 2020

In the wake of the Covid-19 outbreak and the resultant lockdown, the Union health ministry has stepped up interventions for geriatric population as part of Draft National Policy for Senior Citizens 2020, to ensure the safety and health of senior citizens. Seniors are the most vulnerable and high-risk demographic segment due to pre-existing conditions and co-morbidities, requiring active interventions, especially in the midst of a major healthcare crisis.[107]

103 https://www.expresspharma.in/infrastructure/odisha-gives-in-principle-nod-for-bulk-drug-park-at-gopalpur/
104 http://www.pharmabiz.com/ArticleDetails.aspx?aid=131157&sid=1
105 https://www.thehindubusinessline.com/economy/policy/nppa-further-extends-price-cap-on-knee-implants-by-one-year/article32629761.ece
106 http://www.pharmabiz.com/ArticleDetails.aspx?aid=131272&sid=1
107 https://www.expresshealthcare.in/news/nathealth-recommends-steps-to-strengthen-draft-national-policy-on-senior-citizens-2020/425280/

There was a need for structured care programmes, targeted policies, specialised medical services, and economic or financial interventions to ensure better quality of life for seniors. The Draft National Policy for Senior Citizens 2020 reflects the understanding of the evolving needs of seniors and promises to revamp and standardise the existing policy framework to ensure better efficiency and functional relevance.[108]

15. Health ministry to amend D&C Rules to specify batch number on final container label of trade pack for vaccines

The Union health ministry is planning to amend the D&C Rules to specify batch number on separate final container label of trade pack (final packed unit) for vaccines, containing multi-components.

The amendment is based on the premise of CDSCO, apprising the Drugs Technical Advisory Board about its clarification to GSK Pharmaceutical Limited that in case of multi component vaccines, the outer carton of vaccine should contain combined batch number and expiry date of component with shortest expiry date.[109] However, the primary label of individual components may contain their respective batch numbers and expiry dates. Also, the firm is needed to have proper record and traceability for said combined batch number.[110]

16. DCGI bans manufacturing, sale, distribution of ulipristal acetate tablets 5 mg

The DCGI has directed SLAs to direct manufacturers to suspend the manufacturing, sale or distribution of ulipristal acetate tablets 5 (five) mg, based on the recommendation of European Medicines Agency. SLAs have also been directed to recall the stock, in respect of the subject product from the market. The action taken in the matter may be communicated to this directorate at the earliest, as per DCGI directive. [111]

Ulipristal acetate (Fibristal) (5 mg tablets) has been widely used for the treatment of moderate to severe signs and symptoms of uterine fibroids in adult women of reproductive age, who are eligible for surgery.[112]

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108 http://www.pharmabiz.com/ArticleDetails.aspx?aid=134021&sid=1
109 https://thehealthmaster.com/2020/11/24/govt-to-amend-dc-rules-to-specify-batch-number-on-final-container/
110 http://www.pharmabiz.com/ArticleDetails.aspx?aid=133686&sid=1
111 http://www.pharmabiz.com/ArticleDetails.aspx?aid=133514&sid=1
112 https://www.drugscontrol.org/news-detail.php?newsid=28317&act=0&subject=0&bdrugs=0

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