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A quarterly update on the Pharma Industry

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Dear Readers,

We hope that all of you and your families are safe and healthy during this unprecedented and stressful time.

Just when we thought that the worst was behind us, we were hit by an even deadlier second Covid wave, which left the country and its people in a fix. However, by the onset of the third quarter of 2021, the country witnessed a steady decline in the number of daily cases, thereby causing a brisk return to the new normal. This period led the Government to re-evaluate the healthcare ecosystem of the country. Focus shifted to regulatory changes that were required to combat the pandemic.

On the advocacy front, we witnessed a slew of developments in the past few months, when various High Courts and the Supreme Court took cognizance of the mismanagement of Covid-19 relief programmes and regularly issued directions to combat the issues therein. This period also saw a rise in *suo moto* judicial activism when the Supreme Court observed that the vaccination policy of the Government conflicts with the constitutional balance of responsibilities between the Centre and States, wherein the Central Government granted the liberty to the States to procure the vaccines directly from the manufacturers. Acting swiftly, the Government introduced reforms in its Covid-19 vaccination strategy, along with changes in its vaccine procurement norms, thereby reverting to its earlier centralised procurement model. These reforms, coupled with a surge in the number of vaccination doses administered, led to the reduction in the number of Covid-19 related fatalities in the country. In another pivotal matter before the Supreme Court, the Court sought the response of the Central Government to operationalise all provisions of the Clinical Establishments Act, 2010, as well as the Clinical Establishment Rules, 2012, in order to ensure affordable and quality healthcare in the country.

On the policy and governance side, we witnessed a few developments that could have far reaching consequences, for instance, the decision of the National Pharmaceutical Pricing Authority (NPPA) to monitor the prices of *inter alia* oxygen concentrators and directing the manufacturers and importers of such devices to submit the MRPs of such devices, classification of newly notified medical devices as drugs, amending the definition of 'Bioavailability and Bioequivalence Study Centre' in the NDCT Rules, etc.

On the vaccination front, the scope of the vaccination drive was expanded on May 1, 2021, with the inclusion of the population group between 18 to 44 years. During this period, India saw rapid growth in vaccination rates, including the approval of newer Covid-19 vaccines. As of September 14, 2021, there are eight approved Covid-19 vaccines available for restricted use in emergency situations in the country.

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Despite the challenges posed by the second wave of Covid-19, we continued to witness healthy merger and acquisition activity in the pharmaceutical, healthcare and life sciences space. We have endeavoured to cover some of the most important regulatory, litigation, deals, and news updates for the second and third quarter of FY21 in this newsletter.

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

Please stay safe.

Regards,
CYRIL SHROFF

Managing Partner
Cyril Amarchand Mangaldas

India's leading law firm

Regulatory Updates

1. Changes in Covid-19 Vaccination Strategy

Numerous changes were introduced to India's vaccination strategy over the past few months. This period coincided with the catastrophic second wave of Covid-19. During this period, India also faced a shortage in the supply and deployment of vaccines. This resulted in a vaccination strategy that is ever-evolving and highly dynamic in nature. Some of the major changes that have taken place during this period are as follows:

(a) Liberalised Pricing and Accelerated National Covid-19 Vaccination Strategy[1]

The Ministry of Health and Family Welfare (**MoHFW**) on April 21, 2021, issued a revised and liberalised policy for pricing of vaccines and an accelerated National Covid-19 Vaccination Strategy. In terms of the revised vaccination strategy, all vaccine manufacturers in India were required to supply 50% (fifty percent) of their monthly doses to the Central Government and were given the freedom to supply the remaining 50% (fifty percent) to State Governments and 'other than Government of India channel', which include private hospitals. The Central Government run Covid-19 Vaccination Centres (**CVCs**) continued to prioritise the administration of vaccines to Health Care Workers, Front Line Workers, and individuals aged above 45 (forty five) years for free; while all other supply channels catered to everyone aged above 18 (eighteen) years. Fully ready to use imported vaccines were not subject to the aforementioned supply division. The Central Government, from its share, allocated vaccines to the States and Union Territories on the basis of their performance in vaccine administration and the severity of the outbreak in the respective regions.

Further, revised guidelines for vaccination were issued by the MoHFW on June 8, 2021. In terms of these revised guidelines, which came into effect on June 21, 2021, the Government of India would procure 75% (seventy five percent) of the vaccines being produced by the manufacturers in the country. The vaccines procured will be provided free of cost to the States and Union Territories, who will in turn administer such doses free of cost to their citizens through Government vaccination centres. Priority (for vaccination) will be given to (in order of preference) Health Care Workers, Front Line Workers, citizens above 45 (forty five) years of age; citizens whose second dose has become due; and citizens above the age of 18 (eighteen). Allocation to States and Union Territories will be based on criteria such as population, disease burden and the progress of vaccination. Wastage of vaccines will affect the allocation negatively. Private hospitals can only charge a maximum of INR 150 (Indian Rupees One Hundred and Fifty) per dose as service charges for the vaccines administered by them.

(b) Guidelines for Covid-19 Vaccination at Workplace[3]

The MoHFW, on April 7, 2021, issued guidelines for vaccination drives at workplaces, which had 100 (one hundred) or more beneficiaries aged 45 (forty five) years or above. In terms of these guidelines, identification of eligible workplaces (public and private) would be undertaken by a District Task Force (**DTF**). Upon identification, such workplaces would be registered on the CoWIN app as Government or Private CVCs at Workplace. Each eligible workplace ought to have a designated staff member as the 'Nodal Officer' to supervise and make necessary arrangements for such vaccination drives. The beneficiaries of such scheme shall be limited to employees (no family members) of the establishments aged 45 (forty five) years or above, who must register on the CoWIN app. All CVCs at workplace shall be tagged with an existing and nearest CVC, which shall be responsible for deployment of trained vaccination teams at workplaces. Each vaccination team shall consist of a team leader (doctor), vaccinator, and three vaccination officers tasked with CoWIN verification, crowd management, and monitoring of adverse effects following immunisation. Private workplaces shall be subject to a price ceiling of INR 250 (Indian Rupees Two Hundred and Fifty) per dose. DTFs shall undertake random monitoring to ensure compliance with guidelines at all CVCs at workplaces.

(c) Guidance for Import of Vaccines[4]

The Central Drugs Standard Control Organisation (**CDSCO**), *vide* a notification dated May 4, 2021, prescribed the requirements for import of vaccines by a private entity, considering the accelerated vaccination strategy. In case of vaccines that have not been approved/ licenced in India, the importer or an agent of

[1] https://www.mohfw.gov.in/pdf/LiberalisedPricingandAcceleratedNationalCovid19VaccinationStrategy2042021.pdf
[2] https://www.mohfw.gov.in/pdf/RevisedVaccinationGuidelines.pdf
[3] https://www.mohfw.gov.in/pdf/GuidelinesforCOVID19VaccinationatWorkplace.pdf
[4] https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=NzE3Nw==

the manufacturer will be required to obtain permission under the New Drugs and Clinical Trials Rules, 2019 (**NDCT Rules**), and obtain import registration and import licence under the Drug and Cosmetics Rules, 1945. Upon obtaining such licences, the importer may import the vaccine and the same may be supplied to any private entity, subject to the restrictions placed by the national Covid-19 vaccination related guidelines.

(d) **Accelerated Approval of Foreign-Approved Covid-19 Vaccines**[5]

The CDSCO, vide a notice dated April 15, 2021, laid down the pathway for approval of foreign vaccines, which have been granted emergency use approval by the USFDA, EMA, UK MHRA, PMDA Japan, or the WHO Emergency Use Listing. Approval of such vaccines is subject to : (i) the vaccines being used in accordance with the National Covid-19 Vaccination guidelines; (ii) first 100 (one hundred) beneficiaries being monitored for 7 (seven) days for safety before conducting a full-fledged vaccination drive; and (iii) upon approval, the applicant initiating bridging clinical trials within 30 (thirty) days.

The notice also lays down the procedure for such application which may be made by a foreign manufacturer through its subsidiary or agent in India on the SUGAM portal. Such applications will be processed on priority and a decision shall be communicated to the applicant within 3 (three) working days of the application being filed. A foreign manufacturer proposing to import vaccines can apply for registration certificate and import licence along with the application for emergency use approval, and this application will also be processed within 3 (three) working days of grant of emergency use approval. Each batch of vaccine will be tested at Central Drugs Laboratory, Kasauli (**CDL**).

In light of the worsening conditions and the heightened demand for vaccine doses, the CDSCO, *vide* a notice dated June 1, 2021, dispensed with the requirement for testing every batch at CDL, as well as post-approval bridging trials, in case of vaccines that have been granted approval for emergency use by the USFDA, EMA, UK MHRA, PMDA Japan, or the WHO Emergency Use Listing, and if the vaccine batch/ lot has been certified and released by the 'national control laboratory' of its country of origin.[6]

2. Notification of Drugs (3rd Amendment) Rules, 2021[7]

The MoHFW, *vide* Gazette Notification no. GSR 258(E) dated April 7, 2021, notified the Drugs (3rd Amendment) Rules, 2021. The amendment adds 'Tapentadol' in Schedule H1 of the Drugs and Cosmetics Rules, 1945 (**D&C Rules**), and shall come into effect from November 1, 2021.

[5] https://cdsco.gov.in/opencms/export/sites/CDSCO_WEB/Pdf-documents/notice15april21.pdf
[6] https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=NzI4Mg==
[7] https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=NzE0MA==

3. Prohibition on Fixed Dose Combination of Corticosteroid[8]

The MoHFW, *vide* Gazette Notification no. GSR 255(E) dated April 7, 2021, amended the principal notification G.S.R. 578(E), which prohibits the manufacture and sale of certain Fixed Dose Combinations (**FDC**) of steroids for internal use. The amendment provides for substitution of item 14 in the principal notification with 'FDC of corticosteroid with any other drug [excluding FDC of Tamusolin HCI 0.4mg (as film coated modified release tablet) + Deflazacort 30mg (hard gelatin capsule)] for internal use, except for meter dose inhalers and dry powder inhalers'.

4. Enforcement of Measures to Stop Hoarding/ Black Marketing/ Overcharging of Covid-19 Management Drug 'Remdesivir'[9]

The CDSCO, *vide* a letter to the Drug Controllers of all States and Union Territories, dated April 10, 2021, directed them to instruct their enforcement staff to keep strict vigil and take stringent action against instances of hoarding/ black marketing or overcharging for 'Remdesivir' through special investigations.

5. Regulation of Newly Notified Medical Devices[10]

The CDSCO, *vide* an Order dated April 18, 2021, stipulated that importers/ manufacturers are required to take import/ manufacturing licence from Central or State Licensing Authority, as the case may be, for import of: (i) All Implantable Medical Devices, (ii) CT Scan equipment, (iii) MRI equipment, (iv) Defibrillators, (v) PET equipment, (vi) Dialysis Machine, (vii) X-Ray Machine, and (viii) Bone marrow cell separator, with effect from April 1, 2021. In this regard, an existing importer/ manufacturer already importing any of these devices, who has submitted an application to the aforementioned licencing authorities for grant of such licence under Medical Devices Rules, 2017 (**MD Rules**), shall be entitled to import/ manufacture such devices up to 6 (six) months or until a decision is taken by the licencing authority, whichever is earlier.

6. Extension of Permission for Import of Drugs with Residual Shelf Life of Less Than 60%[11]

The CDSCO, *vide* a Circular dated April 13, 2021, extended until October 31, 2021, the permission granted through previous circulars dated April 17, 2020, July 10, 2020, and December 18, 2020, for import of drugs with residual shelf life of less than 60% under special conditions.

7. Supply of Essential In-Vitro Diagnostic Testing Reagents/ Kits[12]

The CDSCO, *vide* a Letter dated April 29, 2021, requested all manufacturers and importers of diagnostic test reagents/ kits i.e. (i) Interlukin 6; (ii) D-Dimer; and (iii) C-reactive protein, to increase manufacturing and imports to maximum capacity in light of surge in the number of Covid-19 cases.

8. Guidance Notes, Standard Operating Procedures and Guidelines

The MoHFW issued various guidance notes, standard operating procedures (**SOPs**) 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) **Revised Guidelines for Home Isolation of Mild/ Asymptomatic Covid-19 Cases (*issued on April 28, 2021*)[13]:** These guidelines, in supersession to the earlier guidelines issued on July 2, 2020, lay down the eligibility for home isolation, along with instructions on monitoring of patient, treatment, etc;

b) **SOP on Covid-19 Vaccination of Persons without prescribed Identity Cards through CoWIN (*issued on May 6, 2021*)[14]:** This SOP lays down the procedure, developed in consultation with the technical experts, for providing vaccination coverage to people who do not possess any of the seven Identity Cards prescribed for availing vaccination services;

[8] https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=NzE0MQ==
[9] https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=NzExMw==
[10] https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=NzE0Ng==
[11] https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=NzE0NA==
[12] https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=NzE2Mg==
[13] https://www.mohfw.gov.in/pdf/RevisedguidelinesforHomeIsolationofmildasymptomaticCOVID19cases.pdf
[14] https://www.mohfw.gov.in/pdf/SOPforCOVID19VaccinationofPersonswithoutPrescribedIdentityCards.pdf

c) **SOP on Covid-19 Containment & Management in Peri-urban, Rural & Tribal Areas (*issued on May 16, 2021*)[15]:** This SOP lays down the containment and clinical management practices to be put in place in peri-urban, rural and tribal areas with respect to Covid-19 management;

d) **Guidance Note on Near to Home Covid-19 Vaccination Centres (NHCVC) for Elderly and Differently Abled Citizens (*issued on May 27, 2021*)[16]:** This guidance note lays down the proposed community-based approach where sessions can be conducted in non-health facility based settings and are nearer to home, process and infrastructure, for vaccination of elderly and differently abled citizens;

e) **Guidelines on Operationalisation of Covid Care Services for Children & Adolescents (*issued on June 16, 2021*)[17]:** These guidelines lay down the infrastructure, manpower and clinical management requirements for treatment of Covid-19 in children and adolescents;

f) **Operational Guidance for Covid-19 Vaccination of Pregnant Women (*issued on July 2, 2021*)[18]:** These guidelines lay down the framework which States must adopt for developing a counselling and vaccination plan for pregnant women; and

g) **Guidelines for Domestic Travel (Flight/ Train/ Ship/ Bus Inter-State Travel) (*issued on August 25, 2021*)[19]:** These, in supersession to the earlier guidelines issued on May 24, 2020, lay down the revised requirements for domestic travel (flight/ train/ ship/ bus inter-state travel) so as to have a uniform protocol across the country.

9. Pricing of Oxygen Concentrators

The NPPA, *vide* an office Memorandum dated June 29, 2020[20], had decided to monitor the prices of, *inter alia*, oxygen concentrators and had directed manufacturers and importers of such devices to submit the MRPs of such devices to the NPPA. In this regard, *vide* Gazette Notification no. SO 2161(E) dated June 3, 2021[21], the MRP of oxygen concentrators was fixed in the below-mentioned manner:

"MRP = Price to Distributor (PTD) + (PTD x TM) + Applicable GST, Where TM = Trade Margin not exceeding 70%.".

10. Notification of Draft Amendments to the D&C Rules

The MoHFW, *vide* Gazette Notification no. GSR 502(E) dated July 22, 2021[22], published the draft of an amendment to the D&C Rules for objections and suggestions from various stakeholders. The proposed amendment is aimed at amending Rule 127 of the D&C Rules to allow for disinfectants to contain colours specified under 'S 4707 (Part I), as amended by the Bureau of Indian Standards'. Objections and suggestions to this draft amendment can be submitted within a period of 30 (thirty) days of their publication.

Further, the MoHFW *vide* Gazette Notification no. GSR 628(E) dated September 13, 2021[23], published another draft amendment to the D&C Rules, which proposes to include '*Liquid Antiseptics for household use*' in Schedule K of the D&C Rules, thereby exempting the same from the requirement of a sale licence (subject to certain conditions). Objections and suggestions to this draft amendment can be submitted within a period of 30 (thirty) days of their publication.

[15] https://www.mohfw.gov.in/pdf/SOPonCOVID19Containment&ManagementinPeriurbanRural&tribalareas.pdf
[16] https://www.mohfw.gov.in/pdf/RevisedVaccinationGuidelines.pdf
[17] https://www.mohfw.gov.in/pdf/GuidelinesonOperationalizationofCoVIDCareServicesforChildrenandAdolescents14062021.pdf
[18] https://www.mohfw.gov.in/pdf/OperationalGuidanceforCOVID19vaccinationofPregnantWoman.pdf
[19] https://www.mohfw.gov.in/pdf/Guidelinesfordomestictravelflighttrainshipbusinterstatetravel.pdf
[20] http://www.nppaindia.nic.in/wp-content/uploads/2020/06/OM-on-Pulse-Oximeter-and-Oxygen-Concentrator-29.06.2020.pdf
[21] https://www.nppaindia.nic.in/wp-content/uploads/2021/06/227375.pdf
[22] https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=NzQ0Ng==
[23] https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=NzY5MA==

11. Classification of Newly Notified Medical Devices

The MoHFW had, *vide* Gazette Notification no. SO 648 (E) dated February 11, 2021[24], notified all devices whether used alone or in combination, including a software or an accessory, intended by their manufacturer to be used specially for human beings or animals, which does not achieve the primary intended action in or on human body or animals by any pharmacological or immunological or metabolic means, but which may assist in its intended function by such means, as drugs. Accordingly, all such devices were brought within the purview of MD Rules. Accordingly, the Drug Controller General of India (**DCGI**) has, in terms of its powers under the MD Rules, notified the final risk-based classification of the following categories of medical devices:

a) **Medical Devices Pertaining to Anaesthesiology:** Notified *vide* Notice dated July 12, 2021[25];

b) **In-Vitro Diagnostic Medical Devices:** Notified *vide* Notice dated July 23, 2021[26];

c) **Medical Device Pertaining to Dermatological and Plastic Surgery:** Notified *vide* Notice dated July 26, 2021[27];

d) **Medical Device Pertaining to Rehabilitation:** Notified *vide* Notice dated July 26, 2021[28];

e) **Medical Device Pertaining to Cardiovascular:** Notified *vide* Notice dated July 26, 2021[29];

f) **Medical Device Pertaining to Interventional Radiology:** Notified *vide* Notice dated July 26, 2021[30];

g) **Medical Device Pertaining to Physical Support:** Notified *vide* Notice dated July 26, 2021[31];

h) **Medical Devices Pertaining to ENT:** Notified *vide* Notice dated August 6, 2021[32];

i) **Medical Device Pertaining to Respiratory:** Notified *vide* Notice dated August 6, 2021[33];

j) **Medical Device Pertaining to Radiotherapy:** Notified *vide* Notice dated August 6, 2021[34];

k) **Medical Device Pertaining to Ophthalmology:** Notified *vide* Notice dated August 9, 2021[35];

l) **Medical Device Pertaining to Software:** Notified *vide* Notice dated September 13, 2021[36];

m) **Medical Device Pertaining to General Hospital:** Notified *vide* Notice dated September 13, 2021[37];

n) **Medical Device Pertaining to Personal Protective Equipment:** Notified *vide* Notice dated September 13, 2021[38];

o) **Medical Device Pertaining to Nephrology and Renal Care:** Notified *vide* Notice dated September 13, 2021[39];

p) **Medical Device Pertaining to Operation Theatre:** Notified *vide* Notice dated September 13, 2021[40];

q) **Medical Device Pertaining to Pain Management:** Notified *vide* Notice dated September 13, 2021[41];

r) **Medical Device Pertaining to Urology:** Notified *vide* Notice dated August 23, 2021[42];

s) **Medical Device Pertaining to Paediatric and Neonatology:** Notified *vide* Notice dated August 23, 2021[43]; and

t) **Medical Device Pertaining to Obstetrical and Gynaecological:** Notified *vide* Notice dated August 23, 2021[44].

[24] https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=NTU0OA==
[25] https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=NzQyNg==
[26] https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=NzQ1Mg==
[27] https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=NzQ1Mw==
[28] https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=NzQ1Ng==
[29] https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=NzQ5Mg==
[30] https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=NzQ1NA==
[31] https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=NzQ1NQ==
[32] https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=NzU2Nw==
[33] https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=NzU2NQ==
[34] https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=NzU2Ng==
[35] https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=NzU2OA==
[36] https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=NzY1OQ==
[37] https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=NzY2NA==
[38] https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=NzY2MA==
[39] https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=NzY2Mw==
[40] https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=NzY2Mg==
[41] https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=NzY2MQ==
[42] https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=NzU5Mg==
[43] https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=NzU5Mw==
[44] https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=NzU5NA==

12. Steps to be followed by the Manufacturers/ Importers for Registration of Non-Notified Medical Devices

The CDSCO, *vide* a notification dated September 21, 2021[45], clarified the procedure to be followed by manufacturers and importers of medical devices for registration of their devices. The document published by the CDSCO, *inter alia*, contains details of the URL where the registration can be carried out, along with a step by step process, list of documents to be uploaded and the timelines for effecting the registration.

13. Clarifications in respect of the Cosmetics Rules, 2020

The CDSCO, *vide* a Notice dated August 6, 2021[46], provided detailed clarifications in respect of the Cosmetics Rules, 2020, with the aim of streamlining the process of import and registration of cosmetics. In terms of the clarifications provided, it has been specified that the validity of product endorsement will be effective from its date of issuance till the validity of the parent registration certificate in Form 43 (of the D&C Rules). Further, the documents required for issuance of registration certificate/ endorsement in Form COS-2, issuance of additional pack size endorsement for already registered products, and issuance of additional manufacturing site endorsements for already registered products, have also been specified.

14. Invitation of Public Comments on Steps Taken by CDSCO to Regulate Products Such as Skin Patches

The CDSCO, *vide* a notification dated July 26, 2021[47], invited all relevant stakeholders to submit their comments on the issue of regulation of products such as skin patches. The CDSCO specified that some importers are voluntarily registering skin patches containing cosmetics products under the Cosmetics Rules, 2020. However, Customs had released some consignments of skin patches based on the undertakings submitted by the importers that such skin patches do not require registration with the CDSCO. The CDSCO had invited comments to be submitted within a period of 30 (thirty) days from this notification.

15. Amendment in the Definition of 'Bioavailability and Bioequivalence Study Centre'

The MoHFW, *vide* Gazette Notification no. GSR 605(E) dated August 31, 2021[48], had notified the New Drugs and Clinical Trials (Amendment) Rules, 2021, which amended the definition of 'bioavailability and bioequivalence study centre' contained in Rule 2(1)(g) of the NDCT Rules from 'a centre created or established to undertake bioavailability study or bioequivalence study of a drug for either clinical part or for both clinical and analytical part of such study' to 'a centre created or established to undertake bioavailability study or bioequivalence study of a drug for either clinical part <u>or analytical part</u> or for both clinical and analytical part of such study'.

16. Extension in Ceiling Prices of Orthopaedic Knee Implants

The NPPA, *vide* Gazette Notification no. S.O. 2668(E) dated August 16, 2017, had notified the ceiling price of orthopaedic knee implants. The validity of this notification has been extended from time to time. Now, the NPPA, *vide* Gazette Notification no. SO 3670(E) dated September 10, 2021[49], has extended the validity of the price ceiling on orthopaedic knee implants till September 15, 2022.

[45] https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=NzcwMQ==
[46] https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=NzU3Mg==
[47] https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=NzQ5NQ==
[48] https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=NzYxNQ==
[49] https://www.nppaindia.nic.in/wp-content/uploads/2021/09/Gazette-Notification-3670-E_Knee-Implants_10092021.pdf

Major Litigation Updates

1. **Supreme Court's Directions on Covid-19 Vaccination and Management**

   The Hon'ble Supreme Court (**SC**), in Suo Motu Writ Petition (Civil) No. 3 of 2021, took *suo moto* notice of the crisis unleashed by the Covid-19 pandemic and issued notices to *inter alia* the Union of India, the Governments of the States and Union Territories, and to several petitioners who were before various High Courts. The parties were directed to show cause why uniform orders be not passed in relation to supply of oxygen; supply of essential drugs; method and manner of vaccination; and declaration of lockdown. *Vide* an order dated April 30, 2021, the SC *inter alia*, asked the National Disaster Management Authority to consider laying down minimum standards of relief regarding Covid-19. Furthermore, the SC also issued directions and recommendations with respect to medical infrastructure and lack of national policy for admission in hospitals, oxygen supply and availability, vaccine distribution, pricing of vaccines, potentiality of compulsory licencing for vaccines and essential drugs, supply of essential drugs, black marketing of essential drugs, and recommendations for augmenting healthcare workforce. Another order was passed on May 31, 2021, specifically dealing with vaccine procurement and distribution, effects of vaccination by private hospitals, impact of differential pricing, vaccine logistics, and the digital divide.

2. **Supreme Court notice to Centre on plea seeking directions for uniform healthcare standard**[50]

   The SC on July 27, 2021, sought the response of the Central Government on a plea filed before it, seeking directions for operationalising all the provisions of the Clinical Establishments Act, 2010 (**CE Act**) , as well as the Clinical Establishment Rules, 2012 (**CE Rules**), in order to ensure affordable and quality healthcare. The plea has sought directions for notification and implementation of the conditions for registration of clinical establishments such as observance of minimum standards, display of rates for procedures and services, compliance with the standard treatment protocol, as provided in Sections 11 and 12 of the CE Act, read with Rule 9 of the CE Rules. The plea has also sought directions that a grievance redressal mechanism be created for patients at the district, state and national level till the lacunae in the CE Act is filled by a suitable legislation.

[50] https://economictimes.indiatimes.com/industry/healthcare/biotech/healthcare/sc-notice-to-centre-on-plea-seeking-directions-for-uniform-healthcare-standard/articleshow/84790546.cms

Major Transactions

1. **Acquisition of Thyrocare by Pharmeasy**[51]

   API Holdings, the parent company of PharmEasy, has agreed to acquire a 66.1% (sixty six point one per cent) stake in Thyrocare Technologies. The value of the deal is estimated to be INR 4,546 Crore (Indian Rupees Four Thousand Five Hundred Forty Six Crore).

2. **Acquisition of 1MG Technologies by Tata Digital**[52]

   Tata Digital Ltd, the subsidiary company of Tata Sons Pvt. Ltd., announced its intention to acquire a majority stake in 1MG Technologies for an undisclosed amount. 1MG Technologies is a leading digital health company, having access to a wide range of products like medicines, health and wellness products, diagnostic services and teleconsultation to customers.

3. **Acquisition of Hemmo Pharmaceuticals by Piramal Pharma**[53]

   Piramal Pharma, a subsidiary of Piramal Enterprises, acquired a 100% (One Hundred per cent) stake in Hemmo Pharmaceuticals for an upfront consideration of INR 775 Crore (Indian Rupees Seven Hundred Seventy Five Crore).

4. **Acquisition of Vikram Hospital by Manipal Hospitals**[54]

   Manipal Hospitals announced its intention to acquire a 100% (One Hundred per cent) stake in Vikram Hospital, located in Bengaluru. Vikram Hospital is a 200 (two hundred) bed hospital, which provides high-end tertiary care, including cardiac and neurosciences.

5. **Ipca Labs Acquires Stake in Trophic Wellness**[55]

   Ipca Laboratories acquired a 13.09% (thirteen point zero nine per cent) stake in Trophic Wellness Pvt. Ltd. The value of the deal is estimated at INR 21.20 Crore (Indian Rupees Twenty One point Two Crore). This, coupled with its previous holdings, will make Trophic Wellness Pvt. Ltd. a subsidiary of Ipca Laboratories.

6. **Acquisition of Vardhman Health Specialties by Aknamed**[56]

   Aknamed acquired Vardhman Health Specialties, in a deal estimated to be worth around USD 35 Million (United States Dollars Thirty Five Million). Aknamed is a hospital-focused supply chain platform, and this deal will allow it to enhance its footprint across India.

7. **Acquisition of Majority Stake in Sanskritech by Mylab**[57]

   Mylab Discovery Solutions acquired a majority stake in Sanskritech, the developer of 'Swayam', an indigenously designed portable diagnostic system. Mylan plans to start deployment of this system with partner labs by November of this year.

8. **Amalgamation of Lincoln Parenteral and Lincoln Pharmaceuticals**[58]

   The Ahmedabad bench of the National Company Law Tribunal approved the scheme of amalgamation of Lincoln Parenteral Ltd. and Lincoln Pharmaceuticals. This amalgamation is expected to enhance the efficiency, cost-effectiveness and productivity of the combined entity i.e. Lincoln Pharmaceuticals.

9. **Acquisition of CareNow by Healthium**[59]

   CareNow Medical Pvt. Ltd., which manufactures medical devices focused on advanced wound management and infection prevention, has been acquired by Healthium Medtech Pvt. Ltd. Healthium Medtech Pvt. Ltd. is owned by Apax partners. The value of the deal has not been disclosed.

10. **Investment in Relisys by Siguler Guff**[60]

    Private equity firm Siguler Guff has invested INR 100 Crore (Indian Rupees One Hundred Crore) in Hyderabad-based cardiovascular medical devices manufacturer Relisys.

[51] https://www.thehindubusinessline.com/companies/pharmeasy-buys-out-thyrocare-for-4546-cr/undefined
[52] https://www.livemint.com/companies/news/tata-digital-to-buy-majority-stake-in-e-pharmacy-1mg-11623306920062.html
[53] https://health.economictimes.indiatimes.com/news/mergers-and-aquisitions/piramal-pharma-completes-acquisition-of-hemmo-pharmaceuticals/83770311
[54] https://health.economictimes.indiatimes.com/news/mergers-and-aquisitions/manipal-hospitals-acquires-100-stake-in-vikram-hospital/83197819
[55] https://health.economictimes.indiatimes.com/news/mergers-and-aquisitions/ipca-labs-acquires-13-stake-in-trophic-wellness-for-rs-21-crore/83432363
[56] https://health.economictimes.indiatimes.com/news/mergers-and-aquisitions/aknamed-acquires-vardhman-health-specialties-for-usd-35-mn/82766979
[57] https://health.economictimes.indiatimes.com/news/pharma/mylab-acquires-majority-stake-in-poc-testing-system-developers-sanskritech/86365554
[58] https://health.economictimes.indiatimes.com/news/pharma/nclt-approves-amalgamation-of-lincoln-parenteral-lincoln-pharmaceuticals/86279989
[59] https://www.vccircle.com/apax-partners-owned-healthium-buys-carenow-in-third-acquisition-this-year
[60] https://thecapitalquest.com/2021/09/03/india-buzz-brookfield-lactalis-siguler-guff-actis-bernstein-hsbc-in-news/

11. Acquisition of Stake in Schott Kaisha by Serum Institute[61]

Vaccine manufacturer, Serum Institute of India has acquired a 50% (fifty percent) stake in Schott Kaisha. Schott Kaisha is a joint venture between Germany's Schott and India's Kaisha, and is engaged in the manufacturing of drug vials. This acquisition will secure the supply chain for Serum Institute.

12. Cadila Healthcare unit inks pact to sell two brands to Integrace Pvt. Ltd.[62]

Zydus Healthcare Ltd., a wholly-owned subsidiary of the Cadila Healthcare, has inked an agreement with Integrace Pvt. Ltd. on September 20, 2021, to sell two brands - Mifegest and Cytolog.

13. Everstone Capital buys Calibre Chemicals for a reported $100 million[63]

Everstone Capital on August 31, 2021, announced the acquisition of a controlling stake in Calibre Chemicals (**Calibre**), which is a specialty ingredients player focused on the pharmaceutical, nutritional and personal care segments, for a reported $100 million. Calibre manufactures a range of specialty chemicals, falling into two product lines – mineral derivatives (iodine, selenium, cobalt) and peroxygens (persulphates, perchlorates). Calibre also offers various packaging solutions, including paper cartons, HDPE drums, LDPE bags, steel drums and fibre drums, apart from manufacturing various customs chemicals at its Sarigam plant in Gujarat.

14. Glenmark Pharmaceuticals enters agreement with SaNOtize Research & Development (SaNOtize) to commercialise nasal spray for Covid-19 treatment in India and other Asian markets[64]

Glenmark Pharmaceuticals and SaNOtize have entered into an exclusive long-term strategic partnership to manufacture, market and distribute its Nitric Oxide Nasal Spray (**NONS**) for Covid-19 treatment in India and other Asian markets, including Singapore, Malaysia, Hong Kong, Taiwan, Nepal, Brunei, Cambodia, Laos, Myanmar, Sri Lanka, Timor-Leste and Vietnam, a statement from Glenmark said.

Notably, in March 2021, SaNOtize's clinical trials showed NONS was a safe and effective anti-viral treatment to prevent the transmission of Covid-19, shorten its course, and reduce the severity of symptoms. In the first 24 hours, NONS reduced the average viral load by around 95% (ninety five percent) and then by more than 99% (ninety nine percent) within 72 (seventy-two) hours. It has been tested in healthy volunteers and patients as part of the UK and Canada clinical trials.

Available in the form of a simple nasal spray, it is designed to kill the virus in the upper airways, preventing it from incubating and spreading to the lungs. It is based on nitric oxide (NO), a natural nanomolecule with proven anti-microbial properties, and which has a direct effect on SARS-CoV-2.

[61] https://www.vccircle.com/elevation-capital-leads-6-mn-series-a-funding-in-edtech-yellow-class
[62] https://health.economictimes.indiatimes.com/news/pharma/cadila-healthcare-unit-inks-pact-to-sell-two-brands-to-integrace/86390499
[63] https://www.expresspharma.in/everstone-buys-calibre-chemicals-for-about-100-million/
[64] https://www.expresspharma.in/glenmark-inks-agreement-with-sanotize-to-commercialise-nasal-spray-for-covid-19-treatment-in-india-and-other-asian-markets/

News Updates

1. List of Approved Covid-19 Vaccines[65]

On September 14, 2021, the CDSCO published the list of 'Covid-19 vaccines approved for Restricted Use in Emergency Situation in the Country'. This list contains names of the vaccines, names of the manufacturing firms, approval dates, dose schedule, ages approved for, route of administration and storage of vaccines that have been approved for emergency use in India. This list includes the following vaccines:

a. ChAdOx1 nCoV-19 Corona Virus vaccine Recombinant) [Chimpanzee Adeno vector] *(M/s Serum Institute of India Pvt. Ltd.);*

b. Whole-Virion Inactivated SARSCoV-2 Vaccine *(M/s Bharat Biotech);*

c. Recombinant Adenovirus vector-based SARS-CoV-2 liquid vaccine Gam COVID Vac (component I & II) (SPUTNIK-V) *(M/s Dr. Reddy's Lab. Ltd. (Importer));*

d. mRNA-1273COVID-19 vaccine (Moderna) *(M/s Cipla Ltd. (Importer));*

e. Recombinant Adenovirus vector-based SARS-CoV-2 liquid vaccine Gam COVID Vac (component I & II) (SPUTNIK-V) *(M/s Panacea Biotec Ltd);*

f. COVID-19 vaccine (Ad26.COV2-S) [recombinant] (Janssen Vaccine) *(M/s Johnson & Johnson Pvt. Ltd. (Importer));*

g. COVID-19 vaccine (Ad26.COV2-S) [recombinant] (Janssen Vaccine) *(Biological E Limited); and*

h. Novel Corona Virus-2019-nCov vaccine (recombinant DNA) (2 mg) *(Cadila Healthcare Limited)*

2. The Union Ministry of Ayush (Ayush Ministry) signs Memorandum of Understanding (MoU) with American Herbal Pharmacopoeia to boost export of Ayurveda, Siddha, Unani and Homoeopathy (ASU&H) drugs[66]

The Ayush Ministry has signed MoU between the Pharmacopoeia Commission for Indian Medicine & Homoeopathy (PCIM&H) and American Herbal Pharmacopoeia. This collaboration will go a long way in enhancing the export potential of the ASU&H drugs. Under this MoU, a joint committee will be constituted to develop an action plan, along with timelines for the development of monographs and other activities for cooperation in the field of traditional medicine.

The MoU was signed virtually and the Ayush Ministry has entered this MoU with the specific purpose of strengthening, promoting, and developing standards in the field of Ayurveda and other Indian Traditional Systems of Medicine between the two countries on the basis of equality and mutual benefit.

[65] https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=NzY2OQ==
[66] http://www.pharmabiz.com/NewsDetails.aspx?aid=142569&sid=1

The Ayush Ministry has paved the way for strengthening the quality of ayurvedic and other Indian traditional medicine products globally and also enhancing their export potential, especially to the US market, said the statement issued by the Ayush Ministry.

3. **Jharkhand rolls out new industrial policy with priority for pharma sector**[67]

A vision to make Jharkhand the "Pharmacy of East India", has made the government of Jharkhand roll out the Jharkhand Industrial and Investment Promotion Policy (**JIIPP**) 2021, with priority being given to the pharma sector. The policy makers of the State noted that the pharma sector was one of the high priority area because it has emerged as a key growth driver and attracted FDI worth over INR 3000,00,00,000 (Indian Rupees Three Thousand Crores) in the period between April and September in 2020 alone. Hence, the Department of Health and Family Welfare in the State is now preparing an exclusive pharma policy on the basis of JIIPP to boost the pharma sector.

4. **Dr Reddy's and Zydus Pharma recall products in the US market**[68]

Dr Reddy's Laboratories and Zydus Pharma are recalling bottles of a product each, in the US market, for different reasons, according to the latest report of the US health regulator. Dr Reddy's Laboratories is recalling 37,560 (thirty-seven thousand five hundred and sixty) bottles of Tizanidine HCl tablets, USP 4 mg. The product is used to treat the symptoms of muscle stiffness associated with conditions such as cerebral palsy or other neurological disorders. The reason behind the recall is "Failed Tablet/ Capsule Specification: Some tablets are shaved." The voluntary ongoing nationwide recall within the United States is a class II recall. Whereas, Zydus Pharmaceuticals (USA) Inc, is recalling 2,880 (two thousand eight hundred eighty) bottles of Carvedilol tablets, USP 25 mg in the US due to the "presence of foreign tablets/ capsules; report of two Paroxetine tablets were found in the bottle." The said tablets are used to treat high blood pressure and heart failure. This, too, is a voluntary class II recall.

5. **Bharat Biotech's intra-nasal Covid-19 vaccine gets DCGI nod for phase-II and -III trials** [69]

The first nasal vaccine against Covid-19, being developed by Bharat Biotech, has received the DCGI's nod for conducting phase-II and III clinical trials, the Department of Biotechnology (DBT) said recently. Phase-I clinical trial has been completed in age groups ranging from 18 to 60 years. BBV154 is an intra-nasal replication-deficient chimpanzee adenovirus SARS-CoV-2-vectored vaccine. Bharat Biotech has in-licensed technology from the Washington University in St Louis, the US.

6. **Dr. Reddy's Labs Launched Covid-19 Drug**[70]

Dr Reddy's Laboratories Ltd. has launched an anti Covid-19 drug namely 2-deoxy-D-glucose (2-DG). It will be sold under the brand name '2DGTM' and has been priced at INR 990 (Indian Rupees Nine Hundred Ninety) for private players, while it will be offered to the government at subsidized rates. This drug was jointly developed by a DRDO laboratory, the Institute of Nuclear Medicine & Allied Sciences and Dr Reddy's Laboratories.

7. **Covaxin's Phase-III Trial Data Gets Approval** [71]

Bharat Biotech's Covid-19 vaccine Covaxin's Phase-III clinical trials data has been approved by the Subject Expert Committee set up to look into this subject. As per the data, Covaxin has demonstrated a 77.8% (seventy-seven point eight per cent) efficacy. Bharat Biotech is now undertaking post trial surveillance to verify the efficacy and safety of the vaccine.

8. **Roche's Covid-19 Drug Approved in USA for Emergency Use**[72]

The USFDA has approved Roche's drug Actemra for emergency use to treat Covid-19 patients. This drug was originally intended to be used in the treatment of arthritis. This was already being used on compassionate basis on same patients, but, with this approval for use in Covid-19 treatment, hospitalised patients can be administered the same.

[67] http://www.pharmabiz.com/NewsDetails.aspx?aid=142467&sid=1
[68] https://www.expresspharma.in/dr-reddys-and-zydus-pharma-recall-products-in-us-market/
[69] https://www.expresspharma.in/bharat-biotechs-intra-nasal-covid-vaccine-gets-dcgi-nod-for-phase-ii-and-iii-trials/
[70] https://health.economictimes.indiatimes.com/news/pharma/dr-reddy-labs-launches-2-dg-oral-anti-covid-drug-commercially/83912753
[71] https://health.economictimes.indiatimes.com/news/pharma/bharat-biotechs-covaxin-gets-sec-approval-on-its-phase-3-trials-efficacy-data/83745867
[72] https://www.expresspharma.in/us-approves-roche-drug-for-emergency-use-against-severe-covid-19/

9. DCGI allows Phase-III Clinical Trials of PNB 001/GPP-BALACOVIN[73]

PNB Vesper has received permission from the DCGI to conduct Phase-III clinical trials of PNB 001/GPP-BALACOVIN, which is a new chemical entity, and a first-in-class cholecystokinin-A (CCK-A) agonist and CCK-B antagonist. GPP-BALACOVIN is the only known molecule in the world that acts as a powerful anti-inflammatory agent with immuno-modulation properties, which allows the molecule to bring the out of tune immune system back to normal and control the aggressive inflammatory response in the body, also known as cytokine storm caused by the Covid-19 infection.

10. Dr. Reddy's, Cipla, Emcure, Sun Pharma and Torrent collaborate for New Covid-19 Antiviral Drug[74]

5 (five) leading pharmaceutical companies in India have entered into a first-of-its-kind clinical trial collaboration agreement, wherein the parties will jointly sponsor, supervise and monitor the clinical trial of the investigational oral antiviral drug, namely Molnupiravir for the treatment of mild Covid-19 in India. Such collaboration for a clinical trial within the Indian pharma industry will be a collective attempt to investigate yet another line of treatment against Covid-19.

11. AYUSH declares AYUSH 64 useful for treatment of mild to moderate Covid-19 infection[75]

The Central Council for Research in Ayurvedic Sciences, AYUSH Ministry, has declared AYUSH 64, a poly herbal formulation developed for the treatment of asymptomatic, mild and moderate Covid-19 infection, as an adjunct to standard care. This drug was originally developed for Malaria in 1980. However, it was repurposed for the management of mild to moderate Covid-19 infection cases after conducting a successful and robust multi-centre clinical trial.

12. Panel for Framing of New Laws for the Regulation of Drugs[76]

The Central Government has set up a committee to frame a new set of laws for the regulation of drugs, cosmetics and medical devices. The committee is led by V.G. Somani (the Drugs Controller General of India). Its report is expected to be submitted by the end of November this year.

[73] https://www.expresspharma.in/dcgi-allows-pnb-vesper-life-science-to-conduct-phase-iii-clinical-trials-on-pnb-001-gpp-balacovin-to-treat-covid-19/
[74] https://economictimes.indiatimes.com/industry/healthcare/biotech/pharmaceuticals/five-local-cos-to-start-trials-of-covid-drug/articleshow/83966511.cms
[75] https://www.pib.gov.in/PressReleasePage.aspx?PRID=1714815
[76] https://www.thehindu.com/news/national/panel-to-frame-new-drugs-cosmetics-and-medical-device-laws/article36362455.ece

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