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synapse

A quarterly update on the Pharma Industry

Volume V | Issue II | October 2021 - March 2022

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Dear Readers,

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

The Covid-19 pandemic, having wreaked havoc across the world, seems to have become part and parcel of our day-to-day life, thus compelling humanity to learn to live in the shadow of this dreaded pathogen. While waves continue to come and go, we are currently witnessing a dip in infections. However, the possibility of increase in numbers looms large with newer, more transmissible variants emerging every now and then. The current Omicron variant, though more transmissible than the killer Delta variant of last year, is not as calamitous. Wide spread vaccination is definitely the reason why the new variant seems to be less fatal. Newer treatment methods continue to be developed and approved across the globe, which is why we are hopeful that humanity's victory over this pandemic is closer than before. Soon Covid -19 will become endemic and pave the way for us to move beyond this dark chapter in the history of the world.

While the first year of the pandemic resulted in large scale research and development in the quest for a cure, the second year marked a milestone for the pharmaceutical and healthcare sector with the roll out of new Covid-19 vaccines, collaboration for new drugs and treatment between domestic and foreign players, and streamlining & restructuring of pharmaceutical and medical device regulations. Digitalisation of pharma and healthcare services came as a saviour for one and all in so many respects. On the policy and regulation side, we saw the much-awaited amendment to the Medical Termination of Pregnancy Rules, 2003, which provides for the increase in the gestational limit for termination of pregnancy from 20 (twenty) to 24 (twenty-four) weeks for certain categories of women, and setting up of a State level Medical Board. In yet another move, which will have far reaching consequences, the Assisted Reproductive Technology (Regulation) Act, 2021 has been notified, which provides for the regulation of assisted reproductive technology clinics and banks, including laying down of standards and registration requirements. Furthermore, we also witnessed several amendment/ publishing of draft amendments to existing legislations such as the Drugs Rules, 1945, the Medical Devices Rules, 2017, New Drugs and Clinical Trials Rules, 2019, etc. which we have covered in this edition of Synapse.

In these months, we saw yet another push to the domestic pharmaceutical industry through the announcements of a new PLI scheme for providing the necessary impetus to the domestic API production. The government also announced the launch of Ayushman Bharat Health Infrastructure Mission aimed at strengthening the critical healthcare infrastructure of the country at several levels.

In the litigation space, we saw the Hon'ble Supreme Court clarifying as to what constitutes sexual assault under the POCSO Act, 2012. In yet another judgment, the Apex Court, while interpreting the provisions of the Rights of Persons with Disabilities Act, 2016 ruled that all possible alternatives must be explored before dismissing from service a person claiming disability in disciplinary proceedings. There was also a judicial pronouncement on the issue of promotional activities by pharma companies.

On the vaccination front, the coverage of the vaccination program was extended to children of certain specified ages and commencement of booster doses for frontline workers and senior citizens with comorbidities from January 2022 was announced.

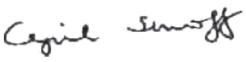
A few significant transactions undertaken in the period under review have also been covered in this edition of our newsletter.

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 keep abreast of the latest developments in this dynamic sector, we present to you the latest issue of Synapse.

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 also created a Covid-19 dedicated section on our website that provides up-to-date information and 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/.

We hope you find this issue of interest. As always, we await your constructive feedback at cam.publications@cyrilshroff.com. In the meanwhile, please stay safe and healthy.

Regards,
CYRIL SHROFF



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Regulatory Updates

1. Notification of Drugs (5th Amendment) Rules, 2021[1]; Licence to manufacture drugs for test purposes

The Ministry of Health and Family Welfare (**MoHFW**), *vide* Gazette Notification no. GSR 766(E) dated October 27, 2021, notified the Drugs (5th Amendment) Rules, 2021. This amendment modifies Rule 90(2) of the Drugs Rules, 1945 (**Drugs Rules**) and replaces the words "Form 29" with "Form 30" therein. This clarifies that the application for obtaining a Form 29 license *(i.e. license to manufacture drugs for purposes of examination, test or analysis)* under the Drugs Rules is indeed required to be made in Form 30.

Further, another provision has been inserted in Rule 90, which stipulates that the licence in Form 29 may be granted by the licensing authority within a period of 7 (seven) working days from the date of receipt of the application in Form 30, and in case where no communication is received by the applicant from licensing authority within the said period, the licensing authority shall be deemed to have granted the license.

2. Notification of Drugs (Amendment) Rules, 2022[2]; Quick Response Code on label

The MoHFW, *vide* Gazette Notification no. GSR 20(E) dated January 18, 2022, notified the Drugs (Amendment) Rules, 2022. This amendment makes it mandatory for every active pharmaceutical ingredient (**API**) (bulk drug) manufactured or imported in India to bear a Quick Response code on its label at each level packaging that store data or information readable with software application to facilitate tracking and tracing. This requirement will come into effect from January 1, 2023.

3. Notification of Drugs (2nd Amendment) Rules, 2022[3]; Liquid antiseptics; Exemption from sales licenses

The MoHFW, *vide* Gazette Notification no. GSR 30(E) dated January 20, 2022, notified the Drugs (2nd Amendment) Rules, 2022. This amendment provides for inclusion of 'Liquid Antiseptics for household use' in Schedule K of the Drugs Rules and consequent exemption from requirement of sale licenses for the same, subject to the specified conditions.

4. Permitting Import of Oxytocin API for Certain Formulations[4]

The MoHFW, *vide* Gazette Notification no. GSR 762(E) dated October 27, 2021, amended the principal notification no. GSR 577(E), dated July 23, 1983. In terms of the said principal notification (and as amended from time to time), the import of "Oxytocin and its formulation in any name or manner except Oxytocin reference standards imported exclusively for the purpose of tests and analysis" into India had been prohibited. The latest amendment widens the exception to now also include 'Oxytocin' API imported exclusively to manufacture formulations for the purpose of export only.

5. Draft Amendments to the Drugs Rules

(a) The MoHFW *vide* Gazette Notification no. GSR 75(E) dated February 1, 2022[5], published the draft of an amendment to the Drugs Rules. The proposed amendment provides for inclusion of Acitretin in Schedule H of the Drugs Rules;

(b) The MoHFW *vide* Gazette Notification no. GSR 227(E) dated March 29, 2022[6], published the draft of an amendment to the Drugs Rules. The proposed amendment permits use of additional colours referred in IS 4707 (Part I) as amended by Bureau of Indian Standards from time to time and any of the colours which is non-staining specified in terms of this amendments, in case of disinfectants.

6. Amendments to the New Drugs and Clinical Trials Rules, 2019 (NDCT Rules)

(a) The MoHFW *vide* Gazette Notification no. GSR 14(E) dated January 13, 2022[7] notified an amendment to the NDCT Rules. The said amendment expands the definitions of 'new drug' to include 'cell or stem cell derived product' as opposed to only 'stem cell derived products';

(b) The MoHFW *vide* Gazette Notification no. GSR 21(E) dated January 18, 2022[8] notified an amendment to the NDCT Rules. The said amendment defines a 'Designated Registration Authority' to mean the authority as

[1] https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=NzqzNQ==
[2] https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=ODEyMg==
[3] https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=ODA3NA==
[4] https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=NzgzNg==
[5] https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=ODA5MQ==
[6] https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=ODI4OA==
[7] https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=ODA3OQ==
[8] https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=ODA3NQ==

specified in Rule 17(1) of the NDCT Rules, and further makes consequential amendments in Form CT-03 *(Grant Of Registration Of Ethics Committee Relating To Biomedical Health Research)*.

7. Draft Amendments to the NDCT Rules

The MoHFW *vide* Gazette Notification no. GSR 32(E) dated January 21, 2022[9] published the draft of an amendment to the NDCT Rules. The proposed amendment provides for deemed approvals for various stages of conducting clinical trials and other studies in India, and the compliances which are required to be observed by applicants who have obtained deemed approvals.

8. Reconstitution of the Drugs Technical Advisory Board (DTAB)

The MoHFW *vide* Gazette Notification no. SO 4326(E) dated October 18, 2021[10] reconstituted the DTAB. The reconstituted DTAB, with the Drugs Controller (India) as its Member-Secretary, became functional with effect from the date of this notification.

9. Drafts of Amendments to the Medical Devices Rules, 2017 (MD Rules)

(a) The MoHFW *vide* Gazette Notification no. GSR 877(E) dated December 23, 2021[11], published the draft of an amendment to the MD Rules. The proposed amendment would substitute the current Rule 46 of the MD Rules to postpone the requirement for inclusion of Unique Device Identification details on medical devices, to a future date appointed by the Central Government, instead of January 1, 2022 (as is required under current Rule 46 of the MD Rules);

(b) The MoHFW *vide* Gazette Notification no. GSR 23(E) dated January 18, 2022[12], published the draft of an amendment to the MD Rules. The proposed amendment contemplates inclusion of a new Rule 43A in the MD Rules, which will provide for and enable the Central licensing Authority to cancel or suspend import licenses in cases where the manufacturer or licensee fails to comply with any of the conditions of an import licence, the D&C Act or MD Rules;

(c) The MoHFW *vide* Gazette Notification no. GSR 104(E) dated February 9, 2022[13], published the draft of an amendment to the MD Rules. The proposed amendment provides for registration certificates to be obtained under the MD Rules to sell, stock, exhibit or offer for sale or distribute a medical device including in vitro diagnostic medical device;

(d) The MoHFW *vide* Gazette Notification no. GSR 228(E) dated March 29, 2022[14], published the draft of an amendment to the MD Rules. The proposed amendment provides that in respect of 'Device Master File For Medical Devices Other Than In Vitro Diagnostic Medical Devices', the requirement of Transmissible Spongiform Encephalopathies (**TSEs**) or Bovine Spongiform Encephalopathy (**BSE**) Certificates shall not be necessary if the source is from animal species from a country of origin recognised as having negligible Bovine Spongiform Encephalopathy risk in accordance with the recommendations of the World Organisation for Animal Health.

10. Amendments to the MD Rules

(a) The MoHFW *vide* Gazette Notification no. GSR 174(E) dated March 4, 2022[15], notified of an amendment to the MD Rules. The said amendment amends Rule 36 of the MD Rules and includes the United Kingdom in the list of countries based on whose free sale certificates, import licenses are granted without carrying out clinical investigations of the concerned medical devices;

(b) The MoHFW *vide* Gazette Notification no. GSR 19(E) dated January 18, 2022, notified an amendment to the MD Rules. The said amendment provides for issue of a provisional registration numbers, valid up to May 31, 2022, to medical devices even in the absence of ISO 13485 certificates, provided an undertaking in lieu of the same is submitted by the applicant.

[9] https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=ODA4NQ==
[10] https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=Nzc5Mw==
[11] https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=ODAxMQ==
[12] https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=ODA3OA==
[13] https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=ODEyNA==
[14] https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=ODI4Nw==
[15] https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=ODIyOA==
[16] https://egazette.nic.in/WriteReadData/2021/230390.pdf

11. Notification of Medical Termination of Pregnancy (Amendment) Rules, 2021

The MoHFW *vide* Gazette Notification no. GSR 730(E) dated October 12, 2021[16], notified the Medical Termination of Pregnancy (Amendment) Rules, 2021 (**MTP Amendment Rules**) to amend the Medical Termination of Pregnancy Rules, 2003. These rules will come into force come on such date as the Central Government may appoint by notification in the Gazette. The key amendments notified through the MTP Amendment Rules *inter alia* provides for the increase in the gestational limit for termination of pregnancy from 20 (twenty) to 24 (twenty-four) weeks for certain categories of women, and setting up of a State level Medical Board to decide if a pregnancy may be terminated after 24 (twenty-four) weeks in cases of foetal malformation.

12. Notification of Assisted Reproductive Technology (Regulation) Act, 2021

The Ministry of Law and Justice *vide* Gazette Notification dated December 20, 2021[17], notified the Assisted Reproductive Technology (Regulation) Act, 2021. This Act will come into force on such date as the Central Government may appoint by notification in the Gazette. This Act *inter alia* provides for the regulation of assisted reproductive technology clinics and banks, lays down their standards and mandates a registration to also be obtained for the same.

13. Notification of Surrogacy (Regulation) Act, 2021

The Ministry of Law and Justice *vide* Gazette Notification dated December 25, 2021, notified the Surrogacy (Regulation) Act, 2021[18]. This Act *inter alia* provides for registration of 'surrogacy clinics', prohibits 'commercial surrogacy', and further lays down the purposes for which surrogacy may be undertaken, and penalties for any contravention in this regard, including imprisonment.

14. Relaxation in Regulation of CT Scan Equipment, Implantable Devices, MRI Equipment etc. as Drugs[19]

In continuation of its earlier order dated April 18, 2021[20], the Central Drugs Standard Control Organization (**CDSCO**), *vide* an order dated November 3, 2021, in light of representations made by various stakeholders regarding their unpreparedness in complying with regulatory requirements (vis-à-vis medical device notified *vide* Gazette notification no. SO 775(E) dated February 8, 2019) within the prescribed timeline, and to ensure smooth transition of manufacturers/ importers, continuity of supply chain and access to the patients, decided that in case an existing importer/ manufacturer who is already importing/ manufacturing any of those devices, and whose application has been submitted for grant of import/ manufacturing licence before April 18, 2021, the said application shall be deemed to be valid and the importer/manufacturer can continue to import/manufacture

[17] https://egazette.nic.in/WriteReadData/2021/232025.pdf
[18] https://dhr.gov.in/document/acts-circulars/surrogacy-regulation-act-2021
[19] https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=Nzq0Mw==
[20] https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=NzE0Nw==

the said devices up to June 30, 2022 or until the time the licensing authority takes a decision on the said application, whichever is earlier.

15. Review of Regulatory Regime for Drug Approval[21]

The CDSCO, *vide* a Notice dated October 14, 2021, stated that in order to enhance the testing capacity of medical devices in the country, it is considering identification, registration and empanelment of government and private testing laboratories for medical device testing. Accordingly, laboratories which have capacity for testing of medical devices and are NABL accredited and are interested in the above process, have been requested to intimate the same to the CDSCO.

16. Online Processing of Applications for Registration of BA/ BE Study Centres[22]

The CDSCO, *vide* a Notice dated October 1, 2021, notified the launch of a module for online processing of applications for registration of bioavailability/ bioequivalence (**BA/ BE**) study centers under the NDCT Rules. The BA/ BE center registration and applications processing has now been made online and no physical applications were to be accepted after October 15, 2021.

17. Notifications by the NPPA and other Price Control Related Measures

(a) **Extension on price caps on oxygen concentrators**: The Ministry of Chemicals and Fertilizers *vide* Gazette Notification no. SO 4909(E) dated November 30, 2021[23], extended the validity of its earlier notification dated June 3, 2021, whereby the trade margins on oxygen concentrators were capped. The price caps have now been extended up until May 31, 2022;

(b) **Submission of stock details on quarterly basis**: The National Pharmaceutical Pricing Authority (**NPPA**) *vide* an Office Memorandum dated December 3, 2021[24], relaxed the requirement for submission of monthly stock details of (i) bare metal stents; (ii) drug eluting stents; (iii) orthopaedic knee implants; and (iv) oxygen concentrators by their respective manufacturers/ importers. Henceforth, the stock details will be required to be submitted only on a quarterly basis, in the prescribed format;

(c) **Clarification regarding Paragraph 28 of Drugs (Prices Control) Order, 2013**: The NPPA *vide* an Office Memorandum dated November 22, 2021[25] in respect of complaints that manufacturers were refusing to appoint some persons/ firms as their authorised dealers, clarified that this being a commercial issue, was outside the scope of the NPPA. However, manufacturers were instructed to ensure proper distribution of drugs and to maintain sufficient availability in the market.

18. Notifications by the FSSAI

(a) **FSSAI. Notification of Food Safety and Standards (Food Products Standards and Food Additives) Fifth Amendment Regulations, 2021**: The Food Safety and Standards Authority of India (**FSSAI**) *vide* Gazette Notification no. F. No. Stds/SC/A-1.34/N-1, dated November 15, 2021[26], notified the Food Safety and Standards (Food Products Standards and Food Additives) Fifth Amendment Regulations, 2021. This amendment comes into force with effect from its publication date, however, food business operators have been given time until June 1, 2022 to comply with the same. This amendment lays down the standards for *inter alia* raw edible oils, dehydrated vegetables, protein rich wheat flour etc;

(b) **FSSAI. Notification of Food Safety and Standards (Food Products Standards and Food Additives) Sixth Amendment Regulations, 2021**: The FSSAI *vide* Gazette Notification no. F. No. M&MP/Notification (05)/FSSAI-2019, dated December 27, 2021[27], notified the Food Safety and Standards (Food Products Standards and Food Additives) Sixth Amendment Regulations, 2021. This amendment comes into force with effect from its publication date, however, food business operators have been given time until July 1, 2022 to comply with the same (except for standards for fatty acid contents for ghee which shall come into force after 2 (two) years of the publication). This amendment requires *inter alia* the

[21] https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=Nzc5Mg==
[22] https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=NzczOQ==
[23] https://www.nppaindia.nic.in/wp-content/uploads/2021/12/Gazette-Notification-signed-for-Oxygen-Concentrators-30.11.2021.pdf
[24] https://www.nppaindia.nic.in/wp-content/uploads/2021/12/Office-Memorandum_Quarterly-Submission_Stock-Details_03.12.2021.pdf
[25] https://www.nppaindia.nic.in/wp-content/uploads/2021/11/OM-refusal.pdf
[26] https://fssai.gov.in/upload/notifications/2021/11/619b553646e10Gazette_Notification_Oil_Flour_22_11_2021.pdf
[27] https://fssai.gov.in/upload/notifications/2021/12/61ce91bf0f10eGazettte_Notification_Ghee_Milk_31_12_2021.pdf

inclusion of a specified logo and declaration on all milk and milk products, including composite milk products. Additionally, the standards for fatty acid composition of ghee have also been laid down;

(c) **FSSAI. Notification of Food Safety and Standards (Import) First Amendment Regulations, 2021**: The FSSAI *vide* Gazette Notification no. F. No. 4067/MOC-Trade/Reg-FSSAI/2017 (Part-1), dated November 3, 2021[28], notified the Food Safety and Standards (Import) First Amendment Regulations, 2021. This amendment comes into force with effect from its publication date, however, food business operators have been given time until June 1, 2022 to comply with the same. This amendment provides for the registration and inspection of certain foreign food manufacturing facilities;

(d) **FSSAI. Notification of Food Safety and Standards (Food Products Standards and Food Additives) Fourth Amendment Regulations, 2021**: The FSSAI *vide* Gazette Notification no. F. No. 1-116/ Scientific Committee/ Notif.28.4/ 2010-FSSAI(1) (Pt.F), dated November 3, 2021[29], notified the Food Safety and Standards (Food Products Standards and Food Additives) Fifth Amendment Regulations, 2021. This amendment comes into force with effect from its publication date, however, food business operators have been given time until June 1, 2022 to comply with the same. This amendment lays down the standards for oat products;

(e) **FSSAI. Notification of Food Safety and Standards (Organic Foods) First Amendment Regulations, 2021**: The FSSAI *vide* Gazette Notification no. F. No. Stds./Organic/Notification-01/FSSAI-2019 dated October 14, 2021[30], notified the Food Safety and Standards (Organic Foods) First Amendment Regulations, 2021. This amendment comes into force with effect from its publication date, however, food business operators have been given time until May 1, 2022 to comply with the same. In terms of this amendment, aggregators or intermediaries who collect organic food from small original producer or producer organisations and sell it to the end consumer directly, are exempted from complying with provisions of systems such as the National Programme for Organic Production (NPOP) and Participatory Guarantee System for India (PGS-India);

(f) **FSSAI. Prescription of Food Safety and Standards (Import) First Amendment Regulations, 2022**: The FSSAI *vide* Gazette Notification no. F. No. 1605 / FSSAI / Import / 2016(pt-2) dated February 14, 2022[31], notified the Food Safety and Standards (Import) First Amendment Regulations, 2022. The requirements specified therein will come into effect from September 1, 2022. This amendments, in respect of clearance from customs authorities without referring to the Food Authority, provides for the additional requirement of a "sanitary/ health certificate issued by the competent authority of an exporting country" to accompany the articles of food or ingredients or additive imported by the manufacturers or processors for their captive use or production of value added products for hundred per cent exports; or the consignments of articles of food or ingredients or additives imported by the firms or companies for use of their sister concerns or wholly owned subsidiary companies, to be used for hundred per cent export production;

(g) **FSSAI. Notification of Food Safety and Standards (Packaging) First Amendment Regulations, 2022**: The FSSAI, *vide* Gazette Notification no. F.No. Std/SP-08/A-1.2019/N-01 dated January 25, 2022[32] notified the Food Safety and Standards (Packaging) First Amendment Regulations, 2022. This amendment permits the use of specified food grade packaging materials, which may or may not contain plastic as component compatible with the water.

[28] https://fssai.gov.in/upload/notifications/2021/11/618b4e7b785d6Gazette_Notification_Inspection_Foreign_Food_10_11_2021.pdf
[29] https://fssai.gov.in/upload/notifications/2021/11/6188bd7ded736Gazette_Notification_Oats_Tolerance_08_11_2021.pdf
[30] https://fssai.gov.in/upload/notifications/2021/10/616ffae29f9c5Gazette_Notification_Organic_Food_Amentment_20_10_2021.pdf
[31] https://fssai.gov.in/upload/notifications/2022/02/620f2f9d40a07Gazette_Notification_Import_18_02_2022.pdf
[32] https://fssai.gov.in/upload/notifications/2022/02/620f2f9d40a07Gazette_Notification_Import_18_02_2022.pdf

19. Guidelines and Standard Operating Procedures (SOPs) for Covid-19

The MoHFW issued guidelines and SOPs for managing and combating Covid-19 in India. Some of the important notifications in this regard are as follows:

(a) **Revised vaccination strategy (issued on December 27, 2021[33])**: In light of the increasing threat of Omicron variant of Covid-19, the vaccination strategy was amended to allow vaccination of children in the age-group of 15-18 years from January 3, 2022, booster doses for healthcare workers and frontline workers from January 10, 2022, and booster doses for persons aged above 60 years with comorbidities from January 10, 2022;

(b) **Guidelines for provision of Family Planning services during and post Covid-19 pandemic (issued on November 24, 2021[34])**: These guidelines have been issued to ensure minimum disruption in availability of family planning services;

(c) **Guidelines on managing Mental Illness in hospital settings during Covid-19 (issued on November 1, 2021[35])**: These guidelines were issued in collaboration with the National Institute of Mental Health and Neurosciences, Bengaluru and have been prepared to address the specific needs of medical officers and mental health professionals regarding prevention of infection and providing Covid-19 related care in hospital-based settings;

(d) **National Comprehensive Guidelines for management of post-Covid sequelae (issued on October 21, 2021[36])**: These guidelines have been prepared to guide doctors on managing post Covid-19 complications affecting cardiovascular, gastrointestinal, nephrological, neurological and respiratory systems;

(e) **Guidelines for Covid-19 vaccination of children in 12-14 year age group (issued on March 21, 2022[37])**: These guidelines expanded the Covid-19 vaccination program to children aged between 12 and 14 years. In this regard, it was clarified that only CorBEvax may be used for the beneficiaries in this age group;

(f) **Clinical guidance for management of adult Covid-19 patients (issued on January 14, 2022[38])**: A revised clinical guidance for management of adult Covid-19 patients was notified by the MoHFW. This guidance documents contains the treatment protocols for mild, moderate and severe disease;

(g) **Revised comprehensive guidelines for management of Covid-19 in children and adolescents (below 18 years) (issued on January 20, 2022[39])**: These guidelines have made the following modifications to the earlier notified guidelines: (i) use of antivirals or monoclonal antibodies is not recommended for children less than 18 years of age, irrespective of the severity of infection; (ii) for diagnosing MIS-C, caution should be exercised while interpreting an isolated increase in Covid-19 antibodies; (iii) The CRP level for diagnosis of MIS-C has been revised as >5mg/dL; (iv) if steroids are used, they should be tapered over 10-14 days, subject to clinical improvement; (v) use of anticoagulants has been revised; and (vi) a new section on post-Covid care has been added;

(h) **Revised guidelines for home isolation of mild/ asymptomatic Covid-19 cases (issued on January 5, 2022[40])**: These revised guidelines have been issued by the MoHFW in respect of Covid-19 patients who have been clinically assessed and assigned as mild /asymptomatic cases of Covid-19 and *inter alia* provide for selection criteria, precautions that need to be followed by such patients and their families, signs that require monitoring and prompt reporting to health facilities;

(i) **Revised advisory for managing health care workers (HCWs) working in Covid and non- Covid areas of the health care facilities (issued on January 9, 2022[41])**: This revised advisory *inter alia* provide guidance on the following: prevention measures to be observed at the institution/ facility level, and testing and isolation measures for health care functionaries.

[33] https://www.mohfw.gov.in/pdf/GuidelinesforCOVID19VaccinationofChildrenbetween15to18yearsandPrecautionDosetoHCWsFLWs&60populationwithcomorbidities.pdf
[34] https://www.mohfw.gov.in/pdf/FinalguidelineProvisionofFPServicesduringandpostPandemic3converted.pdf
[35] https://www.mohfw.gov.in/pdf/GuidelinesforDeliveryofMentalMentalHealthcareServicesduringtheCOVID19.pdf
[36] https://www.mohfw.gov.in/pdf/NationalComprehensiveGuidelinesforManagementofPostCovidSequelae.pdf
[37] https://www.mohfw.gov.in/pdf/GuidelinesCovidvaccination12to14yrchildrenMarch2022.pdf
[38] https://www.mohfw.gov.in/pdf/ClinicalGuidanceforManagementofAdultCovid19Patientsupdatedason17thJanuary2022.pdf
[39] https://www.mohfw.gov.in/pdf/RevisedComprehensiveGuidelinesforManagementofCOVID19inChildrenandAdolescentsbelow18years.pdf
[40] https://www.mohfw.gov.in/pdf/RevisedHomeIsolationGuidelines05012022.pdf
[41] https://www.mohfw.gov.in/pdf/RevisedAdvisoryformanagingHealthCareWorkersHCWsworkinginCOVIDandNonCOVIDareasoftheHealthCareFacilitiesupdatedon9thJanuary2022.pdf

News Updates

1. Corbevax gets nod for clinical trials as booster dose

Corbevax, the Covid-19 vaccine developed by Biological E, which recently received the emergency use approval from CDSCO, has now been given the approval to conduct clinical trials for the said vaccine as a booster dose.[42]

2. Sun Pharma gets Drugs Controller General of India (DCGI) nod to market Molnupiravir for Covid-19 treatment

Sun Pharma received emergency use authorisation (**EUA**) from the DCGI to manufacture and market a generic version of MSD and Ridgeback Biotherapeutic's antiviral drug molnupiravir under the brand name Molxvir in India[43]. Earlier in 2021, Sun Pharma, Torrent Pharma and Cipla had signed a non-exclusive voluntary licensing agreement with MSD and Ridgeback Biotherapeutics to manufacture and supply a generic version of molnupiravir in over 100 low and middle-income countries including India[44]. The DCGI has approved molnupiravir for treatment of adult Covid-19 patients, who have high risk of progression of the disease including hospitalisation or death.[45]

3. Government panel recommends EUA for Covid-19 vaccines Covovax, Corbevax and anti-Covid pill Molnupiravir

An expert panel of the CDSCO has recommended granting EUA to the Serum Institute of India's Covid-19 vaccine Covovax and Biological E's vaccine Corbevax with certain conditions.[46]

Further, the Subject Expert Committee on Covid-19 of the CDSCO also recommended granting permission to manufacture and market anti-Covid pill Molnupiravir for restricted emergency use for treatment of adult patients with SP-O2 93 per cent and who have high risk of progression of the disease, including hospitalisation or death, subject to certain conditions.[47]

Previously, the CDSCO had approved six vaccines including, Serum Institute's Covishield, Bharat Biotech's Covaxin, Zydus Cadila's ZyCoV-D, Russia's Sputnik V and the US-made Moderna and Johnson and Johnson. Currently the total number of approved vaccines is eight (including Covovax and Corbevax).

[42] https://health.economictimes.indiatimes.com/news/pharma/now-corbevax-gets-nod-for-clinical-trials-as-booster-dose/88578243
[43] https://health.economictimes.indiatimes.com/news/pharma/sun-pharma-gets-dcgi-nod-to-market-molnupiravir-for-covid-19-treatment/88548270
[44] https://www.livemint.com/news/india/after-cipla-sun-pharma-gets-dcgi-nod-to-launch-merck-s-covid-drug-in-india-11640681981170.html
[45] Ibid.
[46] https://health.economictimes.indiatimes.com/news/pharma/government-panel-recommends-eua-for-covid-19-vaccines-covovax-corbevax-and-anti-covid-pill-molnupiravir/88537599
[47] Ibid.

4. Children aged 15-18 to be administered only Covaxin from January 3, 2022

Due to the rising Covid-19 cases in the country and the emergence of highly transmissible Omicron, the Union Health Ministry has revised guidelines to inform that children in the age group of 15-18 years now have the option of getting vaccinated with Covaxin only. The vaccination drive, slated to begin from January 3, 2022 is underway and can be availed at the vaccination centres currently in operation for adults[48].

Covaxin has received Emergency Use Listing for administration in children from the DCGI after submission of data from clinical trials and prior recommendation from the Subject Expert Committee in October.

Further, the Union Health Ministry also released extended guidelines on the precaution dose that will be administered to the priority groups from January 10, 2022. The healthcare workers and frontline workers who have received two doses will be provided another precaution on the completion of 9 (nine) months from the date of administration of the second dose. The Government also informed that fully-vaccinated senior citizens aged 60 years or above with comorbidities will also be provided the precautionary dose on advice of the doctor after completion of nine months i.e., 39 weeks from the second dose.[49]

5. Government approves Production Linked Incentive (PLI) scheme to promote domestic API production

To promote the domestic manufacturing of APIs and to discourage imports, the Central Government has approved another PLI scheme in December 2021. This is aimed at promoting domestic manufacturing of critical Key Starting Materials, Drug Intermediates and APIs in India. The total outlay of the scheme is INR 6,940 crore and the said scheme will provide financial incentives for selected participants on incremental sales of 41 identified products in four different target segments for a period of six years.[50]

In the previous year too, the Department of Pharmaceuticals notified a PLI scheme worth INR 15,000 crore, following approval by the Union Cabinet chaired by Prime Minister Narendra Modi. The said PLI scheme aims to boost the existing brownfield API units in the country. The scheme will be in force for the 2020-21 to 2028-29 period and is expected to promote the production of high-value products in the country as well as increase the value addition in exports.[51]

6. Prime Minister announces the Ayushman Bharat Health Infrastructure Mission

The Prime Minister of India, Mr. Narendra Modi, announced the Pradhan Mantri Ayushman Bharat Health Infrastructure Mission in October 2021, which aims to strengthen the critical healthcare infrastructure of the country at several levels (e.g., villages or blocks) over the next five years. The scheme aims to boost citizen's access to the public health infrastructure by building facilities for primary and critical care in urban and rural areas of the country. Through this mission, the Government aims to address three areas in the public health sector in India, namely (a) augment health facilities for treatment; (b) establish integrated public health labs for diagnosis of diseases; and (c) expand existing research institutions that study pandemics.[52]

7. Indian industry inks 12 business Memorandum of Understanding (MOUs) with Vietnam

On December 17, 2022, 12 MOUs in the fields of public health, provision of pharmaceutical materials, drug and vaccine production, oil and gas, information technology and technology transfer, education, and tourism,[53] were exchanged between Vietnamese and Indian enterprises during the visit of Mr. Vuong Dinh Hue, the President of the National Assembly of Vietnam.

8. Stelis Biopharma gets CDSCO nod to export 50 million doses of Sputnik Light vaccine

Stelis Biopharma, the biotech division of Strides Pharma, received permission from CDSCO on December 21, 2021, to export up to 50 million doses of the Sputnik Light vaccine. The export batches will be manufactured at the Stelis' newly-commissioned vaccine manufacturing facility at Bengaluru.[54]

[48] https://health.economictimes.indiatimes.com/news/pharma/children-aged-15-18-to-be-administered-only-covaxin-from-january-3/88527260
[49] Ibid.
[50] https://health.economictimes.indiatimes.com/news/pharma/government-approves-pli-scheme-to-promote-domestic-api-production/88416908
[51] http://www.pharmabiz.com/ArticleDetails.aspx?aid=136038&sid=1
[52] https://www.ibef.org/blogs/ayushman-bharat-health-infrastructure-mission
[53] https://economictimes.indiatimes.com/news/economy/foreign-trade/indian-industry-inks-12-business-mous-with-vietnam/articleshow/88341327.cms
[54] https://health.economictimes.indiatimes.com/news/pharma/stelis-biopharma-gets-cdsco-nod-to-export-50-million-doses-of-sputnik-light-vaccine/88409144

9. Serum Institute's Covovax receives Emergency Use Listing (EUL) by World Health Organisation (WHO)

Covovax, produced by Serum Institute of India under the licence from Novovax, became the ninth Covid-19 vaccine to receive the EUL from the WHO. It is the third vaccine produced in India after Covishield (Indian version of Oxford-Astra Zeneca's Covid vaccine) and Covaxin (Indigenously produced by Bharat Biotech) to receive the approval of WHO.[55]

The Technical Advisory Group for EUL determined that the vaccine meets WHO standards for protection against Covid-19 and the benefits provided by the vaccine far outweighs any risks.

10. Dr. Reddy's inks pact with Singapore firm Prestige BioPharma to commercialise Trastuzumab biosimilar in select countries

Prestige BioPharma Ltd, a Singapore - based biopharmaceutical company and Dr. Reddy's Laboratories Ltd., entered into a binding agreement for an exclusive partnership for the supply and commercialisation of the former's proposed Trastuzumab biosimilar in select countries in Latin America and Southeast Asia.[56]

Prestige BioPharma's Trastuzumab (HD201) is a proposed biosimilar to Roche's Herceptin and can be prescribed for the treatment of HER2 positive breast and metastatic gastric cancer. Trastuzumab targets human epidermal growth factor 2 (HER2). In some types of cancer cells, HER2 is overexpressed and stimulates the growth of the cancer cells. Trastuzumab works by selectively binding to HER2, thereby stopping the growth of these cancer cells. Under the said partnership, Prestige BioPharma will be responsible for ensuring sustainable commercial supply of HD201 from its manufacturing facilities in Osong, South Korea, while Dr. Reddy's would take care of local registrations, marketing and sales in the licensed territories.[57]

11. Directorate General of Trade Remedies (DGTR) recommends imposition of anti-dumping duty on pharma API from China

The Directorate General of Trade Remedies (**DGTR**) has recommended imposition of anti-dumping duty on a pharma raw material Ceftriaxone Sodium Sterile that is being imported from China, to safeguard the domestic players from being adversely affected by cheaper imports. DGTR has recommended the duty after concluding in its probe that the API from China has been exported at dumped prices into India, which impacted the domestic industry.[58]

12. Asian Development Bank (ADB) extends support to India to increase access to Covid-19 vaccination

The ADB has approved a loan of USD 1.5 billion to India to enhance the procurement of the Covid-19 vaccines. The Asian Infrastructure Investment Bank is also expected to co-finance an additional USD 500 million for the project. The loans will fund at least 667 million Covid-19 vaccine doses for an estimated 317 million people.[59] This loan has been provided in collaboration with the WHO and the United Nations Children's Fund.

13. Government classifies genomics and pharma as sunrise opportunities

Giving a boost to the pharmaceuticals sector, the Budget 2022 classified 'Genomics and Pharmaceuticals' as a sunrise sector.

The finance minister stated in her Budget speech that the genomics and pharmaceuticals will get supportive policies,

[55] https://health.economictimes.indiatimes.com/news/pharma/serum-institutes-covovax-receives-emergency-use-listing-eul-by-who/88346713
[56] https://health.economictimes.indiatimes.com/news/pharma/dr-reddys-inks-pact-with-singapore-firm-prestige-biopharma-to-commercialise-trastuzumab-biosimilar-in-select-countries/88185713
[57] Ibid.
[58] https://health.economictimes.indiatimes.com/news/pharma/commerce-ministry-for-imposing-anti-dumping-duty-on-pharma-api-from-china/87982550
[59] https://health.economictimes.indiatimes.com/news/pharma/adb-extends-support-to-india-to-enhance-covid-vaccines-access/87926211

light-touch regulations, facilitative actions to build domestic capacities, and promotion of research and development[60]. However, it is pertinent to note that the Budget document doesn't provide details of the contribution the government intends to provide.

Furthermore, the pharma industry also welcomed the extension of time limit for the commencement of business to claim benefits of concessional tax regime for manufacturing companies which has been extended by a year to March 31, 2024.[61]

14. Local manufacturing of 35 APIs started after PLI scheme

Under the Aatma Nirbhar Bharat scheme, the manufacturing of 35 APIs, which have been imported earlier, has started in India under the Production Linked Incentive scheme for the pharmaceuticals sector. These 35 APIs are among the 53 APIs, for which India has 90 % dependence.[62]

The 35 APIs are being manufactured from 32 different manufacturing plants in the country.

15. NPPA hikes prices of 800 essential drugs from April 1, 2022

NPPA has announced a hike in prices of around 800 essential drugs from April 1, 2022. The rise in drug prices works out at around 10.76% based on the Wholesale Price Index (**WPI**) data.

The drugs which are included in the National List of Essential Medicine (**NLEM**) such as antibiotics, anti-inflammatory drugs, ear-nose and throat medicines, antiseptics, painkillers, gastrointestinal medicines and antifungal medicines among others will see a sharp increase in prices.[63]

Notably, the clause 16 of Drugs Price Control Order 2013, allows NPPA to revise the ceiling price of scheduled formulations as per the annual WPI for the preceding calendar year on or before April 1 of every year and notify the same on the April 1 every year.

The pharmaceutical industry welcomed the government's decision of 10% hike in scheduled drugs.

16. Mylo raises $17 million in funding led by W Health Ventures, ITC, Endiya Partners

Mylo, a platform for expecting and new mothers, has announced a funding round of $17 million led by W Health Ventures, a US-based digital health investor, ITC and Endiya Partners.[64]

Founded in 2018 by Vinit Garg, Mylo began as an online health tool and community platform for new and expecting mothers. Mothers on Mylo can track their baby's development, get expert vetted content for more than 500 topics and ask questions to other mothers at a similar life stage.

Notably, Mylo launched its own D2C brands in 2021 for mothers and babies in personal care, premium ayurveda and daily essentials, based on community feedback and its own R&D facility.

17. Government panel recommends EUA for Biological E's Corbevax for 5 to 11 years

An expert panel of India's central drug authority has recommended granting emergency use authorisation for Biological E's Covid-19 vaccine Corbevax for children in the 5-11 year age group with certain conditions.

Currently, Biological E's Corbevax is being used to inoculate children against Covid-19 in the age group of 12 to 14 years.

18. India-made Covid-19 vaccines supplies under Quad initiative

Thailand on April 21, 2022 received 200,000 doses of India-made Covovax vaccines as part of a flagship initiative of the Quad group to help countries combat the coronavirus pandemic.[65]

This is the second consignment of vaccines delivered by India under the Quad vaccine partnership, after the inaugural supply to Cambodia on April 12, 2022.

The Quad vaccine partnership was announced by leaders of the four-nation group namely, India, Australia, Japan and the United States, at their first summit on March 12, 2021.

[60] https://economictimes.indiatimes.com/industry/healthcare/biotech/pharmaceuticals/govt-classifies-genomics-pharma-as-sunrise-opportunities/articleshow/89278705.cms
[61] Ibid.
[62] https://economictimes.indiatimes.com/industry/healthcare/biotech/pharmaceuticals/local-manufacturing-of-35-apis-started-after-pli-scheme-mandaviya/articleshow/90519863.cms
[63] https://www.livemint.com/news/india/nppa-hikes-prices-of-800-essential-drugs-from-1-april-11648280723327.html
[64] https://health.economictimes.indiatimes.com/news/pharma/mylo-raises-17-million-in-funding-led-by-w-health-ventures-itc-endiya-partners/90995115
[65] https://health.economictimes.indiatimes.com/news/pharma/thailand-gets-india-made-covid-vaccines-under-quad-initiative/90976606

The above-mentioned vaccine doses were supplied to fulfil the commitment made by Prime Minister Narendra Modi at the Quad leaders' Summit in Washington in September, 2021 to donate 500,000 doses of Covid-19 vaccines to countries in the Indo-Pacific region.

19. Siemens Healthineers expands manufacturing footprint in India with new line of CT scanners

In order to accelerate the growth of the medical devices space in the country, Siemens Healthineers announced the expansion of its manufacturing facility in India. The company has launched its new production line for computed tomography scanners at its Bengaluru facility[66].

It is pertinent to note that the Government has identified medical devices as a priority sector for the flagship 'Make in India' programme. With an objective to boost domestic manufacturing, and attract large investment in the Medical Device sector, the Department of Pharmaceuticals launched a PLI scheme.

The new production line set up by Siemens Healthineers at the Bengaluru factory is approved under the Radiology and Imaging Medical devices segment of the PLI scheme.

Siemens Healthcare Private Limited is one of the approved applicants for the PLI scheme with a committed investment of INR 91.9 crore, for the manufacture of computed tomography and magnetic resonance imaging[67].

20. Indian Radiological & Imaging Association (IRIA) and Corporeal Health Solutions (CHS) collaborate to introduce the first AI-based Covid-19 and TB screening systems at international airports in India

A unique collaboration of the IRIA, with CHS, a Chennai-based company that specialises in providing innovative, cognitive Artificial Intelligence-based technology to the healthcare industry, produced a state-of-the-art screening systems that streamline Covid-19 and tuberculosis protocols at international airports.[68]

Named CHOCO, this innovative product is the first-of-its-kind to be introduced in Asia. It was inaugurated at Kempegowda International Airport, Bengaluru.

The enhanced screening solutions combine state-of-the-art Artificial Intelligence and chest X-rays, and deliver results within nanoseconds. Various imaging modalities are used, and potential abnormalities that may not otherwise be detected beyond a clinical setting are instantly traced. This dramatically reduces the standard passenger waiting time of hours, and ensures a queue-free environment at airports. Additionally, the last two years of the pandemic have shown that existing screening systems at international ports of entry are inadequate, and CHOCO eliminates the time and cost issues that have so far prevented effective detections that can prevent travel-related infections in the larger community.

[66] https://health.economictimes.indiatimes.com/news/medical-devices/siemens-healthineers-expands-manufacturing-footprint-in-india-with-new-line-of-ct-scanners/90659352
[67] Ibid.
[68] https://health.economictimes.indiatimes.com/news/medical-devices/iria-and-chs-collaborate-to-introduce-the-first-ai-based-covid-19-and-tb-screening-systems-at-international-airports-in-india/90565256

21. Government launches Ayush Export Promotion Council

The Government has launched Ayush Export Promotion Council (**EPC**) with an aim to oversee exports of products of Ayurveda, Homoeopathic, Siddha, Sowa Rigpa and Unani systems and address their trade related matters[69].

The said Ayush EPC was unveiled by the Prime Minister, Mr. Narendra Modi, at Global Ayush Investment and Innovation Summit in Gandhinagar, Gujarat on April 20, 2022.

Notably the council was created by the Ministry of Ayush in cooperation with the Ministry of Commerce and Industry, along with other stakeholders such as the Federation of Indian Chambers of Commerce and Industry and Invest India. It will have an exclusive focus on the implementation of trade-related initiatives and easing of trade issues while representing the interest of the Ayush exporters in all interactions with domestic and global stakeholders. The council will monitor exports of Ayush drugs and even services of the Ayush systems.

22. NPPA to set up digital platform to track availability of essential drugs across the country

The NPPA has initiated efforts to track the availability of essential drugs across the country, by creating a national level digital platform in which the stock positions could be updated by the stakeholders.

It may be noted that in regulated markets such as the US, the drug regulators regularly update the details of medicines which are in shortage.[70]

The Authority has floated an Expression of Interest to shortlist an agency for tracking the availability of specified medicines in the supply chain across the country, especially in the backdrop of the challenges it faced in tracking the availability of Covid-19 related medicines in various parts of the country. The NPPA said that one of its major roles is to monitor the availability of drugs, identify shortages, if any, and to take remedial steps. It faced constraints in tracking the stocks of drugs in the supply chain during Covid pandemic.

[69] http://www.pharmabiz.com/NewsDetails.aspx?aid=149180&sid=1
[70] http://www.pharmabiz.com/NewsDetails.aspx?aid=149152&sid=1

Major Litigation Updates

1. Pharma companies can't claim freebies to doctors as tax deduction

The Supreme Court in *M/s Laboratories Pvt. Ltd. v. Deputy Commissioner of Income Tax, Large Tax Payer Unit-II*[71], opined that pharma companies cannot claim tax deduction against freebies handed out to doctors. The Court held that *medical practitioners were forbidden from accepting such gifts, or 'freebies' was no less a prohibition on the part of their giver, or donor, i.e., Apex.*

The Court noted that,

"*Thus, pharmaceutical companies' gifting freebies to doctors, etc. is clearly 'prohibited by law', and not allowed to be claimed as a deduction under Section 37(1). Doing so would wholly undermine public policy. The well-established principle of interpretation of taxing statutes – that they need to be interpreted strictly – cannot sustain when it results in an absurdity contrary to the intentions of the Parliament...*

In the present case too, the incentives (or 'freebies') given by Apex, to the doctors, had a direct result of exposing the recipients to the odium of sanctions, leading to a ban on their practice of medicine. Those sanctions are mandated by law, as they are embodied in the code of conduct and ethics, which are normative, and have legally binding effect. The conceded participation of the assessee- i.e., the provider or donor- was plainly prohibited, as far as their receipt by the medical practitioners was concerned. That medical practitioners were forbidden from accepting such gifts, or 'freebies' was no less a prohibition on the part of their giver, or donor, i.e., Apex."

2. Supreme Court clarifies the most important ingredient for constituting an offence of sexual assault under the POCSO Act

The Hon'ble Supreme Court (SC), in batch Criminal Appeal Nos. 1410-1413 of 2021, quashed two judgments of the Nagpur bench of Bombay High Court which concluded that it will not amount to an offence of sexual assault under Section 7 of Protection of Children from Sexual Offences Act, 2012 (POCSO Act) if there is "no direct physical contact, i.e. skin to skin" between the accused and the victim. The Hon'ble SC observed that restricting the meaning of the word "physical contact" to "skin to skin" contact would be a narrow interpretation of Section 7 and would defeat the very objective of the POCSO Act. The Appeals came from two judgments of the Bombay High Court wherein the High Court had acquitted the accused (also an appellant) by holding that the act of pressing breast can be criminal force to a woman/girl with the intention to outrage her modesty punishable under Section 354 of the IPC. The Hon'ble SC

[71] Special Leave Petition (Civil) No. 23207 of 2019.

clarified that the most important ingredient for constituting an offence of sexual assault under Section 7 of the POCSO Act is the "sexual intent", and not the "skin-to-skin" contact with the child".

3. Holding disciplinary proceedings against a person with mental disability amounts to indirect discrimination

The Hon'ble SC, in Civil Appeal No. 6924 of 2021, took a disabled-friendly approach by ruling that all possible alternatives must be explored before dismissing from service a person claiming disability in disciplinary proceedings. The Hon'ble SC The Hon'ble SC set aside the judgment passed by Division Bench of the Gauhati High Court while hearing the appeal against the order filed by Ravinder Kumar Dhariwal, an assistant commandant in Central Reserve Police, who was accused of using offensive language, of appearing in the media without prior approval and assault,.

The Hon'ble SC discovered that the appellant had a history of depression and categorised with up to 40-70% disability. The Court held that *"The mental disability impairs the ability of persons to comply with workplace standards in comparison to their able-bodied counterparts. Such persons suffer a disproportionate disadvantage due to the impairment and are more likely to be subjected to disciplinary proceedings. Thus, the initiation of disciplinary proceedings against persons with mental disabilities is a facet of indirect discrimination..."*. The Hon'ble SC held that such a person is protected under the provisions of Rights of Persons with Disabilities Act, 2016. The Court while setting aside the disciplinary action against the Appellant, directed the protection of his pay and emoluments and gave the authorities the discretion to assign him a job that does not require the use or control of fire arms or equipment, which may pose a danger to the appellant or others in or around the workplace.

Major Transactions

1. Colorcon buys pharma firm Ideal Cures

Colorcon Inc., a global leader in pharmaceutical film coatings and specialty excipients, has acquired Mumbai-based Ideal Cures, which supplies coatings for tablets and capsules to the pharmaceutical and allied sectors. Colorcon has acquired Ideal Cures for about $250 million/ INR 1942.48 crore.[72] Ideal Cures is a global manufacturer and supplier of pharmaceutical excipients and ready-to-use coating systems for solid oral dosage forms.

2. Piramal Pharma Limited (PPL) invests INR 101.77 crore for minority stake in Yapan Bio

PPL invested INR 101.77 crore in Hyderabad-based Yapan Bio Private Limited (**YBPL**) to augment the capabilities of its contract development and manufacturing organisation (**CDMO**) business. PPL has acquired a 27.78 per cent stake in YBPL as a result of the said investment[73]. The investment will allow PPL to strengthen Piramal Pharma Solutions, its CDMO business, by broadening its service offerings.

[72] https://economictimes.indiatimes.com/industry/healthcare/biotech/pharmaceuticals/colorcon-buys-ta-backed-pharma-firm-ideal-cures/articleshow/87024301.cms
[73] https://health.economictimes.indiatimes.com/news/pharma/piramal-pharma-invests-rs-101-77-cr-for-minority-stake-in-yapan-bio/88409280

YBPL provides process development, scale-up and cGMP compliant manufacturing of vaccines and biologics/bio-therapeutics, including high containment product classes (up to BSL-2+), recombinant vaccines, RNA/DNA vaccines, gene therapies, monoclonal antibodies, therapeutic proteins, and other complex biologics.[74]

3. Aurobindo Pharma (AP) buys Veritaz Healthcare Ltd. (VHL) for INR 171 crore

AP acquired the domestic formulations business of VHL for INR 171 crore. This acquisition vehicle will greatly help AP to enable marketing biosimilar and other products in India. VHL caters anti-infective and pain-management therapeutic areas and has a pipeline of products to enter into the cardio-diabetic, ortho and gynaecology segments[75].

4. Healthcare platform GOQii raises $50 million led by Sumeru Ventures

GOQii Inc, a tech-enabled healthcare platform, on Wednesday said it has raised $50 million (around INR 375 crore) in a Series C funding round led by Sumeru Ventures[76].

The Funds raised in this round will be used by GOQii to grow the insurance and digital therapeutics vertical in India. It also plans to target therapeutic areas across diabetes, women's health, and radiology through its digital therapeutics offerings. The company is also looking to launch its international offerings focusing on solutions around preventive healthcare.

5. Tata Capital Healthcare Fund invests in DeepTek in first health tech bet

Tata Capital Healthcare Fund, the healthcare-focused arm of private equity firm Tata Capital Ltd, has led a Series A funding of $10 million/ INR 76.86 crore in new-age health tech startup DeepTek Inc. This marks Tata Capital Healthcare Fund's first foray into the sector of digital healthcare.[77]

Incorporated in 2017, DeepTek is engaged in the medical imaging artificial intelligence space. It seeks to make radiology services more affordable and accessible. Its customers include hospitals and imaging centers across India as well as in Japan, Singapore, Philippines, and other Asia Pacific countries.

[74] Ibid.
[75] https://economictimes.indiatimes.com/industry/healthcare/biotech/pharmaceuticals/aurobindo-pharma-acquires-veritaz-formulation-biz-for-rs-171-crore/articleshow/90500872.cms
[76] https://www.vccircle.com/healthcare-platform-goqii-raises-50-mn-led-by-sumeru-ventures
[77] https://www.vccircle.com/tata-capital-healthcare-fund-invests-in-deeptek-in-first-health-tech-bet

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