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ahead of the curve

synapse

A quarterly update on the pharma, life sciences
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Dear Readers,

We hope that all of you and your families are safe and healthy.

The past few months have seen a modicum of normalcy return to our everyday lives. High vaccination count and a continuously developing arsenal to treat Covid-19 has not only led to the easing of mass movement restrictions but also made it plausible to believe that defeating this virus was possible. We hope this trajectory continues and Covid-19 becomes a thing of the past soon.

Like the previous few quarters, the sector witnessed important regulatory updates even in the last quarter, which we have covered in this edition of *Synapse*. Of particular note are the notification of rules and regulations for operationalisation of the Assisted Reproductive Technology (Regulation) Act, 2021 and Surrogacy (Regulation) Act, 2021 and the Surrogacy (Regulation) Rules, 2022 and the creation of National Assisted Reproductive Technology and Surrogacy Registry. This quarter also saw the notification of Draft National Medical Commission, Registered Medical Practitioner (Professional Conduct) Regulations, 2022, which will govern the duties, responsibilities, and medical ethics and standards to be followed by medical practitioners. In another news, the focus of regulators and Government on new age technologies is evident from the ICMR guidelines for the use of drones in healthcare. Also, freebies given to doctors have been brought under the purview of the Income-Tax Act, 1961, which we have analysed in detail.

In the litigation space, the Hon'ble Supreme Court, in a landmark judgment held that opinion and findings of the Medical Council of India are of great relevance in the consideration of medical negligence compensation claims. In another matter, it was held that bodily integrity is protected under Article 21 and resultantly, no citizen may be forced to get vaccinated. The Court also noted that decisions regarding vaccinations and associated procedures are subject to the advice given by domain experts and generally the court cannot interfere with decisions made utilising the same.

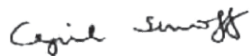
We also witnessed some significant transactions and investments in the sector and have endeavoured to cover the same in this edition of *Synapse*.

Cyril Amarchand Mangaldas, India's premier full-service law firm, has an industry leading and dedicated Pharmaceuticals, 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 of the latest developments in this dynamic sector, we present to you the latest issue of *Synapse*. We hope you find this issue of interest. As always, your feedback makes us improve our efforts. Please feel free to send your comments, feedback and suggestions to cam.publications@cyrilshroff.com.

We also encourage you to visit our blog at <https://corporate.cyrilamarchandblogs.com> for more articles on matters of interest in the Indian pharmaceutical and healthcare sector. We have also created a dedicated section on our website that provides up-to-date information in relation to Covid-19 related notifications across different legal sectors. We encourage our readers to visit our Covid-19 resource page at <https://www.cyrilshroff.com/covid-19-know-how-cyril-amarchand-mangaldas/>.

We hope that you enjoy reading our newsletter as much as we have enjoyed preparing it. Your comments and feedback are most welcome. In the meanwhile, please stay safe and stay healthy.

Regards,
CYRIL SHROFF



Managing Partner
Cyril Amarchand Mangaldas

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Regulatory Updates

1. Reconstitution of Ayurvedic, Siddha and Unani Drugs Technical Advisory Board (ASUDTB)

The Ministry of Ayush *vide* Gazette Notification no. SO 1776(E)¹ dated April 11, 2022, reconstituted the ASUDTB. The Director General of Health Services (**DGHS**), Government of India would be the chairman of the ASUDTB.

2. Establishment of the National Assisted Reproductive Technology and Surrogacy Registry

The Ministry of Health and Family Welfare (**MoHFW**), *vide* Gazette Notification no. SO 1907(E) dated April 21, 2022², notified the establishment of the National Assisted Reproductive Technology and Surrogacy Registry in terms of the Assisted Reproductive Technology (Regulation) Act, 2021 (**ART Regulation Act**) and Surrogacy (Regulation) Act, 2021 (**Surrogacy Regulation Act**). The operations of the said registry began on April 22, 2022.

3. Reconstitution of the Central Council of Health and Family Welfare (CCHFW)

The MoHFW, *vide* Gazette Notification no. SO 1916(E) dated April 22, 2022³, reconstituted the CCHFW. The CCHFW will be an advisory body and shall *inter alia* make policy suggestions and legislation proposals in the fields of health and family welfare and examine possibilities for co-operation between the states with respect to epidemics and calamities.

4. Creation of Union Territory Boards under the ART Regulation Act & Surrogacy Regulation Act

The MoHFW, *vide* Gazette Notifications nos. SO 2074(E) and SO 2075(E) dated May 4, 2022⁴, notified the creation of Union Territory Boards for Union Territories under the ART Regulation Act and Surrogacy Regulation Act. The minister in-charge of health and family welfare/ lieutenant governor/ administrator of the Union Territory, as applicable, would act as the ex-officio chairperson of the board.

5. Composition of National Assisted Reproductive Technology and Surrogacy Board (NARTSB)

The MoHFW, *vide* Gazette Notification no. SO 2076(E) dated May 4, 2022⁵, notified the composition of the NARTSB. The Minister-in-Charge of the MoHFW would act as the ex-officio chairperson of the board.

6. Notification of Medical Devices (Third Amendment) Rules, 2022⁶

The MoHFW, *vide* Gazette Notification no. GSR 356(E) dated May 18, 2022, notified the Medical Devices (Third Amendment) Rules, 2022. This amendment provides for suspension and cancellation of import licences, and destruction of the stock of medical devices, if the licensee fails to comply with any conditions of the license, or any provisions of the Drugs and Cosmetics Act, 1940 (**D&C Act**) or the Medical Devices Rules, 2017 (**MD Rules**).

7. Notification of Drugs (Fourth Amendment) Rules, 2022⁷

The MoHFW, *vide* Gazette Notification no. GSR 357(E) dated May 18, 2022, notified the Drugs (Fourth Amendment) Rules, 2022. This amendment provides for the inclusion of 'Acitretin' in Schedule H of the Drugs and Cosmetics Rules, 1945 (**D&C Rules**) and the consequent restrictions on its sale without a prescription from a registered medical practitioner (**RMP**).

8. Permitted import of Oxytocin Reference Standards for testing and analysis

The Directorate General of Foreign Trade (**DGFT**), *vide* a notification dated May 23, 2022⁸, permitted the import of oxytocin reference standards exclusively for testing and analysis purposes subject to a test license issued by either the Drug Controller General of India (**DCGI**) or the Central Drugs Standard Control Organisation (**CDSCO**).

¹ <https://egazette.nic.in/WriteReadData/2022/235080.pdf>

² <https://egazette.nic.in/WriteReadData/2022/235283.pdf>

³ <https://egazette.nic.in/WriteReadData/2022/235319.pdf>

⁴ <https://egazette.nic.in/WriteReadData/2022/235543.pdf>

⁵ <https://egazette.nic.in/WriteReadData/2022/235539.pdf>

⁶ <https://egazette.nic.in/WriteReadData/2022/235837.pdf>

⁷ <https://egazette.nic.in/WriteReadData/2022/235838.pdf>

⁸ <https://content.dgft.gov.in/Website/dgftprod/3cecc295-dd9d-4a1c-a86c-4f79cf436f20/Notification%2009%20dt%2023-05-22%20Eng.pdf>

9. Notification of Draft National Medical Commission, Registered Medical Practitioner (Professional Conduct) Regulations, 2022

The National Medical Commission (NMC), vide a public noted dated May 23, 2022⁹, published the draft of the 'National Medical Commission, Registered Medical Practitioner (Professional Conduct) Regulations, 2022'. These regulations will govern the duties, responsibilities, and medical ethics and standards to be followed by the RMPs.

10. Notification of Assisted Reproductive Technology (Regulation) Rules, 2022

The MoHFW, vide Gazette Notification no. GSR 419(E) dated June 7, 2022¹⁰, notified the Assisted Reproductive Technology (Regulation) Rules, 2022. These rules *inter alia* provide for the registration of 'Assisted Reproductive Technology (ART)' level 1 and level 2 clinics as well as ART banks and lay down the minimum standards and compliance requirements for such institutions.

11. Notification of Medical Devices (Fourth Amendment) Rules, 2022

The MoHFW, vide Gazette Notification no. GSR 450(E) dated June 15, 2022¹¹, notified the Medical Devices (Fourth Amendment) Rules, 2022. This amendment inserts a proviso in Paragraph 7.4 of Part III of Appendix II, of the Fourth Schedule of the MD Rules, exempting the requirement of Transmissible Spongiform Encephalopathies (TSEs) or Bovine Spongiform Encephalopathy (BSE) certificates if a material of animal origin used in a medical device is derived from an animal species originating from a country which is classified as having a low risk of Bovine Spongiform Encephalopathy by the World Health Organisation.

12. Notification of Surrogacy (Regulation) Rules, 2022

The MoHFW, vide Gazette Notification no. GSR 460(E) dated 21 June 2022¹², notified the Surrogacy (Regulation) Rules, 2022. The rules lay down the requirements for *inter alia* the equipment and staff required to operate a surrogacy clinic,

manner of taking consent, etc. Further the number of attempts of surrogacy procedures on the surrogate mother has been restricted to not more than 3 (three) procedures. Additionally, these rules also stipulate that the couple seeking surrogacy services must provide for 3 (three) years of general health coverage for the surrogate mother.

13. Draft Amendments to the D&C Rules

- a) The MoHFW, vide Gazette Notification no. GSR 383(E) dated May 23, 2022¹³, published the draft of an amendment to the D&C Rules. The proposed amendment provides that in respect of 'liquid antiseptics for household use', the condition for exemption under Schedule K, i.e. the drugs are purchased from a licensed wholesaler or a licensed manufacturer, will apply only to drugs manufactured after November 30, 2022.
- b) The MoHFW, vide Gazette Notification no. GSR 382(E) dated May 23, 2022¹⁴, published the draft of an amendment to the D&C Rules. The proposed amendment provides for simultaneous submission of applications under Rule 75(3) of the D&C Rules (for licence to manufacture for sale or for distribution of drugs in 'Large Volume Parenterals' and 'Sera and Vaccines'), Rule 80 of the New Drugs and Clinical Trial Rules, 2019 (for grant of permission to manufacture new drug for sale or distribution) or Rule 122B of the D&C Rules. The proposed amendment further provides that the licence to manufacture the drug for sale or distribution shall only be approved after the approval of the drug as a new drug.
- c) The MoHFW, vide Gazette Notification no. GSR 393(E) dated May 25, 2022¹⁵, published the draft of an amendment to the D&C Rules. The proposed amendment provides for the inclusion of 16 (sixteen) drugs in Schedule K of the D&C Rules. These drugs, in terms of the exemption specified in Schedule K, may then be sold by retail Over the Counter without prescription of an RMP.
- d) The MoHFW, vide Gazette Notification no. GSR 448(E) dated June 14, 2022¹⁶, published the draft of an amendment to the D&C Rules. The proposed amendment provides for the inclusion of a new Schedule H2 and 300 (three hundred) drugs therein which would be subject to

⁹ <https://www.nmc.org.in/MCIRest/open/getDocument?path=/Documents/Public/Portal/LatestNews/NMC%20RMP%20REGULATIONS%202022%20Draft%20Final%20YM.pdf>

¹⁰ <https://egazette.nic.in/WriteReadData/2022/236395.pdf>

¹¹ https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=ODYxOQ==

¹² <https://egazette.nic.in/WriteReadData/2022/236719.pdf>

¹³ <https://egazette.nic.in/WriteReadData/2022/235965.pdf>

¹⁴ <https://egazette.nic.in/WriteReadData/2022/235964.pdf>

¹⁵ <https://egazette.nic.in/WriteReadData/2022/236010.pdf>

¹⁶ https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=ODYyMA==



additional packaging requirements including *inter alia* the display of a QR code or a bar code on the packaging of these drugs.

14. Notifications by the Food Safety and Standards Authority of India

- a) **Notification of Draft Food Safety and Standards (Food Products Standards and Food Additives) Amendment Regulations, 2022:** The Food Safety and Standards Authority of India (FSSAI), vide Gazette Notification no. F. No. STD/FA/38/FSSAI, dated May 25, 2022¹⁷, published the draft of an amendment to the Food Safety and Standards (Food Products Standards and Food Additives) Regulations, 2011. The proposed amendment lays down the standards for *inter alia* khoa, cheese and cheese products, peanut butter, etc;
- b) **Notification of Draft Food Safety and Standards (Packaging) Amendment Regulations, 2022:** The FSSAI, vide Gazette Notification no. F. No. STD/SP-20/T(Recycledplastics-N), dated May 17, 2022¹⁸, published the draft of an amendment to the Food Safety and Standards (Packaging) Regulations, 2018. The proposed amendment allows for the utilisation of products made from recycled polyethylene terephthalate (PET) for packaging, storage, carrying or dispensation of food

products subject to notification of standards and guidelines by the FSSAI. Further, such products should also comply with any other applicable national regulations and standards;

- c) **Notification of Draft Food Safety and Standards (Alcoholic Beverages) Amendment Regulations, 2022:** The FSSAI, vide Gazette Notification no. F. No. STD/SP-21/T(Alcohol-4), dated May 17, 2022¹⁹, published the draft of an amendment to the Food Safety and Standards (Alcoholic Beverages) Regulations, 2018. The proposed amendment revises the definition of a 'Single Malt Whiskey' to include 'Single Grain Whiskey'. Further, the amendment provides that alcoholic beverages shall not contain any nutritional information on the label except energy content in 'K.Cal' and such declaration related to energy content shall be voluntary;
- d) **Notification of Food Safety and Standards (Ayurveda Aahara) Regulations, 2022:** The FSSAI, vide Gazette Notification no. F. No. Stds/SP-05/A-1. Y(01), dated May 5, 2022²⁰, notified the Food Safety and Standards (Ayurveda Aahara) Regulations, 2022. These regulations regulate the manufacture, packaging, sale, distribution and import of 'Ayurveda Aahara' i.e. a food prepared in accordance with the recipes or ingredients or processes as per method described in the authoritative books of Ayurveda listed in the said regulations;

¹⁷ <https://egazette.nic.in/WriteReadData/2022/236096.pdf>

¹⁸ <https://egazette.nic.in/WriteReadData/2022/235826.pdf>

¹⁹ <https://egazette.nic.in/WriteReadData/2022/235825.pdf>

²⁰ <https://egazette.nic.in/WriteReadData/2022/235642.pdf>

e) **Notification of Draft Food Safety and Standards (Food Products Standards and Food Additives) Amendment Regulations, 2022:** The FSSAI, *vide* Gazette Notification no. F. No. Stds/Pan Masala Issue/FSSAI/2019, dated April 21, 2022²¹, published the draft of an amendment to the Food Safety and Standards (Food Products Standards and Food Additives) Regulations, 2011. The proposed amendment provides for the inclusion of ‘pan masala and arecanut based mouth fresheners’ under the food category of ‘Processed nuts including coated nuts and nuts mixtures’;

f) **Compliance with FSS (Labelling and Display) Regulations, 2020:** The FSSAI, *vide* an Order dated June 14, 2022²², directed E-Commerce Food Business Operators to comply with the provisions related to ‘Display of Information in Food Service Establishments’ as contained in the FSS (Labelling and Display) Regulations, 2020, and which are set to come into force from July 1, 2022. The said provisions mandate food business operators having a central licence or outlets at more than 10 (ten) locations to display nutritional value and calorific content of food items on their menus, boards or booklets. These provisions are also applicable to E-commerce food business operators which are required to display such information on their online platforms after getting the required information from respective food business operators.

15. Extension on Price Caps on Oxygen Concentrators

The National Pharmaceuticals Pricing Authority (NPPA), *vide* Gazette Notification no. SO 2465(E), dated May 30, 2022²³, extended the validity of its earlier notifications dated June 3, 2021 and November 30, 2021 whereby trade margins on oxygen concentrators were capped up to June 30, 2022.

16. Extension on Import of Drugs with less than 60% Residual Shelf Life

The CDSCO, *vide* a circular dated May 6, 2022²⁴, extended the validity of its earlier circular dated September 13, 2021 whereby the import of drugs with less than 60% residual

shelf life was permitted. The permission for import of such drugs has been extended up till October 31, 2022 in light of the Covid-19 pandemic.

17. Procedure for Regularisation of 294 Fixed Dose Combinations (FDCs)

The CDSCO, *vide* a letter to all State/ Union Territories’ Drug Controllers, dated April 28, 2022²⁵, extended the deadline for submission for application of regularisation of FDCs to the DCGI. The CDSCO specified that in light of the Covid-19 pandemic and various representations, the deadline for filing applications for the regularisation of such FDCs to the DCGI was extended up to October 31, 2022.

18. Classification of Dental Treatment Medical Devices

The CDSCO, *vide* a notice dated June 3, 2022²⁶, classified ‘Medical Devices Pertaining to Dental’ on the basis of intended use, risk associated with the utilisation of such devices, and other relevant parameters as per the MD Rules.

19. Classification of Obstetrical and Gynecological Medical Devices

The CDSCO, *vide* a notice dated June 3, 2022²⁷, classified ‘Medical Devices Pertaining to Obstetrical and Gynecological’ on the basis of intended use, risk associated with the utilisation of such devices, and other relevant parameters as per the MD Rules.

20. Registration of Licensed Blood Centres on e-Raktkosh Web Portal

The CDSCO, *vide* an advisory notice dated June 3, 2022²⁸, directed all licensed blood centres to register themselves on the e-Raktkosh web portal within a period of 1 (one) week from the issuance of the notice and to regularly update data regarding blood stock, blood donors, monthly reports, etc. on the e-Raktkosh web portal.

²¹ <https://egazette.nic.in/WriteReadData/2022/235318.pdf>

²² https://www.fssai.gov.in/upload/advisories/2022/06/62a86bfa4849eOrder_FBO_ECommerce_14_06_2022.pdf

²³ <https://egazette.nic.in/WriteReadData/2022/236114.pdf>

²⁴ https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=ODM2NA==

²⁵ https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=ODM4NW==

²⁶ https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=ODU0NW==

²⁷ https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=ODU0OA==

²⁸ https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=ODUxNW==



News Updates

1. Integration of E-Sanjeevani Telemedicine Service with Ayushman Bharat Digital Mission²⁹

The National Health Authority (NHA) successfully integrated the E-Sanjeevani service with the Ayushman Bharat Digital Mission. The inclusion of the E-Sanjeevani service has brought the tally of health applications which have been integrated with the ABDM to over 40 (forty).

2. ICMR issues guidelines for use of Drones in healthcare

The Indian Council for Medical Research (ICMR) has issued guidelines for the usage of drones in the healthcare sector. Recognising the benefits of employing drones in healthcare services, the ICMR has noted that the usage of drones in medical logistics will drastically improve the efficiency. The guidelines in this regard were formulated by the ICMR in conjunction with the Ministry of Civil Aviation, Directorate General of Civil Aviation, and the Airports Authority of India.

3. Adani Group to enter Healthcare business³⁰

Adani Enterprises Ltd., the flagship entity of the Adani Group established a wholly owned subsidiary, Adani Health

Ventures with an aim to offer healthcare related services and run diagnostic laboratories and medical research centres amongst various others. The subsidiary has already acquired a minority stake in an Israeli startup, Foresight Robotics for USD 20 Million.

4. Biological Research Regulatory Approval Portal Launched (BioRRAP)³¹

The Central Government launched the BioRRAP on May 21, 2022. The newly launched platform aims to provide a single national portal for biotech researchers and start-ups for the purposes of seeking regulatory approvals for various projects. Hon'ble Union Minister Jitendra Singh said the portal has been launched to increase the parameters of ease of doing science and scientific research as well as ease of start-ups in this field in India.

5. Rationalisation of Ayushman Bharat Health Insurance Scheme³²

The NHA, with a view to rationalise the packages under the Ayushman Bharat Health Insurance Scheme, introduced differential pricing based on the type of city and the level of

²⁹ <http://www.pharmabiz.com/NewsDetails.aspx?aid=151227&sid=1>

³⁰ <https://health.economictimes.indiatimes.com/news/industry/adani-targets-health-biz-forms-arm-for-segment/91653256>

³¹ <http://pharmabiz.com/ArticleDetails.aspx?aid=150919&sid=1>

³² <https://health.economictimes.indiatimes.com/news/industry/more-procedures-city-specific-pricing-in-new-ayushman-offer/90737668>

care sought. The NHA also included 365 (three hundred and sixty-five) new procedures under the scheme, including bone marrow transplant, cochlear implant surgery, etc.

6. Genovax's mRNA Vaccine gets nod from DCGI³³

Genovax Biopharmaceuticals announced that its mRNA vaccine, Gemovac-19 against Covid-19 has received the Emergency Use Authorisation (EUA) from the office of the DCGI. Gemovac-19 is the first mRNA vaccine developed in India and the third mRNA vaccine to be approved for Covid-19 in the world.

7. Pfizer's Paxlovid gets nod from DCGI³⁴

The DCGI has given its assent to Pfizer's antiviral medication 'Paxlovid' under the 'restricted emergency use' category for the purposes of use against Covid-19 cases.

8. Covid-19 vaccine for Animals launched³⁵

'Anocovax' manufactured by Haryana-based ICAR- National Research Centre on Equines was launched by Hon'ble Agriculture Minister, Narendra Singh Tomar. The vaccine is the first homegrown Covid-19 vaccine made for animals.

9. Flipkart enters the Healthcare Sector³⁶

Flipkart, a leading online marketplace owned by the Walmart Group, launched the 'Flipkart Health Plus' application marking its foray into the healthcare sector. The application aims to facilitate the delivery of medicines across the nation.

10. Government Panel approves vaccine for Cervical Cancer³⁷

An expert panel of the DCGI recommended granting market authorisation to Serum Institute's indigenously developed



vaccine for Quadrivalent Human Papillomavirus (qHPV). The vaccine is intended for those in the age group of 9-26.

11. TDS for 'Freebies' Given to Doctors

Circular No. 12 of 2022, dated June 16, 2022, issued by the Ministry of Finance, Department of Revenue, re-stated that the Finance Act, 2022 inserted a new Section 194R in the Income-Tax Act, 1961 with effect from July 1, 2022. The said Section mandates a person, who is responsible for providing any benefit or perquisite to a resident, to deduct tax at source of the value or aggregate of the value of such benefit or perquisite, before providing such benefit or perquisite. The benefit or perquisite may or may not be convertible into money but should arise either from carrying out of business, or from exercising a profession.

This circular clarified that the said section is also applicable to doctors who receive 'freebies' from the pharmaceutical companies.

³³ <https://www.expresspharma.in/dcgi-approves-indias- maiden-mrna-vaccine-against-covid-19/>

³⁴ <https://economictimes.indiatimes.com/industry/healthcare/biotech/pfizers-game-changing-covid-19-pill-paxlovid-gets-dcgi-nod/articleshow/91018614.cms>

³⁵ <https://economictimes.indiatimes.com/industry/healthcare/biotech/pharmaceuticals/indias-first-covid-19-vaccine-anocovax-for-animals-launched/articleshow/92126478.cms>

³⁶ <https://economictimes.indiatimes.com/industry/healthcare/biotech/healthcare/flipkart-forays-into-healthcare-sector-launches-flipkart-health-plus-app/articleshow/90691700.cms>

³⁷ Cervical Cancer Vaccine: Indian Govt panel approves country's first indigenous vaccine for cervical cancer for aged 9-26 years - The Economic Times Video | ET Now



Major Litigation Updates

1. The findings of Medical Council of India have great relevance in medical negligence cases

The Supreme Court (SC), in the matter of *Harnek Singh v. Gurmit Singh*³⁸, noted that the opinion and findings of the Medical Council of India (MCI) are of great relevance in the consideration of medical negligence compensation claims. The instant matter was arising out of an appeal from the National Consumer Dispute Redressal Commission (NCDRC) wherein the decision of the State Consumer Dispute Resolution Commission (SCDRC), which had found the doctors negligent, was set aside.

The complainants in the matter had also made a complaint to the Punjab State Medical Council alleging misconduct on part of the doctors which was summarily disposed of. The MCI however, in an appeal to the said order, found a doctor medically negligent and issued a strict warning. In the appeal before the SC, the complainants *inter alia* alleged that the NCDRC, in setting aside the decision of the SCDRC, did not take into consideration the findings of the MCI. In this regard, the Supreme Court noted that the NCDRC had erred in not considering the findings of the MCI, which clearly makes a case of medical negligence. The SC also observed that in

proceedings of damages due to professional negligence, the question of intention would not arise.

2. Impermissibly of coercive vaccination

The Hon'ble SC, in the matter of *Jacob Puliyeel v. Union of India*³⁹ reiterated that bodily integrity is protected under Article 21 and resultantly, no citizen may be forced to be vaccinated. Further, this includes the right to refuse medical treatment. Additionally, the Court held that if there is a likelihood of such individuals spreading the infection to other people or contributing to mutation of the virus or burdening of the public health infrastructure, thereby affecting communitarian health at large, the Government can regulate such public health concerns by imposing certain limitations on individual rights that are reasonable and proportionate to the object sought to be fulfilled.

The Court also noted that decisions regarding vaccinations and associated procedures are subject to the advice of domain experts and generally the court cannot interfere with such advice. However, it could judicially review executive decisions based on expert opinion, provided such decisions were manifestly arbitrary or unreasonable.

³⁸ Civil Appeal no. 4126-4127/2022.

³⁹ Writ Petition (Civil) No. 607 of 2021.

3. Challenge to National Medical Commission Regulations for foreign medical graduates

The Hon'ble SC, in the matter of *Aravindh R.A. v. Secretary to Government of India Ministry of Health and Family Welfare*⁴⁰, upheld the validity of Regulations 4(a)(i), 4(a)(ii), 4(b) and 4(c) of the National Medical Commission (Foreign Medical Graduate Licentiate) Regulations 2021, Para 2(a) and 2(c)(i) of Schedule II of the National Medical Commission (Compulsory Rotating Medical Internship) Regulations, 2021.

The matter came up in an appeal following a decision of the Madras High Court, which had dismissed the writ petition of the appellant seeking a declaration that the above mentioned provisions were *ultra vires* of Articles 14, 19(1)(g) and 21 of the Constitution. The appellant argued that the said regulations imposed arbitrary and heavy burdens upon students who wish to pursue medical education abroad. Responding to the contentions made by the appellant, the Supreme Court noted that the National Medical Commission was well within its powers to issue such regulations. Further, it was noted that in order to practice in India, graduates from foreign courses need to fulfil the requirements under the aforementioned regulations and that India need not emulate the standards followed by other nations in this regard.

4. Supreme Court issues directions to curb capitation fees in medical colleges

The Supreme Court, in the matter of *Rashtreeya Sikshana Samithi Trust v. Committee for Fixation of Fee Structure of Private Professional Colleges & Ors. Etc*⁴¹, issued an order prohibiting the management of private medical colleges for accepting payment of fees in cash. The rationale behind the same is to prevent the levy of capitation fee. The Court also directed that a web-portal under the aegis of the Court be setup wherein students may report such colleges that are charging capitation fees.



Major Transactions

1. Macleods Pharmaceuticals to offer IPO

The Securities and Exchange Board of India gave the go ahead to Macleods Pharmaceuticals to raise funds via an Initial Public Offering. As per the company's Draft Red Herring Prospectus (DRHP), the initial share sale is expected to be purely an 'offer for sale' of 6.05 Crore shares by the promoters⁴². The size of the IPO is expected to be INR 5000 Crore.

2. Honasa Consumer acquires majority stake in skincare company Dr. Sheth's

Honasa Consumer Private Ltd., the company which owns new age FMCG brands such as Mamaearth and The Derma Co, acquired a majority stake in skin care brand Dr. Sheth's valued at INR 28 Crore⁴³. Dr. Sheth's product portfolio consists of solutions for various skin care issues such as acne, dryness, etc.

⁴⁰ Civil Appeal no. 3585-3586/2022.

⁴¹ Civil Appeal no. 3978-3995/2017.

⁴² <https://health.economictimes.indiatimes.com/news/pharma/macleods-pharma-tbo-others-get-nod-for-ipos/91754844>

⁴³ <https://health.economictimes.indiatimes.com/news/industry/honasa-consumer-acquires-majority-stake-in-skincare-brand-dr-sheths/91604331>

3. Cipla to acquire stake in Achira Labs

Cipla Ltd., a leading Indian multinational pharmaceutical company is set to acquire 21.05% stake in Achira Labs Pvt. Ltd., valued at INR 25 Crore. Cipla has signed definitive agreements with Achira Labs for the same⁴⁴. Achira Labs is engaged in the development and sale of Point of Care medical testing kits.

4. BDR Pharma raises INR 685 Crore from Investors

BDR Pharmaceuticals International Pvt. Ltd., has sold 9.3% equity stake for a total valuation of INR 685 Crore to a consortium of lenders lead by the private equity firm Multiples⁴⁵. The funds raised in this round of investment are expected to be used to bolster the research and development capabilities of the company.

5. Eris Lifesciences acquires Oaknet Healthcare

Eris Lifesciences Ltd. acquired Oaknet Healthcare Pvt. Ltd. via a share purchase agreement for INR 650 Crore⁴⁶. Oaknet Healthcare is a dermatology focused company with a portfolio that includes women's health products and skincare products such as moisturisers, anti-fungal creams, etc.

6. Torrent Pharmaceuticals acquires Brands from Dr. Reddy's Laboratories

Torrent Pharmaceuticals acquired certain brands, namely 'Styptovit-E', 'Finast', 'Finast-T', and 'Dynapress' from Dr. Reddy's Laboratories⁴⁷. 'Styptovit-E' is a gynaecology product with a reasonable market size and is expected to expand Torrent's presence in the segment. 'Finast', 'Finast-T', and 'Dynapress' are utilised in the treatment of 'Benign Prostatic Hyperplasia' and will expand Torrent's presence in the urology segment.

7. Pristyn Care acquires Lybrate

Pristyn Care acquired the health-tech platform Lybrate⁴⁸. Lybrate is a telemedicine platform which connects patients

and doctors to provide primary healthcare. The acquisition by Pristyn Care will bring in synergies on overall healthcare delivery and make their foray into primary care.

8. Marksans Pharma to acquire Access Healthcare

Marksans Pharma Ltd., an Indian pharmaceutical company signed a share purchase agreement to acquire a 100% stake in a Dubai-based company, namely Access Healthcare for Medical Products LLC⁴⁹. Access Healthcare for Medical Products LLC is known for providing marketing and promotion solutions to pharmaceutical companies in the Middle East and North Africa region.

9. Mayo Clinic invests in Karkinos Healthcare for minority stake

US-based Mayo clinic invested an undisclosed amount, for a minority stake, in Karkinos Healthcare, a technology-driven oncology focused platform⁵⁰. Karkinos healthcare announced that it will utilise these funds to develop innovative healthcare solutions.

10. Accumax Lab raises USD 68 Million from investors

Accumax Lab, an Ahmedabad-based laboratory equipment manufacturer raised USD 68 Million (INR 520 Crore) from private equity firms Creador and India Life Sciences Fund⁵¹. The investment is set to bolster the efforts of the company in biopharma and pharma research.

11. Redcliffe Lifetech raises USD 61 Million

Redcliffe Lifetech Pvt. Ltd., a diagnostics platform raised USD 61 million (INR 466 Crore) in its latest funding round⁵². This funding round was led by investors such as LeapFrog Investments, Healthquad, Schroders, etc. The company is expected to utilise this investment to expand its geographic reach, with a focus on expansion in Tier 2, 3, and 4 cities.

⁴⁴ <https://health.economictimes.indiatimes.com/news/pharma/CIPLA-to-acquire-21-pc-stake-in-achira-labs-for-rs-25-cr/92292106>

⁴⁵ <https://health.economictimes.indiatimes.com/news/pharma/bdr-pharma-raises-rs-685-crore-from-multiples-other-investors/91606463>

⁴⁶ <https://health.economictimes.indiatimes.com/news/pharma/eris-lifesciences-acquires-oaknet-healthcare-for-650cr/91331896>

⁴⁷ <https://health.economictimes.indiatimes.com/news/pharma/torrent-pharma-acquires-4-brands-from-dr-reddys-laboratories/91818798>

⁴⁸ <https://health.economictimes.indiatimes.com/news/mergers-and-aquisitions/pristyn-care-acquires-lybrate/92056467>

⁴⁹ <https://health.economictimes.indiatimes.com/news/pharma/marksans-pharma-to-acquire-100-stake-in-dubai-based-access-healthcare-for-medical-products-ll-c/91083228>

⁵⁰ <https://economictimes.indiatimes.com/industry/healthcare/biotech/healthcare/mayo-clinic-invests-in-ratan-tata-backed-cancer-care-platform-karkinos-healthcare/articleshow/91724036.cms?from=mdr>

⁵¹ <https://economictimes.indiatimes.com/markets/stocks/news/creador-india-life-sciences-fund-buy-into-accumax-lab/articleshow/91959285.cms>

⁵² <https://health.economictimes.indiatimes.com/news/pharma/redcliffe-lifetech-raises-usd-61-mn-from-investors/91369857>

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