May-June 2024 Edition

This edition of the JSA Healthcare Newsletter focuses on key developments undertaken in the Indian healthcare ecosystem for the months of May and June 2024.

Regulatory updates

Medical Termination of Pregnancy (Amendment) Rules, 2024

The Ministry of Health and Family Welfare ("**MoHFW**") *vide* notification dated June 10, 2024, amended the Medical Termination of Pregnancy Rules, 2003. Under Rule 3B and in Form E of the Medical Termination of Pregnancy Rules, 2003, the word 'mental retardation' is substituted with 'women with intellectual disability'.

Circular on medical device licence holder under materiovigilance programme of India

The Central Drugs Standard Control Organisation ("**CDSCO**") issued a circular dated May 15, 2024, regarding the Materiovigilance Programme of India ("**MvPI**"). The MvPI is an important program for reporting of adverse events, and coordinated analysis related to the medical devices including in-vitro diagnostic devices. In this regard, the license holders are suggested to use the MvPI platform for reporting of any adverse events/serious adverse events associated with the devices to enhance the procedure for identifying risk associated with medical devices.

Circular on blood centre situated in hospital

CDSCO, *vide* circular dated May 22, 2024, clarified that the blood centre run by hospital means the blood centre situated in the hospital premises. Further, the applications for grant/renewal of license are accepted by the state drugs department and CDSCO for operation of blood centre/processing of human blood components run by the Government, Indian Red Cross Society, hospitals, charitable trust or voluntary organisation.

Circular on regulation of all Class C and D medical devices under licensing regime

CDSCO, *vide* circular dated May 16, 2024, stated that if an existing importer/manufacturer who is already importing/manufacturing any of the Class C or Class D medical devices, has submitted application on or before September 30, 2023 to the Central Licensing Authority, for the grant of import/manufacturing licence under the provisions of Medical Devices Rules, 2017, the said application must be deemed valid. The importer/manufacturer can continue to import/manufacture the said device(s) for up to 3 (three) months from the date of issue of this circular or till the Central Licensing Authority, takes a decision on the said application (*whichever is earlier*).

Circular on retention of license/certificates under Medical Devices Rules, 2017

CDSCO, *vide* circular dated May 15, 2024, requested all the stakeholders to ensure that the requisite fee payable under the Medical Devices Rules, 2017 ("**MDR 2017**") for manufacturing/import license of medical devices and registration of quality management system certification, may be deposited in appropriate account of the Government, before the stipulated timeline under MOR, 2017. The stakeholders must also submit the application to the licensing authority in order to maintain continuity of the product in the market.

Employees' State Insurance Corporation issues revised guidelines and standard operating procedure for home delivery of drugs

The Employees' State Insurance Corporation ("**ESIC**") *vide* circular dated January 10, 2024, revised the guidelines and Standard Operating Procedure ("**SOP**") relating to home delivery of drugs to the ESIC beneficiaries. ESIC medical colleges, on a pilot project basis, are authorised to provide the facility of home drug delivery to ESIC beneficiaries. These services are limited to the districts as decided by the dean/medical superintendent of the concerned hospitals.

Eligibility: (a) all senior citizens with chronic illness entitled for treatment with ESIC, receiving consultations from the hospital and prescribed for more than 30 (thirty) days; (b) all ESIC beneficiaries, ESIC employees and their dependents, pensioners seeking consultation through e-Sanjeevani; and (c) handicapped and bed ridden patients on medication for chronic disease.

Hospital's responsibility: Hospitals are required to float a bid on the Government e-Marketplace (GeM) portal for procuring doorstep delivery services for drugs, including packaging, collection and electronic notifications to the beneficiary *via* SMS/WhatsApp regarding dispatch and delivery confirmation. The medical stores' in-charge are to act as nodal officer to monitor smooth functioning of the delivery process. Further, each hospital is required to adopt its own SOPs basis the process flow requirement and local needs, guidance for the vendor, pharmacist, other stake holders and grievance redressal system.

Vendor's responsibility: The vendor must ensure that the delivery of the drugs should be done through one time password based/signature of the authorised recipient. The vendor will be responsible for sending an SMS/WhatsApp notification to the beneficiary intimating: (a) parcel tracking number along with the link of tracking webpage; and (b) delivery of drug packet information. Additionally, vendors are required to ensure maintenance of cold chain as and when required for certain drugs.

Re-operationalisation of the regulations governing health supplements, nutraceuticals, special dietary food and medical purpose and prebiotic and probiotic food

While Food Safety and Standards Authority of India ("**FSSAI**") is finalising the provisions of draft FSS (Health Supplements, Nutraceuticals, Food for Special Dietary Use, Food for Special Medical Purpose, and Prebiotic and Probiotic Food) Regulations, 2022 ("**Heath Supplements Regulations**"), it has *vide* direction dated June 5, 2024 decided to re-operationalise the provisions of the Health Supplements Regulations from April 1, 2024. These regulations are applicable to:

1. health supplements;
2. nutraceuticals;
3. food for special dietary use;
4. food for special medical purpose; and
5. prebiotic food and probiotic food.

Mandatory Ayushman Bharat Health Account ID for patient registration

The National Medical Commission ("**NMC**") *vide* public notice dated June 4, 2024, has mandated that all medical colleges are required to ensure that patients visiting for outpatient department/inpatient department/emergency services are registered with an Ayushman Bharat Health Account ("**ABHA**") ID in addition to the hospital's registration number. The authentication of patients and clinical material using ABHA ID is crucial for decisions regarding college assessments, such as increasing under graduate/post graduate seats, establishing new colleges, and renewing permissions/recognitions to admit students.

Press release on reforms in health insurance

The Insurance Regulatory and Development Authority on May 29, 2024, issued the Master Circular on health insurance business, repealing 55 (fifty five) circulars. Key aspects of the master circular are as follows:

1. wider choice to be provided by the insurers by making available products/add-ons/riders by offering diverse insurance products catering to all ages, regions, occupational categories, medical conditions/ treatments, all types of hospitals and health care providers to suit the affordability of the policyholders/prospects;
2. introduction of customer information sheet which is provided by the insurer along with every policy document, which explains the basic features of insurance policies in simple words; and
3. customer to be provided with the flexibility to choose products/add-ons/riders as per his/her medical conditions/specific needs.

Centre withdraws the powers of states for issuing no objection certificate for export of drugs

CDSCO, *vide* an order dated April 30, 2024 has withdrawn the power of State Governments to issue no-objection certificates ("**NOC**") for the manufacture of unapproved/banned/new drugs solely for export amid the heightened global scrutiny of Indian drugs. This power currently remains solely with CDSCO, and the existing players can file fresh applications for the NOC from May 15, 2024, via online mode through CDSCO zonal offices.

CDSCO drafts norms to report adverse effects of vaccines

The CDSCO on May 29, 2024, released "Guidance for industry on Pharmacovigilance requirements for Human Vaccines' directing the manufacturers and importers of vaccines to report Serious Adverse Events (SAEs) in India and distributing countries within 15 (fifteen) days to the CDSCO. After a vaccine is approved, requirement of stringent follow-up is essential, to monitor vaccine safety in routine use through phase IV-post marketing trials, practice management system, observational or non-interventional study for active surveillance, including assessment of Adverse Events Following Immunisation (AEFI) and Adverse Events of Special Interest (AESI).

CDSCO mandates adherence to Bureau of Indian Standards for medical devices

CDSCO, *vide* circular dated May 29, 2024, has mandated that medical device manufacturers and in-vitro diagnostic testing laboratories comply with the Bureau of Indian Standards ("**BIS**") for product testing. The circular was issued in consonance with the observation that the testing of the Medical Devices which have BIS Standards available has not be carried out as per the standards.

Self-Certificate for advertisement

On June 3, 2024, the Ministry of Information and Broadcasting in line with the directions issued by the Supreme Court of India ("**Supreme Court**") issued press release requiring a self-declaration certificate ("**SDC**") to be submitted before publishing or broadcasting any content effective from June 18, 2024. The advertising agencies are required to file their SDCs through the Broadcast Seva Portal and print and digital Media must submit the same *via* the Press Council of India's portal.

Case laws

The complaint of medical negligence may not be entertained unless supported by credible opinion given by another doctor

The High Court of Jharkhand in the case of ***Dr. Suman Kumar Pathak vs. the State of Jharkhand and Ritesh Kumar Sinha***[1] has quashed the criminal proceedings against the petitioner citing the need for credible medical evidence to support claims of negligence. The court emphasised that mere allegations without expert medical opinion are insufficient for criminal prosecution. The judgment referenced the Supreme Court's guidelines in the Jacob Mathew case, highlighting the need for caution in prosecuting medical professionals for negligence.

No person should be denied of quality medical treatment: Madras High Court

In ***B Anantha Lakshmi and S Kiruthika vs. the State of Tamil Nadu***[2] while adjudicating the bond period of post graduate doctors, the Madras High Court observed that any poor person who is unable to afford paid treatment can in no way be treated differently. A life is a life, and it has its value. No person should be denied quality treatment on economic grounds. The court dismissed the petitions, stating that the petitioners must fulfil the bond conditions as agreed, emphasising the importance of serving the poor and needy in government hospitals. The court upheld the bond conditions, requiring the petitioners to complete their service period in government hospitals.

Bombay High Court emphasised on the importance of preventing confusion in medicinal products, citing potential health risks

Glenmark Pharmaceuticals Limited[3] sought an injunction against Gleck Pharma for using the trademark "XIGAMET," claiming it was deceptively similar to their trademark "ZITA-MET. The court granted the ad-interim injunction, restraining Gleck Pharma from using "XIGAMET" due to the likelihood of confusion between the 2 (two) trademarks, especially given the medicinal nature of the products.

Fundamental right to health includes customer's right to be made aware of quality of products: Supreme Court

The Supreme Court in the case of ***Indian Medical Association and Anr. vs. Unions of India and Ors.***[4] has held that the fundamental right to health encompasses the right of a consumer to be made aware of the quality of products being offered for sale by manufacturers, service providers, advertisers and advertising agencies. To protect this right, the Court directed that henceforth, before an advertisement is printed/aired/displayed, a self-declaration shall be submitted by the advertiser/advertising agency on the lines contemplated in Rule 7 of the Cable Television Networks Rules, 1994.

[1] Cr.M.P. No. 2866 of 2016 dated June 18, 2024.
[2] WP N 6432 and 6434 of 2024 dated April 30, 2024
[3] Glenmark Pharmaceuticals Ltd. v. Gleck Pharma (OPC) Pvt. Ltd IP Suit (L) No 30149 of 2023
[4] W.P.(C) No. 645/2022

Not every death in hospital indicates medical negligence unless proven otherwise: National Consumer Disputes Redressal Commission

The National Consumer Disputes Redressal Commission ("**NCDRC**") presided by AVM J. Rajendra, in ***Hridylal Sahu vs. Dr. Roshan Upadhyay and Anr.***[5] held that not every death occurring in a hospital setting can automatically be considered medical negligence based on an assumption of inadequate medical care. It was further held that in order to prove medical negligence, concrete evidence has to be submitted.

Unsuccessful treatment or differing opinions does not equate to medical negligence: NCDRC

NCDRC presided by Mr. Binoy Kumar, in the case of ***Jagdish K Sharma vs. Medanta, the Medicity***,[6] dismissed a complaint against Medanta Hospital and ruled that an unfavorable outcome of treatment alone or a divergence in professional opinion does not amount to negligence on the part of the medical professionals as long as they're acting as per the accepted practice.

Interesting Reads

Expedite framing of policy on online sale of medicines, Madras High Court directs Centre

The Madras High Court has directed MoHFW as well as CDSCO to expedite the process of finalising a policy for the online sale of medicines and notify it at the earliest. A Division Bench made it clear that till then only licensed druggist and chemists could indulge in online sales and the competent authorities must initiate actions in the event of any violation.

Punjab and Haryana High Court seeks response from Punjab and Haryana Governments on establishing community home for persons with mental illnesses

The Punjab and Haryana High Court has sought response from both the states on public interest litigation filed seeking directions to establish community-based group homes for persons with mental illness and to frame comprehensive guidelines as per the Mental Health Care Act, 2017.[7]

MoHFW and Ministry of Defence sign memorandum of understanding to set up dedicated Tele MANAS cell for armed forces

A memorandum of understanding was signed between MoHFW and the Ministry of Defence on June 5, 2024, to facilitate collaboration between the 2 (two) ministries in operating a special cell of Tele MANAS, the National Telemental Health Helpline of MoHFW, as a pilot project for a period of 2 (two) years at the Armed Forces Medical College in Pune.[8]

FSSAI directs food business operators to remove claim of 100% fruit Juices from the label and advertisement of fruit juices

FSSAI has issued a directive mandating all Food Business Operators ("**FBOs**") to remove any claim of '100% fruit juices' from the labels and advertisements of reconstituted fruit juices with an immediate effect. All the FBOs have also been

[5] F.A. No. 2482/2017
[6] C.C. No. 1934/2018
[7] livelaw.in
[8] pib.com

instructed to exhaust all existing pre-printed packaging materials before September 1, 2024.[9]

Central council for research in ayurvedic sciences launches "PRAGATI-2024", an initiative to shape the future of ayurveda

The Central Council for Research in Ayurvedic Sciences ("**CCRAS**"), an autonomous body under the Union Ministry of Ayush, has launched "PRAGATI- 2024" (Pharma Research in AyurGyan and Techno Innovation). It offers an efficacious opportunity for collaborative research in the field of Ayurveda. It aims to explore research opportunities and foster collaboration between CCRAS and the Ayurveda drug industry.[10]

Healthcare Practice

JSA provides a full range of transactional and advisory services in the healthcare sector. We represent clients in the entire spectrum of the health care system, including, hospital networks and individual hospitals, managed care organisations, health insurers, pharmaceutical and biotechnology companies, medical device manufacturers; and major financial investors in the sector. These include domestic as well multinational clients. Our clients in the sector range from start-ups to industry leaders. We also represent the leading trade associations representing these industries, namely, Centre for Scientific & Industrial Research, Centre for DNA finger printing & Diagnostics, Institute of Microbial Technology, All India Institute of Medical Science-Department of Biotechnology, National Institute of Health & Family Welfare, etc.

JSA also has substantial experience in matters relating to regulation of foods, drugs, medical devices, cosmetics, product packaging, and dangerous chemicals. Our attorneys advise manufacturers on Indian labelling questions, national rules for testing and review of new products, reporting of safety information, and proceedings relating to product withdrawals. We regularly advise clients on regulatory standards governing advertising, the distinction between advertising and labelling and the differing regulatory standards that apply to each, and the roles of the states and self-regulatory mechanisms. JSA has been actively involved in advising clients with respect to regulation of nutrition and health claims in food advertising.

We also have extensive experience in litigating cases in courts and administrative agencies in the healthcare sector.

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[9] pib.com
[10] pib.com

Chambers TOP RANKED Asia-Pacific 2023 JSA	The LEGAL 500	asialaw OUTSTANDING FIRM 2023-24
17 Practices and 24 Ranked Lawyers	16 Practices and 11 Ranked Lawyers	19 Practices and 19 Ranked Lawyers
IFLR 1000 TOP TIER FIRM 2023	INDIA BUSINESS LAW JOURNAL BEST OVERALL LAW FIRMS 2023 LAW ASIA	ALB EMPLOYER OF CHOICE 2021 THOMSON REUTERS
11 Practices and 39 Ranked Partners **IFLR1000 APAC Rankings 2022** --- Banking & Finance Team of the Year --- Fintech Team of the Year --- Restructuring & Insolvency Team of the Year	Among Top 7 Best Overall Law Firms in India and 9 Ranked Practices --- 11 winning Deals in IBLJ Deals of the Year --- 10 A List Lawyers in IBLJ Top 100 Lawyer List	Banking & Financial Services Law Firm of the Year 2022 --- Dispute Resolution Law Firm of the Year 2022 --- Equity Market Deal of the Year (Premium) 2022 --- Energy Law Firm of the Year 2021
BENCHMARK LITIGATION	vahura	
7 Practices and 2 Ranked Lawyers	**Ranked #1** **The Vahura Best Law Firms to Work Report, 2022** --- Top 10 Best Law Firms for Women in 2022	

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