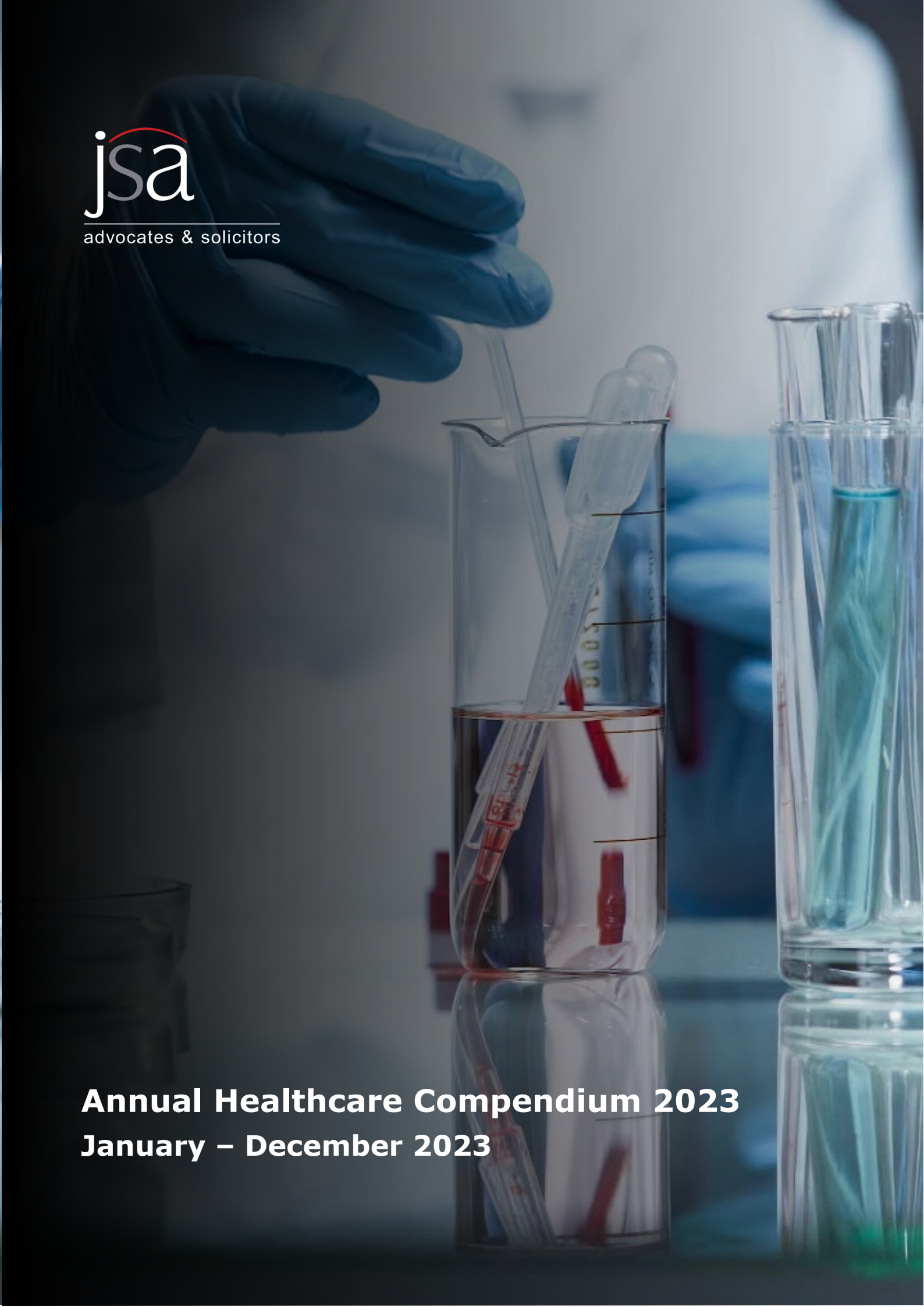

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Annual Healthcare Compendium 2023

January – December 2023

This Annual Healthcare Compendium comprises and provides insight into the relevant regulatory developments and case laws in the Healthcare sector in 2023.

The Union Budget for 2023-2024 (the "**Budget**") largely appears to focus on improvement of the public healthcare system in India, through Government run initiatives, as well as close co-operation with the private sector. The Budget envisages preparation for the adoption of futuristic technologies in medicine, through various up-skilling services and training services. Towards this goal for the healthcare sector, as set out in the Budget, a sum of INR 88,956,00,00,000 (Indian Rupees eighty-eight thousand nine hundred fifty six crore) has been allocated to health expenditure.

Regulatory Developments

Guidelines for the production linked incentive scheme for promoting domestic manufacturing of medical devices

The Government of India, in July 2020 issued the Production Linked Scheme for Promoting Domestic Manufacturing of Medical Devices (the "**PL Scheme**"). The PL Scheme proposed a financial incentive to boost domestic manufacturing and attract large investments in the medical device sector.

On February 25, 2023, the Department of Pharmaceuticals, Government of India issued the Guidelines for the effective and smooth implementation of the PL Scheme. The tenure of the PL Scheme is from April 1, 2020, till March 31, 2028. These guidelines outline the project criteria, investment criteria, eligibility criteria, incentive calculation, disbursement, etc. *Read more*

National Medical Device Policy, 2023

On May 2, 2023, the Government of India notified the National Medical Device Policy, 2023, to ensure that the medical device sector:

1. contributes to the objectives of public health by making quality products;
2. facilitates an orderly growth to meet the public health objectives of access, affordability, quality and innovation; and
3. achieves sustained growth and development in a holistic and coordinated manner. *Read more*

Scheme for assistance to medical devices clusters for common facilities

The Union Health Minister Mr. Mansukh Mandaviya launched on May 26, 2023, the 'Scheme for Assistance to Medical Devices Clusters for Common Facilities' during the eighth edition of the international conference on 'India Pharma & India Medical Device 2023'. Earlier, on May 9, 2023, the Department of Pharmaceuticals of the Government of India had released detailed guidelines for this scheme, which supplements the recently notified National Medical Device Policy, 2023 and aims to strengthen the existing infrastructural framework for medical devices clusters. *Read more*

Draft amendments proposed to Medical Devices Rules, 2017

The Ministry of Health and Family Welfare ("**MoHFW**") , on March 1, 2023, issued the draft Medical Devices (Amendment) Rules, 2023 to further amend the Medical Device Rules, 2017. The proposed amendment enables state governments to establish medical devices testing laboratories in the states for the purposes of testing and evaluation of medical devices. The proposed amendment also empowers state governments to designate any laboratory, accredited by the National Accreditation Body for Testing and Calibration Laboratories and having facilities for carrying out test and evaluation of medical devices, as such a testing laboratory.

Notification of standards for medical devices

The Bureau of Indian Standards has notified the Indian standards in relation to particular requirements for basic safety and essential performance of critical care ventilators.

Exemption to medical devices from the E-Waste (Management) Rules, 2022

The Ministry of Environment, Forest and Climate Change vide the E-Waste (Management) Second Amendment Rules, 2023 exempted certain medical devices and monitoring and control instruments (including laboratory equipment) from application of Rule 16 (1) of the E-Waste (Management) Rules, 2022. Rule 16 (1) prescribes a threshold for use of hazardous substances in the manufacture of electrical and electronic equipment and their components or consumables or parts or spares, during production.

Inclusion of additional medical devices under the licensing regime

The Central Drugs Standard Control Organisation ("**CDSCO**") ssued a circular on October 12, 2023, regulating Class C and D medical devices under a licensing regime, effective from October 1, 2023. Existing importer/ manufacturers who submitted applications for grant of import/ manufacturing license under the provisions of Medical Devices Rules, 2017 prior to such regulation will be held valid and can continue to import/manufacture for up to 6 (six) months from the date of issue of the said circular.

CDSCO issues advisory to uphold drug quality through strict manufacturing standards

The CDSCO issued an advisory guideline on December 5, 2023, alerting drug manufacturers to comply strictly with good manufacturing practices and licensing conditions. Emphasizing the critical role of excipients and active pharmaceutical ingredients (APIs) in ensuring drug quality, safety, and efficacy, the advisory urges the use of pharmaceutical-grade excipients in cough syrup production to prevent contamination, especially during increased usage in winters. Stakeholders are directed to ensure adherence to quality standards.

CDSCO directs updating of label for a fixed-dose combination

The CDSCO issued a circular on December 18, 2023, addressing concerns over unapproved promotion of an anti-cold drug formulation for infants. The committee's recommendation suggests restricting the use of fixed-dose combination (FDC) of Chlorpheniramine Maleate IP 2mg + Phenylephrine HCl IP 5mg drop/ml for children below 4 (four) years. Manufacturers are directed to update labels and promotional literature accordingly. All stakeholders are urged to notify action taken on such matter to the office.

Classification of In-vitro Diagnostic Medical Devices under MDR, 2017

The CDSCO, in consultation with Drugs Technical Advisory Board vide circular on October 25, 2023, classified invitro diagnostic medical devices under Rule 4(2) of the Medical Devices Rules, 2017. The said medical devices were previously regulated under the Drugs and Cosmetics Act, 1940 and the rules thereunder. The updated list of in-vitro diagnostic medical devices is available in annexure A of the said circular.

Fixation of retail and ceiling prices of various formulations by National Pharmaceutical Pricing Authority

The National Pharmaceutical Pricing Authority ("**NPPA**") vide order dated February 2, 2023, notified the retail and ceiling prices of various formulations. It also specified the details of the formulation along with

the strength, unit and name of manufacturer and marketing company. All such retail and ceiling pricings are exclusive of goods and services tax.

Retail price of new drugs

The Drugs (Prices Control) Amendment Order, 2023 sets out that the retail price of a new drug (or that which contains molecules or components that have either become off-patent or about to become off-patent) will be calculated by reducing 50% of the price arrived at under paragraph 4 of the Drugs (Prices Control) Order, 2013, and if the new drug is not available in the domestic market, the price will be determined by a Standing Committee of Experts.

Prohibition of the manufacture and sale of certain fixed dose combinations of drugs

The MOHFW issued a notification dated June 2, 2023, prohibiting the manufacture, sale, and distribution for human use of certain fixed dose combinations ("**FDCs**") of drugs. The decision was based on recommendations from an expert committee and the Drugs Technical Advisory Board. The expert committee concluded that there is no therapeutic justification for these FDCs and they may pose risks to human beings. Therefore, in the interest of public health, the government invoked Section 26A of the Drugs and Cosmetics Act, 1940 to prohibit the manufacture, sale, and distribution of FDCs. The move aims to ensure the safety and well-being of the public by regulating the use of such drug combinations.

NPPA fixes ceiling and retail prices for scheduled formulations and new drugs

The NPPA issued various orders dated June 8, 2023, and June 28, 2023, fixing the ceiling prices for certain scheduled formulations and retail prices for certain new drugs. The ceiling prices were set to regulate the pricing of various essential medicines and address inter-brand price variations. The NPPA aims to reduce the financial burden on consumers and ensure accessibility to affordable medications. The orders also highlight the need to control price increases for non-scheduled formulations.

Submission of Pharmacist Details at Kendra Level

The Pharmaceuticals and Medical Bureau of India issued a circular on June 5, 2023, emphasizing the importance of submitting the details of pharmacists employed at Janaushadhi Kendras (dedicated outlets which are opened to provide generic medicines at affordable prices). These details include the pharmacist's name, father's name, registration number, and other relevant information. The use of 'point of sale' software is mandatory for all Janaushadhi Kendras as part of the Pradhan Mantri Bhartiya Janaushadhi Pariyojana, which aims to enhance supply chain solutions and IT services for effective governance and transparency.

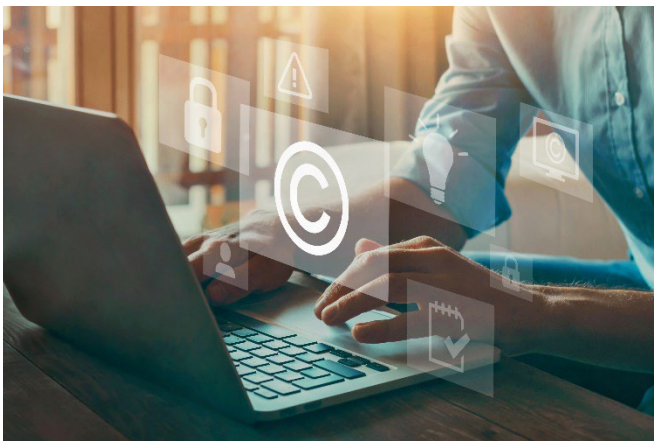
Avoidance of sale of certain over the counter (OTC) drugs

The Drugs Control Department, Government of New Delhi issued an advisory on July 19, 2023, advising all retail chemists to not undertake any over the counter sale of drugs such as aspirin, ibuprofen and diclonofenac group of medicines owing to increase in dengue and chikungunya cases. Such drugs may only be sold with a prescription issued by a registered medical practitioner. Retail chemists have also been instructed to keep a register of recording the stock of pain killer drugs falling under the said category.

Issuance of test license for veterinary drugs

The CDSCO issued a circular on July 19, 2023, indicating that all applications for issuance of Form 11 (test license) for veterinary drugs is now to be submitted online on the SUGAM portal (an e-governance initiative implemented by CDSCO) and that physical applications would no longer be accepted.

Pharmacists registered under Jammu and Kashmir Pharmacy Act, 2011, deemed to be registered under the Pharmacy Act, 1948



The Lok Sabha passed the Pharmacy (Amendment) Bill, 2023 ("**Amendment**") on August 7, 2023, allowing persons qualified or registered under the Jammu and Kashmir Pharmacy Act, 2011, to be registered as pharmacists under the Pharmacy Act,1948. The Amendment proposes to remove the ambiguity with respect to the 2 (two) legislations. Upon enactment, persons whose name has been entered in the register of pharmacists maintained under the Jammu and Kashmir Act, 2011 will be deemed entered in the registry of pharmacists prepared and maintained under Chapter IV of the Pharmacy Act, 1948.

Export Promotion Council for Medical Devices

The Directorate General of Foreign Trade, vide *public notice No. 18/2023* dated June 23, 2023 ("**Public Notice**") amended Appendix 2T (List of Export Promotion Councils/ Commodity Boards/Export Development Authorities) of Appendices and Aayat Niryat Forms under the Foreign Trade Policy, 2023. With effect from June 23, 2023, the amendment authorizes the Export Promotion Council for Medical Devices to issue registration-cum-membership certificates for the medical devices indicated in the aforementioned public notice.

Import of high-risk food products at specific ports

The Central Board of Indirect Taxes and Customs has vide *Instruction No. 5 of 2023* – Customs, dated February 8, 2023 instructed that certain high risk food products, including nutraceuticals, health supplements, and foods for special medical or dietary purposes are required to be imported only through 79 (seventy nine) specified ports, with effect from March 1, 2023.

Exemption of import duty on drugs, medicines or food needed for special medical purposes

The Government of India, vide notification dated March 29, 2023, exempted basic customs duty on all drugs, medicines and food for special medical purposes imported (for personal use) for treatment of rare diseases listed under the National Policy for Rare Diseases, 2021. .

Export sample of cough syrup to be tested by government approved laboratories

The Directorate General of Foreign Trade, vide *Notification No. 06/2023* dated May 22, 2023 ("**Notification**") amended the ITC (HS) Export Policy. With effect from June 1, 2023, the amendment mandates that cough syrups may be exported, subject to the export sample being tested by Government approved laboratories and production of a Certificate of Analysis issued by such laboratories, as specified in the said Notification. This direction has been issued following global concerns over the quality of cough syrups exported by Indian companies.

Approval of Medical Procurement Authority Act by the Maharashtra Cabinet with respect to single authority for procurement of medicines for state-run hospitals

The Government of Maharashtra in its cabinet meeting of February 14, 2023, approved the Medical Procurement Authority Act. This paves the way for formation of an independent entity for procurement of medicines in state-run hospitals and all municipal corporations in the State of Maharashtra.

'One Nation, One Policy' for Organ Donation and Transplantation

The Government of India, as per a press release issued on March 24, 2023, adopted the 'One Nation, One Policy' for organ donation and transplantation. The policy aims to bring in uniformity and oneness by proposing the removal of the requirement of state domicile for registration of patients requiring organ transplantation from a deceased donor thereby allowing anybody to register in any state for an organ transplant. Further, the new guidelines also allow persons of all ages to be eligible to receive deceased organ donation by removing the present upper age limit of 65 (sixty five) years.

Ayushman Bharat Digital Mission creates longitudinal electronic health record facilitating interoperability of health data

The MoHFW on March 17, 2023, designated premier institutions like AIIMS Delhi, PGIMER Chandigarh and AIIMS Rishikesh as Centres of Excellence for Artificial Intelligence to promote the creation and use of artificial intelligence ("**AI**") based solutions in healthcare system in India. The introduction of AI in healthcare aims to achieve the objectives of Ayushman Bharat Digital Mission ("**ABDM**"), which is the MoHFW's flagship scheme, of building a digitally connected healthcare ecosystem by creating a platform enabling interoperability of health data within the health ecosystem so as to generate a longitudinal electronic health record of every citizen. In addition to the introduction of AI, ABDM also envisages the integration of other cutting-edge technologies like Internet of Things (IoTs), blockchains etc. with existing health IT applications with a view to improve the performance of the healthcare services in India.

Inclusion of rare diseases under the National Policy for Rare Diseases, 2021

The MOHFW has classified 6 (six) diseases as rare diseases under the National Policy for Treatment of Rare Diseases ("**NPRD**"). These include Laron's Syndrome, Wilson's Disease, among others. Financial assistance to patients suffering from such rare diseases will be provided as per the provisions of the NPRD and other relevant guidelines issued by the MOHFW.

Constitution of state allied and healthcare councils

The MOHFW issued the National Commission for Allied and Healthcare Professions 5th (Removal of Difficulties) Order, 2023 and directed all state governments and union territories to constitute state allied and healthcare councils within 2 (two) years and 6 (six) months from the date of commencement of the National Commission for Allied and Healthcare Professions Act, 2021 i.e. on or before November 22, 2025.

National Medical Commission puts Registered Medical Practitioner (Professional Conduct) Regulations, 2023 on hold

The National Medical Commission issued a notification on August 23, 2023, suspending the National Medical Commission Registered Medical Practitioner (Professional Conduct) Regulations, 2023 with immediate effect. Instead, the Indian Medical Council (Professional Conduct, Etiquette, and Ethics) Regulations, 2002 will be enforced. This decision is in accordance with the powers vested under the National Medical Commission Act, 2019.

Department-Related Parliamentary Standing Committee on Health and Family Welfare release its 146th Committee Report

The Department-Related Parliamentary Standing Committee on Health and Family Welfare prepared the 146th report on the 'Action Taken by the Government on the Recommendations/ Observations contained in the 138th Report on Medical Devices: Regulations and Control' pertaining to the Department of Health & Family Welfare, Ministry of Health & Family Welfare.

The said report was laid before the Lok Sabha on August 4, 2023. The 138th report contained 49 (forty nine) recommendations of which 9 (nine) recommendations were accepted.

Approval of the National Research Foundation (NRF) Bill, 2023

The Ministry of Science and Technology issued a press release dated June 28, 2023, with respect to grant of approval by the Union Government for the introduction of National Research Foundation (NRF) Bill, 2023 in the Parliament. This legislation will enable the establishment of the NRF, which aims to initiate, nurture, and advance research and development (R&D) activities, while fostering a culture of research and innovation across universities, colleges, research institutions, and R&D laboratories throughout India.

National Medical Council ("NMC") releases notification for the maintenance of standards of medical education

The NMC issued a gazette notification on September 19, 2023, outlining regulations for medical education to maintain standards and streamline compliance processes. The key highlights of the notification include mandatory annual disclosure by medical institutions and oversight process through individual and joint evaluations by the respective governing board of medical education.

Pharmacy Council of India ("PCI") releases circular seeking implementation of the Jan Vishwas Act, 2023

The PCI issued a circular on October 25, 2023, to all the State Governments, Pharmacy Councils and approved institutions for the implementation of the Jan Vishwas (Amendment Provisions) Act, 2023 which amended certain punitive provisions of the Drugs and Cosmetics Act, 1940 and the Pharmacy Act, 1948, included inquiry and appeal related provisions, increased fine amounts, and increased authority for the State Councils Presidents to adjudicate violations.

Release of the draft National Pharmacy Commission Bill, 2023

The MOHFW has released the preliminary National Pharmacy Commission Bill, 2023, with the intention of revoking the Pharmacy Act of 1948 and substituting the Pharmacy Council of India with a nationwide commission. On November 14, 2023, the MOHFW published the draft bill on its website, inviting feedback from the general public and stakeholders. The proposed legislation seeks to establish a pharmacy education system that enhances the accessibility of quality and cost-effective pharmaceutical education, ensures the presence of sufficient and high-calibre pharmacy professionals across the entire nation, advocates for fair and inclusive healthcare, and facilitates the accessibility of pharmacy professionals' services to all citizens.

Issuance of Guidelines for Umbilical Cord Blood Banking, 2023 by Indian Council of Medical Research

The Guidelines for Umbilical Cord Blood Banking, 2023 (the "**UCBB Guidelines**") have been issued by the Indian Council of Medical Research. The UCBB Guidelines are meant to serve as a guidance document on the quality and ethical aspects of umbilical cord blood collection, processing, banking, and release. The UCBB Guidelines are applicable to all stakeholders including umbilical cord blood banks and personnel involved in all its procedures, obstetricians, neonatologists, and transplant physicians along with parents and all individuals providing support services. It may be stated that the said UCBB Guidelines are not meant to be construed to replace or overrule but to substantiate the existing regulatory requirements as described in Drugs and Cosmetic Act, 1940, read with corresponding rules and amendments, that are already in place for umbilical cord blood banking.

NMC issues a public notice banning e-cigarettes and heated tobacco products ("HTPs")

The NMC issued a public notice on December 15, 2023, notifying healthcare professionals about the ban on e-cigarettes and HTPs under the Prohibition of Electronic Cigarettes (Production, manufacture, import, export, transport, sale, distribution, storage and advertisement) Act, (PECA), 2019. Affiliated

professionals must refrain from researching or engaging in related activities without prior approvals from Directorate General of Health Services and MoHFW. The public notice also provides that healthcare professionals affiliated with National Medical Commission must comply with D.O. letter H.11013/03/2021-TC dated December 8, 2023.

Issuance of Assisted Reproductive Technology (Regulations) Amendment Rules, 2023 by MoHFW

The MoHFW vide notification dated February 24, 2023, issued the Assisted Reproductive Technology (Regulations) Amendment Rules, 2023, by which any person intending to transfer their gametes and embryos for personal use within or outside India is required to apply or furnish declarations in prescribed forms and obtain the prior permission of the National Assisted Reproductive Technology and Surrogacy Board.

Surrogacy (Regulation) Amendment Rules, 2023

The MoHFW, on March 14, 2023, notified the Surrogacy (Regulation) Amendment Rules, 2023 to amend paragraph 1 (d) under Rule 1 of Form 2 of the Surrogacy (Regulation) Rules, 2022. The amendment disallowed the use of donor gametes for couples undergoing surrogacy and mandated the requirement of having both the gametes from couples intending to undergo surrogacy. The amendment however allowed single woman, whether widow or divorcee, to use donor sperms along with self-eggs to avail surrogacy.

New Drugs and Clinical Trials (Amendment) Rules, 2023

The MoHFW , on March 9, 2023, notified the New Drugs and Clinical Trials (Amendment) Rules, 2023, in terms of which the following non-clinical testing methods for assessing the safety and efficacy of a new drug or investigational new drug have been permitted: (a) cell-based assay; (b) organ chips and micro physiological systems; (c) sophisticated computer modelling; (d) other human biology-based test methods; and (e) animal studies.

Product for persons with disabilities (PWD), persons afflicted with HIV/AIDS, and those with mental illness

The Insurance Regulatory and Development Authority of India ("**IRDAI**") directed all general and stand-alone health insurers to make available, with immediate effect, a specific insurance cover for persons with disabilities, persons afflicted with HIV/AIDS, and those with mental illness. Such policy must be for a tenure of 1 (one) year and renewable. According to the circular, insurers may determine the price of the insurance cover subject to compliance of the norms specified in IRDAI (Health Insurance) Regulations, 2016.

Enforcement drive for verification of quality and safety of health supplements

The Food Standards and Safety Authority of India, vide circular dated March 7, 2023, required all food regulators in the states to conduct a special enforcement drive to ensure that all nutraceuticals and health supplements are in compliance with the extant regulations, being the Food Safety and Standards (Health Supplements, Nutraceuticals, Food for Special Dietary Use, Food for Special Medical Purpose, and Prebiotic and Probiotic Food) Regulations, 2022 and the Food Safety and Standards (Advertising and Claims) Regulations, 2018.

Distinction between pharmacy education and para-medical education

The Pharmacy Council of India issued a notification dated June 19, 2023, clarifying that pharmacy education is different from para-medical education and that the two cannot be clubbed. Pharmacy education for the purpose of registration of pharmacists is

regulated under the Pharmacy Act, 1938 and cannot be extended to para-medical personnel.

Introduction of Tobacco Products (Prohibition of Advertisement and Regulation of Trade and Commerce, Production, Supply and Distribution) Amendment Rules, 2023 requiring anti-tobacco warnings on streaming platforms

The MOHFW vide a notification dated May 31, 2023, unveiled the Cigarettes and other Tobacco Products (Prohibition of Advertisement and Regulation of Trade and Commerce, Production, Supply and Distribution) Amendment Rules, 2023 ("**2023 Amendment**") mandating publishers of online curated content such as over-the-top streaming platforms ("**OTT Platforms**") to prominently display warnings about smoking and tobacco use during shows featuring such scenes. The 2023 Amendment requires OTT Platforms to include 'anti-tobacco health spots' at the beginning and middle of programs, display static anti-tobacco health warnings at the bottom of the screen when showing tobacco products, and incorporate audio-visual disclaimers about the harmful effects of tobacco. Pursuant to the 2023 Amendment, OTT Platforms will have access to sample disclaimers made available on the National Control Tobacco Programme website (available at ntcp.mohfw.gov.in) or the MOHFW website (available at mohfw.gov.in).

'SMART' program for Ayurveda professionals to boost R&D in Ayurveda in the country

The National Commission for Indian System of Medicine and the Central Council for Research in Ayurvedic Sciences, the 2 (two) institutions operating under the Ministry of Ayush for regulating medical education and conducting scientific research in India, launched the 'SMART' (Scope for Mainstreaming Ayurveda Research in Teaching) program ("SMART Program") that aims to transform clinical research in Ayurveda by boosting scientific research in priority healthcare research areas through Ayurveda colleges and hospitals. The Ministry of Ayush issued a press release on January 2, 2023, to announce the launch of the SMART Program.

New system to measure and grade performance of hospitals empanelled under Ayushman Bharat PM-JAY scheme

The National Health Authority ("**NHA**") introduced a new system to grade and measure the performance of hospitals enlisted under the Ayushman Bharat PM-JAY scheme (as per the press release issued by the MoHFW on January 9, 2023). The objective of the new system is to maximise health benefits by incentivizing and encouraging the healthcare providers to focus on delivering patient centric services. The rationale for introducing the new system is to shift the focus of measuring hospital performance from a 'volume-based' healthcare model where case-based bundled payment is made on the basis of number of services provided to a 'value-based care' model where payment will be outcome based and providers will be rewarded according to the quality of treatment delivered.

Key points of the 'new value-based' system are: (i) The performance of hospitals enlisted in Ayushman Bharat PM-JAY will be graded and measured on five performance indicators: a) Beneficiary Satisfaction; b) Hospital Readmission Rate; c) The extent of Out-of-Pocket Expenditure; d) Confirmed Grievances; e) Improvement in inpatients' Health-Related Quality of Life. (ii) A public dashboard displaying the performance of all hospitals as per these five indicators will be available to help the beneficiaries under the scheme to make an informed decision; (iii) The new system enables the beneficiaries of the scheme to exercise cost controls; and (iv) Suppliers would benefit from being able to align their products and services with positive patient outcomes and reduced cost.

New scheme to promote the adoption of ABDM

The NHA started the Digital Health Incentive Scheme ("**DHIS**") to promote digital health transactions under the ABDM (as per the press release issued by the MoHFW on December 22, 2022). The objective of the scheme is to encourage healthcare facilities and digital solution companies to come forward and join the ABDM for providing patient-centric healthcare. The scheme intends to provide incentives to hospitals and diagnostic labs and to providers of digital health solutions, such as, hospitals, Health Management Information Systems and the Laboratory Management Information System.

Key points of the DHIS are: (i) Health facilities with 10 (ten) or more beds, laboratory or radiology diagnostic centres, and digital solution companies that provide ABDM-enabled digital solutions would be eligible to avail the incentives under the DHIS. (ii) The incentives will be provided on the basis of the number of Ayushman Bharat Health Account ("**ABHA**")-linked transactions i.e. the digital health records created and linked to ABHA. (iii) Digital Solution Companies will be given an incentive of 25% of the incentive amount received by the eligible health facilities using their digital solutions. (iv) For ABHA linked transactions done by facilities not eligible for direct incentives under the DHIS for example clinics / small hospitals / health lockers / teleconsultation platforms etc., an incentive would be provided to digital solution companies.

Case Laws

1. The Supreme Court of India ("**Supreme Court**") in the case of ***M.A. Biviji v. Sunita & Others***,[1] reiterates the requirement of a higher burden to establish medical negligence. Every case of occupational negligence cannot be compared with professional negligence.

2. In its 2018 judgment in ***Common Cause v Union of India***[2], the Supreme Court had, while recognising the legality of passive euthanasia, framed certain guidelines in relation to living wills/advance medical directives. One of the guidelines required the living will to be attested to by 2 (two) independent witnesses, and a Judicial Magistrate, First Class. By its order dated January 24, 2023, the court, whilst recognising the cumbersome nature of the said guidelines, has removed the requirement of the attestation by the magistrate, and has instead indicated that the living will could be attested by a notary, or a gazette officer.

3. The Supreme Court in the case of ***Baharul Islam and Ors. v. Indian Medical Association and Ors.***[3] held that any variation in the standards of the qualifications required of medical practitioners who render services in rural areas vis-à-vis those rendering services in urban and metropolitan areas is violative of the constitutional values of substantive equality and non-discrimination. Further, the Supreme Court struck down the Assam Rural Health Regulatory Authority Act, 2004, which permitted diploma holders in Medicine and Rural Health Care to treat certain common diseases, perform minor procedures, and prescribe certain drugs.

4. The Supreme Court in the case of ***Prakash Bang v. Glaxo SmithKline Pharma Ltd.***[4], has upheld the order of National Consumer Disputes Redressal Commission ("**NCDRC**") citing a lack of mention of side effects on the packaging and subsequent damage in the form of myositis as an adverse reaction to the vaccine 'EnergixB'. The Supreme Court held that it is the duty of the doctor who prescribes such a drug to reveal the side effects.

5. The Supreme Court ruled in ***Mrs. Kalyani Rajan v. Indraprastha Apollo Hospital & Ors.***[5], that there was a lack of evidence regarding the heart attack and the actual treatment, thus missing out on the causal effect. The court considered the evidences and the decision of the NCDRC was upheld in the matter reiterating that the doctor cannot be held liable for medical negligence.

6. The Supreme Court in the case of ***M.A. Bivji v. Sunita & Ors.***[6], set aside the order passed by the NCDRC to pay compensation for a complainant who had suffered permanent damage to her respiratory tract and voice loss, due to medical negligence during Nasotracheal Intubation (NI). The Supreme Court considered the opinions of all treating doctors and found no adverse link to the prescribed treatment route. The Supreme Court also held that there was no causal link between the NI procedure and the medical complications. Therefore, the subsequent injury cannot be attributable to medical negligence by the doctors.

7. The Supreme Court in the case of ***CPL Ashish Kumar Chauhan v. Commanding Officer and Others***[7], ordered the Indian Air Force to pay compensation of INR 1,60,00,000 (Indian Rupees one crore sixty lakh) to the retired officer, he having contracted the human immunodeficiency virus during a blood transfusion at a military hospital. The Supreme Court observed that only superficial attention was paid during the blood transfusion and that there was lack of adherence to or breach of relevant standards of care, as may be reasonably expected from a medical establishment. The Supreme Court went on to hold the Indian Army and the Indian Air Force vicariously liable for the conditions in the medical establishment and directed that in addition to the compensation, these institutions were directed to bear all expenses incurred by the person during any visit for bi-monthly check-ups.

8. In the case of ***Arun Muthuvel v Union of India***[8], certain provisions of India's Surrogacy Regulation Act, 2021, and the Assisted Reproductive Technology (Regulation) Act, 2021, have been challenged before the Supreme Court . On February

[1] *Civil Appeal No. 4847 OF 2018 (Supreme Court)*
[2] *WP (C) No. 215 OF 2005 (Supreme Court)*
[3] *SLP(C) No. 32592-32593/2015 (Supreme Court)*
[4] *Civil Appeal No. 6791 OF 2013 (Supreme Court)*
[5] *Civil Appeal No. 10347 OF 2010 (Supreme Court)*
[6] *Civil Appeal No. 4847 OF 2018 (Supreme Court)*
[7] *Civil Appeal No. 7175 OF 2021 (Supreme Court*
[8] *W.P. (Civil) No. 756 of 2022 (Supreme Court)*

7, 2023, the Supreme Court directed the Government of India (through the National Assisted Reproductive Technology and Surrogacy Board (the "Board")) to implement forthwith, those suggestions which are feasible and acceptable by the Board. During the hearing on February 7, 2023, the Government of India in relation to the aforementioned statutes had clarified its position viz., (a) child to be born through surrogacy must be genetically related to the intending couple or intending woman; (b) constitution of a state-level Board in all states and union territories; and (c) constitution of appropriate authorities in all states and union territories for the purposes of the 2 (two) legislations. The government informed the Supreme Court that other than the States of Bihar, Haryana, and Uttar Pradesh, the Board had been constituted in all other states and union territories.

9. The Supreme Court modified a slew of directives regarding advance medical directives, or living wills, under the 2018 ruling of ***Common Cause v. UOI***[9], that had recognised the right to die with dignity, and had accordingly upheld the legal validity of passive euthanasia.

10. In ***S. Athilakshmi v The State. Rep by the Drugs Inspector***[10] the Supreme Court has held that when a small quantity of medicine has been found in the premises of a registered medical practitioner, it would not amount to sale of medicines across an open counter in a shop, while quashing the criminal proceedings against the medical practitioner under the Drugs and Cosmetics Act, 1940.

11. The Supreme Court in the case of ***Gostho Behari Das v Dipak Kumar Sanyal and Ors.***[11] has held that a doctor's license to practice cannot be suspended as penalty under the Contempt of Court Act, 1961. The court went on to observe that a medical practitioner guilty of contempt of Court may also be so for professional misconduct but the same would depend on the gravity/nature of the contemptuous conduct of the person in question. The court further held that they are, however, offences separate and distinct from each other. The former is regulated by the Contempt of Court Act, 1971 and the latter is under the jurisdiction of the National Medical Commission Act, 2019.

12. In the case of ***ABC v. State of Maharashtra***[12], the Bombay High Court allowed a married woman to terminate her 32 (thirty two) week pregnancy after the foetus was detected with severe abnormalities, stating that in cases of severe foetal abnormality the length of the pregnancy does not matter and that a woman has a right to choose whether to continue her pregnancy or not, as refusing termination solely on the basis of delay would be denial of her right to dignity, and her reproductive and decisional autonomy. The court further held that, "it is the woman alone who is the ultimate decision-maker on the question of whether she wants to undergo an abortion once the conditions in the statute are met".

13. Vide its order dated January 24, 2023, in the case of ***Haider Khalid v Union of India (WP(C) 7588/2016)***[13] and in the case of ***The Indian Association of Physiotherapists (IAP) v. Union of India***[14], the Delhi High Court directed the MoHFW to establish a National Commission and Professional Council for Physiotherapists. The direction has been issued in response to a request from several physiotherapists who wanted the Government of India to take steps in recognising physiotherapy as a separate and independent profession, establishing a separate regulatory body to oversee them, and rewriting the standards established for the profession.

14. In ***Master Arnesh Shaw v Union of India***[15], the Delhi High Court has directed the government to immediately release INR 50,000,000 (Indian Rupees fifty million) to AIIMS to ensure that the treatment of children with rare diseases, which has already commenced, is not stopped due to lack of funds.

15. In a petition filed by the petitioners who are mostly children suffering from rare diseases claiming that medicines and therapies are exorbitantly expensive, the Delhi High Court in ***Arnesh Shaw and Ors. V. Union of India***[16] constituted a 5 (five) member committee to implement the National

[9] *WP (C) No. 215 OF 2005 (Supreme Court)*
[10] *SLP (Crl.) No. 9978 of 2022 (Supreme Court)*
[11] *Civil Appeal No. 4725/2023 (Supreme Court)*
[12] *WP (ST) No. 1357/2023 (Bombay High Court)*
[13] *WP(C) 7588/2016 (New Delhi High Court)*
[14] *WP (C) 8322/2017 & C.M. No. 41667/2017 (Delhi High Court)*
[15] *W.P.(C) 5315/2020 & connected matters (Delhi High Court)*
[16] *2023/DHC /003423 (Delhi High Court)*

Policy for Rare Diseases, 2021. This will be undertaken in close coordination among the medical community, therapy providers and governmental organizations.

16. The Delhi High Court in the case of ***Glenmark Pharmaceuticals and Ors. V. Union of India***[17] has given the central government a 2 (two) week period to file a reply in response to a writ petition filed by a pharmaceutical company. The petition seeks the court's intervention to overturn a notification dated June 2, 2023, issued by the Union health ministry, which prohibits the manufacturing and sale of certain FDCs for human use.

17. The Delhi High Court in the case of ***Surgical Manufacturers and Traders Association v Union of India***[18], has held that the MoHFW's decision to bring all medical devices within the ambit of the expression "drug" is a clear policy matter and that no fault can be found with the 2020 notification, whereby all medical devices were brought within the purview of the expression "drug". The Delhi High Court went on to observe that the MoHFW's reasons for doing so are manifold and include the desire to align itself with the international regulatory regime and to further the interest of patients.

18. The High Court of Delhi in the recent of ***Union of India and Another v. Bharat Serums and Vaccines Limited***[19] addressed several key points related to the Drug Price Control Order ("**DPCO**") of 2013. It held that the DPCO of 2013 applies to drug formulations, not bulk drugs. It establishes a price control mechanism for scheduled drug formulations and a price monitoring mechanism for non-scheduled formulations and that non-scheduled formulations are not part of the price control regime but fall under the price monitoring mechanism as per the National Pharmaceutical Pricing Policy (NPPP) of 2012. It also held that the price monitoring mechanism for non-scheduled formulations prioritizes public/consumer interest, aligning with the objective of ensuring equitable distribution of drugs at fair prices.

19. The High Court of Delhi in its recent order in ***Dr. Zaheer Ahmed v Preeti Sudan, Secretary, Union of India and Ors***[20] has directed the Government of India to formulate a policy for sale of medicines by e-pharmacies within a period of 8 (eight) weeks, while acknowledging the delay in formulation and implementation of such a policy. The Court has also required the Joint Secretary dealing with such a policy to appear before the court if such policy has not been framed before the next date of hearing, being March 4, 2024.

20. The High Court of Bombay, in the case of ***Khalil Ahmad Hasanmiya Wasta v. State of Maharashtra and Ors***.[21], raised concerns regarding the underutilization of healthcare budget allocations and substantial staff vacancies in medical departments. The court highlighted the need to expedite recruitment processes to fill vacancies, emphasizing the adverse impact on healthcare facilities due to high number of unfilled positions. Additionally, the court requested detailed affidavits from authorities regarding past budgetary lapses and plans to address vacancies.

21. In ***Hindustan Medical Products v State of Karnataka***[22], the Karnataka High Court held that "it is well settled and as per the definition and explanation to the Section 34 (of the Drugs and Cosmetics Act, 1940) that Company means including firm and Director including the partners. Normally, as per the definition of Partnership Act, 1932 they are individually called as partners and collectively they are called as firm. Therefore, it cannot be said the partners are not responsible for the day to day affairs of the firm". It had been alleged by the partners of Hindustan Medical Products that as partners they could not be held liable, and only the technical person could be held liable, in relation to manufacture of sub-standard drugs. Referring the matter back to the trial courts, the Karnataka High Court opined that the partners would have to stand trial, in relation to the allegations of manufacture of sub-standard drugs made against the partnership.

[17] *W.P.(C) 8466/2023 (Delhi High Court)*
[18] *WP (C) No. 10478/2020 (Delhi High Court)*
[19] *LPA 118/2023 & C.M. No. 7868/2023, C.M. No. 7871/2023 (Delhi High Court)*
[20] *Cont. Cas(C)355/2019 & C.M.Nos. 12361-12362/2023, 44233/2023 (Delhi High Court)*
[21] *Public Interest Litigation Stamp No. 16 of 2021 (Bombay High Court)*
[22] *CrlP No. 6742/2020 (Karnataka High Court)*

22. In ***Sundaram Surgicals v Drugs Inspector, Doda***[23] the Jammu and Kashmir High Court has held that a retailer cannot escape liability in relation to spurious or sub-standard quality drugs, merely because he has obtained the same from a licensed dealer. A retailer can seek discharge only if he shows that he has acquired the drug from a duly licensed manufacturer, distributor or dealer and that he did not know and could not, with reasonable diligence, ascertain contravention of the provisions of the section and further that the drug or the cosmetic was properly stored and remained in the same state as and when he acquired it. The burden to prove the aforesaid 3 (three) conditions would always be upon the concerned dealer.

23. In the recent case of ***Dr. Vijay Singh v The State of Jharkhand***[24], the Jharkhand High Court held that proceeding further on a protest petition when the expert committee finding in a medical negligence case is in favour of the doctor, amounts to abuse of the legal process.

24. In the case of ***Pink City Heart & General Hospital v Banarsi Devi and Ors.***[25], the NCDRC dismissed the complaint filed by the appellant relating to medical negligence of the hospital on the grounds that the complainant failed to bring on record appropriate medical evidence to prove medical negligence. The NCDRC held that "every death of a patient cannot, on the face of it, be considered as death due to medical negligence, unless there is material on record to suggest to that effect".

25. In the case of ***Amar Singh Bhatia & Anr. v. Sir Ganga Ram Hospital & Ors.***[26], plea was moved by a man seeking organ donation, and challenging the delay on the part of Sir Ganga Ram Hospital to take a decision on the kidney transplant which the petitioner required. The issue raised in the plea is that there are no prescribed timelines for holding the interview by the authorisation committee under Transplantation of Human Organs and Tissues Rules, 2014, once the requisite documentation is submitted.

26. The NCDRC in ***Pushpa Verma and Ors. V. Bhardwaj Nursing and Maternity Home Private Limited***[27] vide its judgement dated June 12, 2023, dismissed a case alleging medical negligence in the death of the former Chief Justice of India, J.S. Verma. The complaint was filed by Late Justice J.S. Verma's wife and children against prominent doctors and major hospitals.

27. The NCDRC in ***Priyanka Tandon V. Bhatia Global Hospital and Endosurgery Institute and Others***[28] fined Bhatia Global Hospital INR 1,50,00,000 (Indian Rupees one crore fifty lakh) for medical negligence owing to a mix up of sperm donated by the biological father.

28. The Calcutta High Court in the case of ***Dhirarastra Dutta v State of West Bengal and Ors.***[29] has restrained an individual registered with the Alternate Medical Council, Kolkata from using the prefix 'Doctor.'

29. The Kerala High Court in a recent ruling of ***XXX v State of Kerala***[30] instructed the state police chief to take necessary measures in sensitizing all police officers regarding the relevant provisions outlined in the Mental Healthcare Act of 2017. The court took into account the suggestion put forth by the amicus curiae during the proceedings that competent authorities must ensure that police officers receive appropriate training under the said legislation.

30. In a landmark decision, the Allahabad High Court in the case of ***M/S Nicholas Piramal India Ltd. And Ors Vs Presiding Officer Labour Court Lko. And Ors***[31]. affirmed the status of medical representatives as "workmen" under the Industrial Disputes Act, 1947 ("**ID Act**"). This ruling overturned a previous contention that medical representatives were not considered "workmen" under the ID Act. The court upheld a Labour Court's decision that a medical representative's dismissal, based on allegations of submitting false call reports, was unfair and illegal. The court's decision clarified that medical representatives are entitled to the same protections under the ID Act as other workers.

[23] CRMC No. 396/2018 (Jammu and Kashmir High Court)
[24] Cr. M.P. No. 588 of 2013 (Jharkhand High Court)
[25] First Appeal No. 1018 of 2019 (NCDRC)
[26] W.P.(C) 3590/2020 and CMAPPL. 12775/2020 (Delhi High Court)
[27] Consumer Case No. 257 of 2015 (NCDRC)
[28] Consumer Case No. 14 of 2010
[29] WPA(P)/21/2023 (Calcutta High Court)
[30] Crl.MC No. 428 of 2023 (Kerala High Court)
[31] Writ – C No. – 1004529 of 2007 (Allahabad High Court)

31. The Madras High Court in the case of ***Dr. D. Hariharan and Others v. UOI and Others and connected matters***[32] upheld Tamil Nadu government's decision to grant incentive marks to doctors serving in COVID-19 duties for regular government appointments. The court dismissed petitions by doctors challenging the order, stating that COVID-19 pandemic warranted special consideration. It emphasized the laudable service of government doctors, justifying the classification for incentive marks. The court disagreed with excluding postgraduate students, allowing them to seek a COVID duty certificate for consideration within ten days. Overall, the decision supports recognizing and incentivizing medical professionals during the pandemic.

[32] W.P. Nos. 25827, 25785 and 27568 of 2023 (Madras High Court)

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.

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

The authors of this Compendium are:

Sidharrth Shankar
Partner

Ayisha Mansoor
Partner

Arjun Krishnamoorthy
Principal Associate

Adil Khan
Associate

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