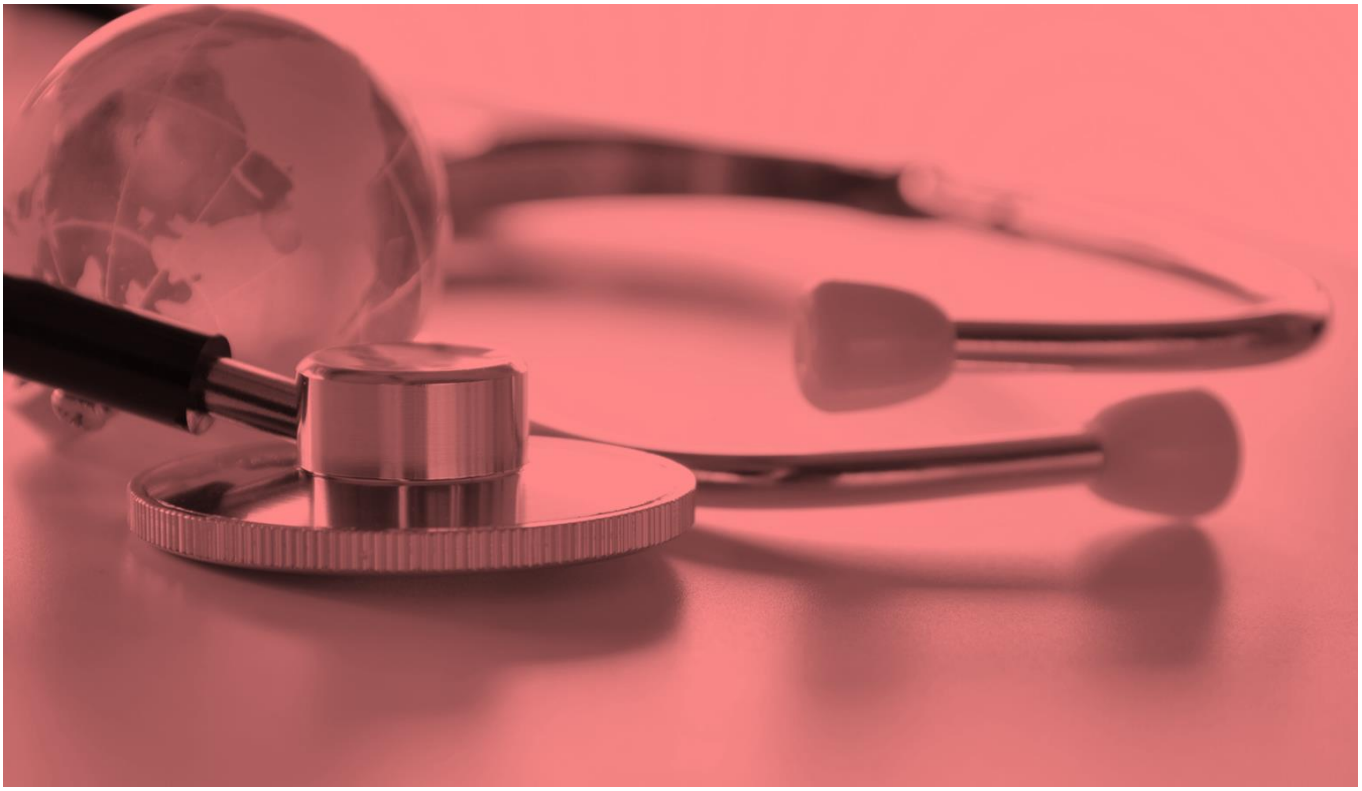
jsa
advocates & solicitors

Knowledge Management

Semi-Annual Healthcare Compendium 2025

July – December 2025

Semi-Annual Healthcare Compendium 2025



Introduction

India and the United Kingdom ("**UK**") signed the Comprehensive Economic and Trade Agreement ("**CETA**") on July 24, 2025. CETA offers opportunity to the Indian healthcare and pharmaceutical sector by opening pathways for Indian drug manufacturers to expand in the UK, including access to government procurement schemes such as the NHS, while also allowing India to benefit from advanced British healthcare technologies. At the same time, the agreement preserves India's key safeguards on patents and regulation, ensuring that affordable generics and biosimilars remain available. By fostering collaboration in biotechnology, joint research, and supply chain resilience, the pact deepens bilateral ties and supports improved healthcare delivery and global health preparedness.

The National Health Authority ("**NHA**"), at the Central Vigilance Commission workshop as part of Vigilance Awareness Week 2025, showcased the use of Artificial Intelligence ("**AI**") to strengthen transparency and integrity in India's digital health ecosystem. Dr. Sunil Kumar Barnwal, IAS, CEO, (NHA) shared his insights on the integration of AI within India's digital health ecosystem, particularly through flagship initiatives such as the *Ayushman Bharat* Digital Mission and *Ayushman Bharat – Pradhan Mantri Jan Arogya Yojana*. He further focused on 'Fraud Detection in Government Health Schemes using AI' highlighting NHA's innovative use of AI and machine learning to identify, prevent and address fraudulent activities in real time. AI and machine learning are revolutionising the world's largest public health assurance scheme, shifting the paradigm from reactive fraud detection to proactive integrity management.

Further, India signed a Memorandum of Understanding ("**MoU**") with Australia in the area of food safety. The MoU will strengthen cooperation in the field of food safety, through the exchange of best practices, knowledge sharing, import procedures and other technical collaboration including capacity-building initiatives.

This Compendium consolidates all the key developments undertaken in the healthcare sector which were circulated as JSA Newsletters/Prisms during the calendar period from July 2025 till December 2025.

Regulatory updates

Ministry of Health and Family Welfare

Cosmetics (Amendment) Rules, 2025

The Ministry of Health and Family Welfare ("**MoHFW**"), *vide* notification dated July 29, 2025, notified the Cosmetics (Amendment) Rules, 2025. The amendment rules aim to streamline and improve regulatory clarity and ensure consumer safety within the Indian cosmetics market. Some of the key amendments are as follows:

1. an explanation is inserted to Rule 3 (w) defining the expression 'use before' as, use before the first day of a month mentioned on label and the expression 'date of expiry' mean the cosmetic expires on the last day of the month;
2. under Rule 6, the words 'controlling officer' are substituted with the words 'Controlling Authority';
3. Rule 31A is inserted dealing with cancellation/suspension of licence. It states that if a licensee fails to comply with any of the conditions of license or with any provision of the Drugs and Cosmetics Act, 1940 or the rules made thereunder, the State Licensing Authority may, after giving the licensee an opportunity to show cause as to why an order for cancellation or suspension of license should not be passed and after giving an opportunity of being heard, by an order in writing, stating the reasons thereof, cancel a licence or suspend it for such period as he thinks fit, either wholly or in respect of some of the substances to which it relates. Further, a licensee whose licence has been suspended or cancelled, may, within a period of 90 (ninety) days from the date of the order, appeal to the State Government which will, after considering the appeal and after giving an opportunity of being heard to the said appellant for hearing, pass such order as it deems fit which will be final; and
4. a proviso has been inserted to Rule 34(10) dealing with labelling/packaging requirements of cosmetics being exported. It states that where a cosmetic is required by the consignee to be not labelled with the name and address of the manufacturer, the label on package or container must bear a code number as approved by the State Licensing Authority.

Drugs (2nd Amendment) Rules, 2025

MoHFW, *vide* notification dated August 18, 2025, notified the Drugs (2nd Amendment) Rules, 2025. This amendment mandates inclusion of qualitative details of excipient into the data stored in the label of drug formulation products as bar code or Quick Response (QR) code. The amended rules will come into force on March 1, 2026.

Transplantation of Human Organs and Tissues (Amendment) Rules, 2025

MoHFW, *vide* notification dated November 6, 2025, amended the Transplantation of Human Organs and Tissues Rules, 2014. The amendment has replaced the word 'Specular' with 'Specular (optional)' in the second column for 'Corneal Transplantation Centre' entries in Form 15 of the Transplantation of Human Organs and Tissues Rules, 2014. This change removes the mandatory requirement for a specular microscope in these centres, which is used to assess the density of corneal endothelial cells.

Central Drugs Standard Control Organisation

New online dual use system on SUGAM portal

The Central Drugs Standard Control Organization ("**CDSCO**"), *vide* circular dated August 1, 2025,

streamlined the process of issuing dual use No Objection Certificate ("**NOC**") for drugs imported in bulk for non-medicinal use through SUGAM portal. Further, to promote ease of doing business, CDSCO has initiated the issue of 1 (one) year NOC, subject to prescribed conditions for such drugs. Accordingly, the SUGAM checklist and procedure is revised. The new online dual use system is live from August 31, 2025.

Grant of World Health Organization Good Manufacturing Practice Certificate of Pharmaceutical Product through Online National Drugs Licensing System Portal

CDSCO, *vide* circular dated August 7, 2025, re-emphasised that no physical applications/ files will be accepted after August 15, 2025, for the grant of Certificate of Pharmaceutical Product ("**COPP**") issued under the World Health Organization ("**WHO**") Good Manufacturing Practice ("**GMP**") certification scheme for the purpose of international trade. All applications for WHO-GMP (COPP) must be submitted exclusively through the Online National Drugs Licensing System ("**ONDLS**") portal. Further, CDSCO requested the State Licensing Authority to ensure proper mapping of the concerned officials along with their respective jurisdictions who are handling these files, and that they may be instructed to approve the list of products after due verification.

Strict compliance with the Drugs Rules, 1945, for testing of raw materials and finished formulations

CDSCO, *vide* circular dated October 7, 2025, reiterated the critical importance of the testing of raw materials, including the excipients, before its use in the manufacturing of pharmaceutical formulations. As per Rule 74 (c) and Rule 78 (c) (ii) of the Drugs Rules, 1945, the licensee must either in their own laboratory or in any laboratory approved by the licensing authority: (a) test each batch or lot of the raw material used by them for the manufacture of their product; and (b) test each batch of the final product, and must maintain records or registers showing the particulars in respect of such tests as specified in Schedule U of the Drugs Rules, 1945. CDSCO has requested all the State/Union Territory drug controllers to take measures to ensure testing before the manufacture and release of a product batch to the market. Further, it must also be ensured that the manufacturers have robust vendor qualification systems in place and use raw materials, including excipients, from reliable approved vendors only.

Digital monitoring system on the ONDLS portal for monitoring the supply chain of high risk solvents

CDSCO, *vide* circular dated October 22, 2025, acknowledging the safety concerns arising from the contamination of cough syrups with diethylene glycol, directed the establishment of a digital monitoring system on the ONDLS portal for monitoring the supply chain as well as quality of the high risk solvents including propylene glycol. CDSCO has upgraded the ONDLS portal to address this issue. All State/Union Territory drug controllers must direct all the manufacturers of pharma grade solvents to obtain a manufacturing licence through the ONDLS portal. In case the manufacturer already holds the manufacturing licence, he must register on the ONDLS portal and submit the data through 'Old Licence Management' under ONDLS. Further, the solvent manufacturers must also upload details on the ONDLS portal regarding each batch manufactured and details of the vendors to whom the solvents are sold from time to time.

Requirement of license issued for procurement of medical devices by procurement agencies

CDSCO, *vide* circular dated November 17, 2025, informed all the procurement agencies, including hospitals and health institutions, that the CDSCO license or the license issued by the State/Union Territories licensing authority under the Medical Devices Rules, 2017, will be made mandatory as a part of the requirements for procurement of medical devices, without which the medical device cannot be sold in the country. Any other certifications which are required by the procurement agency should be over and above of the CDSCO or State/Union Territories licensing authority approval under the said rules.

New provision for risk classification of medical devices on the CDSCO online system for medical devices

CDSCO, *vide* circular dated December 4, 2025, issued a circular on a new risk classification module made functional on the CDSCO online system for medical devices. This facility has been provided in order to simplify the regulatory approval procedures and easing the process of risk classification of medical devices other than in-vitro diagnostic medical devices. The new risk classification module is functional on the CDSCO Online System for Medical Devices (http://cdscomdonline.gov.in) for all stakeholders with effect from November 27, 2025.

Department of Pharmaceuticals

Amendments to the Uniform Code for Marketing Practices in Medical Devices, 2024

The Department of Pharmaceuticals ("**DoP**"), *vide* notification dated September 1, 2025, notified amendments to the Uniform Code for Marketing Practices in Medical Devices ("**UCMPMD**") 2024 ("**Code**"). The amendments aim to simplify disclosure requirements, streamline reporting and provide clarity on the sample evaluation process. Some of the key amendments are as follows:

1. clarifications have been inserted with respect to the disclosure of marketing expenditure in relation to the method of arriving at the value of free evaluation samples distributed to healthcare professionals:
    a) in case the company is a manufacturer of such samples, the samples should be valued on a per unit basis, i.e., per device/vial/ml etc., and its value should be the price charged to the stockist or immediate customer on a per unit basis for the same make, brand, product variant and value of the medical device; and
    b) in case the company has purchased such samples from another supplier, the purchase price should be used for determining the monetary value of free evaluation samples under the Code. The price of such free samples should be recorded as the average price charged to the stockist or immediate customer, or the average price paid for the purchase of the medical device for the same make, brand, product variant and value on annual basis.
2. a new UCMPMD portal has been introduced for compliance purposes under the Code;
3. the Chief Executive Officer of the company is now responsible for adherence to the Code. Disclosure of marketing expenditure must be submitted by the executive head of the company within 2 (two) months of the end of every financial year or be uploaded on the website of the association of which the company is a member. In case the company is a member of more than 1 (one) association, it must, submit the disclosure to any 1 (one) association of which it is a member, while informing the other association(s) of such disclosure being made; and
4. with respect to data security, associations must now have a system in place to ensure that data disclosed by its members is stored securely and is adequately protected and must be retained for a minimum period of 5 (five) years or for such longer period as may be necessary for the purpose of facilitating inquiry.

Guidelines for Promotion of Research and Innovation in Pharma MedTech Sector Scheme

DoP, *vide* notification dated October 1, 2025, has notified the Guidelines for Promotion of Research and Innovation in Pharma MedTech ("**PRIP**") Sector Scheme ("**Scheme**"). The Scheme aim to encourage industry investment in research and development in pharmaceutical and medical technology sectors, to foster quality research and nurture a pool of scientists in the country, and promote industry-academia linkage, for leading India to a sustained global competitive advantage. Some of the key aspects are as follows:

1. Centres of Excellence ("**CoEs**") established at the National Institutes of Pharmaceutical Education and Research (NIPERs) will help in building specific research capacities in the identified priority areas in a focused time-bound programme;
2. Government academic and research institutions eligible for collaboration have been prescribed; and
3. institutes must ensure the following in respect of the CoEs:
    a) the proposing institute will furnish an undertaking that: (i) no expenditure will be incurred from the financial assistance provided under the Scheme towards the salary and allowances payable to any regular employee; (ii) it will bear expenditure incurred on any employees engaged for the CoE for the period beyond the Scheme period; and (iii) it will ensure that the CoE achieves self-sufficiency within the Scheme period;
    b) the institute will delineate the precise allocation and utilisation of funds and provide a detailed breakup of the financial resources deployed. Such breakup will outline the allocation for essential activities, such as development of research infrastructure, procurement of equipment and operations;
    c) the institute will ensure prudent fiscal management and effective resource utilisation aligned with the objectives of the Scheme; and
    d) in carrying out the activities of the CoE, the institute will adhere to the provisions of the General Financial Rules, 2017 and related instructions issued by the Ministry of Finance.

Food Safety and Standards Authority of India

Withdrawal of permissions for use of the term 'ORS' along with brand names

The Food Safety and Standards Authority of India ("**FSSAI**"), *vide* circular dated October 14, 2025, stated that all the previous permissions allowing the use of the term Oral Rehydration Salts ("**ORS**") alongside brand names on food labels will be revoked. The earlier permissions, issued through orders dated July 14, 2022, and February 2, 2024, had allowed such use with a disclaimer stating that the product was not an ORS formula as recommended by the WHO.

Further, FSSAI, *vide* notification dated October 14, 2025, issued a clarification on withdrawal of permissions for use of the term 'ORS' along with brand names. It clarified that the use of the term 'ORS' in the trademarked name or in the naming of any food product otherwise-whether fruit-based, non-carbonated, or ready-to-drink beverages even when accompanied by a prefix or suffix, constitutes a violation of the provisions of the Food Safety and Standards Act, 2006 and the regulations made thereunder. Such practices are misleading to consumers by way of false, deceptive, ambiguous, and erroneous names/label declarations, and are in contravention of Sections 23 and 24 of the Food Safety and Standards Act, 2006, Sub-regulation 4(3) of the Food Safety and Standards (Labelling and Display) Regulations, 2020, Sub-regulation 5(1) of the Food Safety and Standards (Labelling and Display) Regulations, 2020 and Sub-regulations 4(1) and 4(13) of the Food Safety and Standards (Advertising & Claims) Regulations, 2018, and is liable for punishment under Sections 52 and 53 of the Food Safety and Standards Act, 2006.

Further, all food business operators have been directed to remove the word 'ORS' from their food products, irrespective of its use as a standalone term or in combination with any prefix/suffix or as part of the trademark with prefix/suffix in the product name, and ensure strict compliance with the labelling and advertisement requirements prescribed under the Food Safety and Standards Act, 2006 and the regulations framed thereunder.

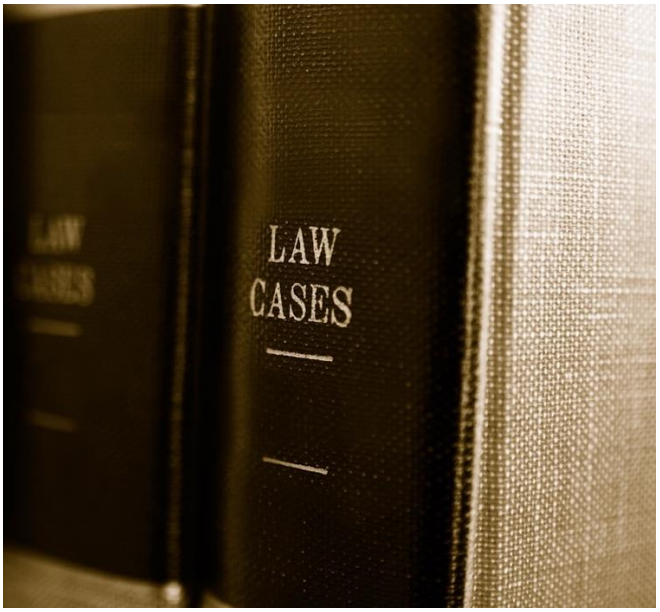
Compliance of scheme of testing for packaged drinking water and mineral water

FSSAI, *vide* circular dated October 17, 2024, omitted the provision for mandatory Bureau of Indian Standards ("**BIS**") certification under the Food Safety and Standards (Prohibition and Restriction of Sales) Regulation, 2011. In continuation of the above omission, the mandatory BIS certification mark is no longer required for packaged drinking water and mineral water. Pursuant to the same, FSSAI, *vide* notification dated December 17, 2025, notified a scheme of testing of packaged drinking water and mineral water. The scheme is made to ensure safety and compliance of packaged drinking water and mineral water in the Indian market. Therefore, all food business operators are directed to strictly comply with the same effective January 1, 2026.

Ministry of Labour and Employment

Occupational Safety, Health and Working Conditions Code, 2020

The Ministry of Labour and Employment, *vide* notification dated November 21, 2025, fully enforced the Occupational Safety, Health and Working Conditions Code, 2020 ("**OSHWC Code**"). The OSHWC Code consolidates various labour laws for improved worker safety, health, and welfare across sectors, including provisions for working hours, health check-ups, and female worker safety.



Case laws

The Supreme Court of India revokes the interim order stay on *Ayush* Ministry's notification that permitted advertisements of *Ayurvedic, Unani* & *Siddha* drugs without prior approval

The Supreme Court of India ("**Supreme Court**"), in the case of ***Indian Medical Association & Anr. vs. Union of India & Ors.***[1], has vacated the interim order staying the omission of Rule 170 of the Drugs and Cosmetics Rules, 1945 which prohibits advertisements of Ayurvedic, Siddha, or Unani drugs without licensing authorities' approval.

The Ministry of Ayush had, by a notification dated July 1, 2024, issued the Drugs (Fourth Amendment) Rules omitting Rule 170 of the Drugs and Cosmetics Rules, 1945. However, the Supreme Court, *vide* order dated August 27, 2024, stayed the notification, observing that it ran contrary to its earlier May 7, 2024 order, which had directed adherence to Rule 170.

The petitioners herein claimed that the impugned Rule 170 violates their fundamental rights under Articles 14, 19(1)(g) and 301 of the Constitution of India. The Supreme Court also observed that once you allow manufacture, advertising is a natural business practice.

Supreme Court: Mental Health Integral Part of Right to Life Under Article 21

The Supreme Court, in the case of ***Sukdeb Saha vs. The State of Andhra Pradesh & Ors.***[2], ruled that the right to mental health is an integral part under Article 21 of the Constitution of India of the fundamental i.e., right to life and dignity. The Supreme Court while issuing a set of guidelines for ensuring psychological well-being of students observed that "*Mental health is an integral component of the right to life under Article 21 of the Constitution of India. The Supreme Court has, in a consistent line of precedents, affirmed that the right to life does not mean mere animal existence, but a life of dignity, autonomy, and well-being. Mental health is central to this vision.*" Further, it also referenced International Law to underline India's obligation to ensure mental health care. The Supreme Court stated that "*under International Law, India's obligations under various human rights instruments and treaties reinforce*

[1] Writ Petition (C) No.645/2022

[2] 2025 INSC 893

the above constitutional imperative to protect and promote mental health. The International Covenant on Economic, Social and Cultural Rights, to which India is a State Party, under Article 12 recognises the right to the highest attainable standard of physical and mental health. The United Nations Committee on Economic, Social and Cultural Rights, in its General Comment No. 14, has affirmed that this right includes timely access to mental health services and prevention of mental illness, including suicide."

Supreme Court issues 4 weeks' notice to Central Government to respond to a Public Interest Litigation challenging the severe lack of criminal prosecution for physicians in medical malpractice cases

The Supreme Court, in its order dated December 20, 2025, in the case of ***Sameeksha Foundation-A Crusade Against Medical Negligence vs. Union of India & Anr.***[3], issued a 4 (four) weeks' notice to Central Government to respond to a Public Interest Litigation ("**PIL**") seeking statutory rules for the criminal prosecution of doctors in medical negligence cases. The PIL highlighted a 20 (twenty) year delay by the Government in framing these guidelines, as previously directed by the *Jacob Mathew vs. State of Punjab* (2005) judgment, and the potentially mandatory jail time for negligence introduced by the new Bharatiya Nyaya Sanhita.

Delhi High Court dismisses Dr. Reddy's Laboratories petition against FSSAI

The High Court of Delhi ("**Delhi HC**"), in its order dated October 31, 2025, in the case of ***Dr. Reddys Laboratories Limited & Ors. vs. Union of India & Anr.***[4], dismissed the petition against the decision of FSSAI banning ORS labelling on drink beverages. The Delhi HC stated that is not inclined to interdict with the impugned order passed by FSSAI. This is particularly in light of the deleterious effect and adverse health outcomes caused by the consumption of fruit-based or non-carbonated or ready-to-drink beverages by consumers who are in medical need of an ORS formulation. The petitioner had submitted that the stock which is already in the supply chain be allowed to be sold to prevent monetary loss. However, the Delhi HC, ruling to the contrary, stated its reluctance in ruling over a measure taken by the regulatory body i.e., FSSAI on public health considerations. Accordingly, the Delhi HC dismissed the petition, while directing FSSAI to consider and address through a reasoned order the irreparable loss caused by the ban pleaded by the petitioner, if a representation is made by the petitioner in this regard.

[3] 2025 INSC 1487

[4] 2025:DHC:9592

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.

The author of this Compendium is:

Sidharrth Shankar
Partner

19 Practices and
40 Ranked Lawyers

7 Ranked Practices,
21 Ranked Lawyers

15 Practices and
20 Ranked Lawyers

13 Practices and
49 Ranked Lawyers

20 Practices and
24 Ranked Lawyers

8 Practices and
10 Ranked Lawyers
Highly Recommended in 5 Cities

Regional Legal Expertise Awards (APAC) of the Year
Energy Firm Competition/
Antitrust Firm

Among Best Overall
Law Firms in India and
14 Ranked Practices
---
9 winning Deals in
IBLJ Deals of the Year
---
15 A List Lawyers in
IBLJ A-List – 2026

Recognised in World's 100 best
competition practices of 2026

Ranked Among Top 5 Law Firms in
India for ESG Practice

Asia M&A Ranking
2025 – Tier 1

For more details, please contact km@jsalaw.com

www.jsalaw.com

Ahmedabad | Bengaluru | Chennai | Gurugram | Hyderabad | Mumbai | New Delhi