July-August 2025 Edition

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.

This edition of the JSA healthcare Newsletter focuses on the key developments undertaken in the Indian healthcare ecosystem during July and August 2025.

Regulatory updates

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 has been 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' have been substituted with the words 'Controlling Authority'; and
3. Rule 31A has been 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 issued under these rules 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

New online dual use system on SUGAM portal

The Central Drugs Standard Control Organization ("**CDSCO**") *vide* circular dated August 1, 2025, has 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 will be live from August 31, 2025.

Grant of WHO GMP COPP through ONDLS Portal

CDSCO *vide* circular dated August 7, 2025, has 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 has 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.

Drugs (2nd Amendment) Rules, 2025

The 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.

Case laws

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

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

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

The Supreme Court of India, in the case of ***Sukdeb Saha vs. The State of Andhra Pradesh & Ors***.[2], has 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 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. This 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, the court also referenced International Law to underline India's obligation to ensure mental health care. The court stated that 'under International Law, India's obligations under various human rights instruments and treaties reinforce 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.'

[2] 2025 INSC 893

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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18 Practices and
41 Ranked Lawyers

7 Ranked Practices,
21 Ranked Lawyers

14 Practices and
12 Ranked Lawyers

12 Practices and 50 Ranked Lawyers

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