June 2023 Edition

This edition of the JSA Healthcare Newsletter focuses on key developments undertaken in the Indian healthcare ecosystem for the month of June.

Regulatory updates

Export Promotion Council for Medical Devices

The Directorate General of Foreign Trade, *vide* public notice No. 18/2023 dated June 23, 2023 ("**Public Notice**") has 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.

Distinction between pharmacy education and para-medical education

The Pharmacy Council of India has 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 Ministry of Health and Family Welfare ("**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 ("**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 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 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).

While the move aims to address the high consumption of tobacco in India and prevent online platforms from becoming a channel for tobacco advertising, it imposes a heavy burden of compliance on OTT Platforms. OTT platforms will be required to make changes to large volumes of content available on their platforms, to incorporate the requisite health warnings and disclaimers.

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

The MOHFW has 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 has 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 National Pharmaceutical Pricing Authority ("**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 has 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.

Interesting reads

Policy on safe disposal of unused drugs

Industry bodies such as the Karnataka Drugs and Pharmaceutical Manufacturers Association and the Federation of Pharma Entrepreneurs have called on the Government of India to frame a policy for the safe disposal of unused drugs following reports of chaotic dumping of medicines from households, resulting in environmental pollution leading to anti-microbial drug resistance.

Prescription for nicotine replacement therapies

The Drugs Technical Advisory Board which is India's premier technical advisory body on drugs has recommended that all formulations containing up to 2 (two) - 4 (four) mg of nicotine be sold only with a prescription, in a bid to ensure that nicotine replacement therapies such as nicotine patches, lozenges etc. are not misused.

Case laws

Petition against notification on prohibition of manufacture for sale or distribution of FDCs

The Delhi High Court in the case of ***Glenmark Pharmaceuticals and Ors. V. Union of India***[1] 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.

The notification banned the manufacturing, sales, and distribution of 14 (fourteen) FDCs licensed prior to 1988 due to potential risks to human beings, based on recommendations from an expert committee. The petitioners filed this petition challenging the prohibition of manufacture for sale or distribution of their cough syrups that fall within the ambit of FDCs, which has been on the market for over 30 (thirty) years and contains non-narcotic and non-habit-forming ingredients. The petitioner company argued that the notification lacks specific reasons or justification for the prohibition of their product.

The court held that the drugs already in the distribution channel by the petitioner company are not required to be withdrawn and that no fresh manufacturing should take place until the next hearing. The petitioner has been instructed to provide details of their existing stock, and the matter is scheduled for further hearing on July 3, 2023.

Dismissal of medical negligence case

The National Consumer Disputes Redressal Commission, New Delhi ("**NCDRC**") in ***Pushpa Verma and Ors. V. Bhardwaj Nursing and Maternity Home Private Limited***[2] *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.

The NCDRC held that there was no medical negligence on the part of the accused parties, stating that standard medical protocols were followed and there was no failure of duty or deficiency in their care. The complaint was dismissed based on the failure to prove necessary elements of medical negligence i.e., duty, dereliction, direct cause, and damages. The NCDRC concluded that Late Justice J.S. Verma's death was not attributable to the actions of the hospitals/doctors.

Compensation for sperm mix-up by hospital

The NCDRC in ***Priyanka Tandon V. Bhatia Global Hospital and Endosurgery Institute and Others***[3] 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.

The NCDRC went on to observe that there was a requirement for prompt and fixed timeline in relation to gynecology clinics and stressed upon the need for Assisted Reproductive Technology (ART) clinics to mandatorily issue DNA profiling of children born through ART procedures.

[1] W.P.(C) 8466/2023 (Delhi HC)
[2] Consumer Case No. 257 of 2015
[3] Consumer Case No. 14 of 2010

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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17 Practices and
24 Ranked Lawyers

16 Practices and
11 Ranked Lawyers

7 Practices and
2 Ranked Lawyers

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

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11 winning Deals in IBLJ Deals of the Year

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10 A List Lawyers in IBLJ Top 100 Lawyer List

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Dispute Resolution Law Firm of the Year 2022

Equity Market Deal of the Year (Premium) 2022

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