December 2022 Edition

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

Registration of medical devices testing laboratories

The Central Drugs Standard Control Organisation ("**CDSCO**") has *vide* notice dated December 22, 2022, directed the laboratories which have capacity for testing medical devices with adequate quality accreditation by the National Accreditation Board for Testing and Calibration Laboratories, to submit an application *vide* Form MD-39. This exercise has been undertaken to enhance the testing capacity of medical devices and empanelment of private testing laboratories. As on the date of the notification, more than 28 (twenty eight) laboratories have been registered with the office for testing purposes.

Inspection/audits of pharmacovigilance system of importers and manufacturers of human vaccine

The CDSCO *vide* notification dated December 23, 2022 requires the importer or manufacturer of any new drug for sale and distribution must have a pharmacovigilance system in place for collecting, processing, and forwarding the adverse drug reaction ("**ADR**") reports to the Central Licensing Authority. The pharmacovigilance system must be managed by qualified and trained personnel and the Officer-In-Charge of the collection and processing of data must be a trained Pharmacist or Medical Officer in the collection and analysis of ADR Reports.

Joint inspection of drug manufacturing units for compliance under the Drugs and Cosmetics Act, 1940 and rules thereunder

The Ministry of Health and Family Welfare *vide* the press release dated December 27, 2022, has indicated that the CDSCO and the State Drugs Control Organization have commenced the joint inspection of drug manufacturing units, as per risk based approach, to ensure that such units are in compliance with the Drugs and Cosmetics Act, 1940 and the Drugs and Cosmetics Rules, 1945, including the Good Manufacturing Practice issued thereunder.

Extension of timeline for trade margin capping of medical devices

The National Pharmaceutical Pricing Authority has *vide* an order dated December 30, 2022, (a) extended the timelines for prices fixed for Liquid Medical Oxygen and Oxygen Inhalation (Medicinal Gas) in Cylinder; and (b) extended the capping of trade margins at first point of sale for pulse oximeter, BP machine, nebulizer, digital thermometer, and glucometer, till March 31, 2023.

Directors' vicariously liability for offences under the Drugs and Cosmetics Act, 1940

Recently Madras High Court ("**Madras HC**") in the case of ***Vikas Rambal vs. State of Madras***[1] has held that all the directors are vicariously liable under the Drugs and Cosmetics Act, 1940 ("**Drug Act**") for the sub-standard drugs manufactured by a company and the directors cannot claim that they are not directly involved in the production of drugs.

The Madras HC has deviated from the settled position of law that vicarious liability cannot be fastened upon directors or officials, who are not involved in the day-to-day affairs of a company.

The Supreme Court, in various decisions, has laid down a set of guiding principles that hold prominence in ascertaining whether the director of a company is liable to be prosecuted for the offence charged or otherwise.[2]

It is now settled that a director/official can be held liable for an offence by a company if:

(1) there is evidence of the individual's active role coupled with criminal intent;

(2) the director / official is in charge of and responsible for the conduct of business of the company at the relevant time when the offence was committed, and not on the basis of merely holding a designation or office in a company.

Therefore, the liability of directors or officials depends on the role they play in the affairs of a company and not on designation or status.

For a detailed analysis, please refer to the JSA Prism of December 6, 2022.

[1] 2022 SCC OnLine Mad 4822

[2] Sunil Bharti Mittal v CBI MANU/SC/0016/2015 ; Pooja Ravinder Devidasani v State of Mahaarashtra & Ors MANU/SC/1328/2014; SEBI v Gaurav Varshney (2016) 14 SCC 430; National Small Industries v Harmeet Singh Paintal (2010) 3 SCC 330; K.K. Ahuja v V.K. Vora and Another (2009) 10 SCC 48.

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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