January - February 2024 Edition

This edition of the JSA Healthcare Newsletter focuses on key developments undertaken in the Indian healthcare ecosystem for the months of January and February 2024.

Regulatory updates

Launching of National Single Window System

The Central Drugs Standard Control Organisation ("**CDSCO**"), on January 1, 2024, issued a public notice that with effect from January 15, 2024, applications in relation to regulatory approvals for medical devices (specifically, the certificate of registration, and licenses to manufacture and import) would only be accepted through online filing at the National Single Window System (NSWS) Portal, and that applications would no longer be accepted in the existing SUGAM portal[1].

New guidelines issued for intensive care unit admission and discharge criteria

The Ministry of Health and Family Welfare ("**MoHFW**") has introduced guidelines for regulating the admission and discharge criteria for intensive care units for hospitals to decide the need of admitting a patient for treatment in an intensive care unit ("**ICU**"). Altered level of consciousness of recent onset, hemodynamic instability, need for respiratory support, patients with severe acute (or acute-on-chronic) illnesses requiring intensive monitoring or organ support or any medical condition or disease with anticipation of deterioration, patients who have undergone major surgery, among others, have been listed as criteria for ICU admission. Blood pressure, pulse rate, respiratory rate, breathing pattern, heart rate, oxygen saturation, urine output and neurological status among other parameters should be monitored in a patient awaiting an ICU bed.

CDSCO issues notice regarding pathway for clearance of fixed dose combinations ("FDCs") for sale in India

The CDSCO had issued a letter on January 15, 2013, stating that all State/UT Drugs Controllers were requested to ask the concerned manufacturers in their state to prove the safety and efficacy of FDC's within 18 (eighteen) months which were permitted by the State Licencing Authorities without due approval from the office of Drug Controller General of India ("**DCGI**"). An expert committee was constituted based on the Supreme Court order dated February 15, 2017 to examine certain FDCs licensed for manufacturing without due approval from the DCGI. The expert committee subsequently provided recommendations with respect to 3 specific FDCs.

[1] An online platform launched by CDSCO to facilitate the electronic submission of applications, tracking of status, and other regulatory services.

The CDSCO has issued a public notice on January 11, 2024, providing a pathway for clearance of such FDCs based on whether (a) manufacturers are holding licenses for such FDCs from State Licensing Authorities prior to October 1, 2012; (b) manufacturers are new manufacturers for the proposed FDCs; (c) manufacturers are holding licenses from State Licensing Authorities prior to October 1, 2012, and did not apply to DCGI.

Surrogacy Amendment Rules, 2024

The MoHFW on February 21, 2024, has notified the Surrogacy (Regulation) Amendment Rules 2024. The earlier requirement was that the couple undergoing surrogacy was supposed to have both gametes from the intending couple and donor gametes for surrogacy was not permitted. Following this amendment, couples can now opt for surrogacy, and use donor gametes if either spouse is certified by the District Medical Board as having a medical condition which prevents the spouse from contributing the gamete.

Interesting Reads

Dispensation of antibiotics only on doctor prescriptions

The Director General of Health Services has issued an appeal to all pharmacy associations to ensure that antibiotics are only sold on a prescription from a registered medical practitioner. This has been issued following the over usage of antibiotics resulting in antimicrobial resistance (AMR). The concerned official also observed that AMR has resulted in non-effective treatment of infections leading to prolonged illness and often death.

Proposed amendment to the Drugs and Magic Remedies (Objectional Advertisements) Act, 1954

The Government of India proposes to amend the aforementioned statute to include the prohibition of misleading advertisements in relation to AYUSH drugs. These amendments were originally proposed in 2020 and sought to prevent misleading advertisements in relation to drugs for treatment for enhancing sexual performance, fairness of skin, improvement in the height of kids and adults, and premature ageing.

Closing down of small pharma units

Following inspections of various pharma manufacturing units, as part of a crackdown on spurious and sub-standard drugs, the CDSCO along with state regulatory authorities, has issued show cause notices to several small and medium scale pharma units, including requiring some units to close down.

Sale of antibiotics in Kerala

The government of Kerala, with a view to controlling the extensive use of antibiotics, has required all pharmacies and hospitals in Ernakulam to only sell antibiotics in a blue cover, and only with the prescription of a doctor. All pharmacies and hospitals are required to put up posters indicating that any antibiotic will be sold only with a doctor's prescription.

Reimbursement of durable medical equipment

The Vadodara District Consumer Disputes Redressal Commission ("**District Commission**") has ruled that a patient is entitled to be reimbursed for durable equipment used in medical treatment after getting discharged from the hospital. The patient, Vijay Joshi had been admitted to hospital and diagnosed with a disorder similar to sleep apnea. The insurance company paid only a part of his claim, on the grounds that all external durable equipment that could be used

at home were excluded under the insurance policy. Rejecting this argument, the District Commission, taking note of the hospital discharge summary, held that the treatment was to continue at home, and hence the use of durable equipment at home was a continuation of the treatment in the hospital, and directed the insurance company to compensate the patient.

Rejection of European free trade agreements 'data exclusivity' provisions

The Government of India, with an aim to protect the generic drug manufacturers in India, has rejected the 'data exclusivity' provisions in proposed free trade agreements with Iceland, Liechtenstein, Norway, and Switzerland. In the pharma sector, any data exclusivity would permit innovator companies to prevent their competitors from obtaining market licenses for low-cost versions of the drugs, during the tenure of the exclusivity.

Walk-in meetings

In a public notice dated February 14, 2024, the CDSCO has indicated that the DCGI would hold walk-in meetings with stakeholders every Tuesday and Thursday at New Delhi, with an aim to address all grievances and complaints in a swift and suitable manner. This move is introduced keeping in mind the government's aim of easing doing business in India.

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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