April 2023 Edition

This edition of the JSA Healthcare Newsletter focuses on key developments undertaken in the Indian healthcare ecosystem for the month of April (with few relevant updates for the month of March).

Regulatory Updates

Exemption of import duty on drugs, medicines or food needed for special medical purposes

The Government of India, *vide* notification dated March 29, 2023 has exempted basic customs duty on all drugs, medicines and food for special medical purposes imported (for personal use) for treatment of rare diseases listed under the National Policy for Rare Diseases, 2021. The import duty waiver has come into effect from April 1, 2023.

Inclusion of rare diseases under the National Policy for Rare Diseases, 2021

The Ministry of Health and Family Welfare ("**MOHFW**") has classified 6 (six) diseases as rare diseases under the National Policy for Treatment of Rare Diseases ("**NPRD**"). These include Laron's Syndrome, Wilson's Disease, among others. Financial assistance to the patients suffering from such rare diseases will be provided as per the provisions of the NPRD and other relevant guidelines issued by the MOHFW.

Product for persons with disabilities (PWD), persons afflicted with HIV/AIDS, and those with mental illness

The Insurance Regulatory and Development Authority of India ("**IRDAI**") has directed all general and stand-alone health insurers to make available, with immediate effect, a specific insurance cover for persons with disabilities, persons afflicted with HIV/AIDS, and those with mental illness. Such policy must be for a tenure of 1 (one) year and renewable. According to the circular, insurers may determine the price of the insurance cover subject to compliance of the norms specified in IRDAI (Health Insurance) Regulations, 2016.

Enforcement drive for verification of quality and safety of health supplements

The Food Standards and Safety Authority of India, *vide* circular dated March 7, 2023, has required all food regulators in the states to conduct a special enforcement drive to ensure that all nutraceuticals and health supplements are in compliance with the extant regulations, being the Food Safety and Standards (Health Supplements, Nutraceuticals, Food for Special Dietary Use, Food for Special Medical Purpose, and Prebiotic and Probiotic Food) Regulations, 2022 and the Food Safety and Standards (Advertising and Claims) Regulations, 2018.

Interesting Reads

National Medical Devices Policy, 2023

The Union Cabinet has approved the National Medical Devices Policy, 2023 (the "**Policy**") on April 26, 2023.

The Policy is expected to help the medical devices sector grow to $50Bn by 2030. The Policy envisages an accelerated growth path with a patient-centric approach with a vision to emerge as the global leader in the manufacturing and innovation of medical devices by achieving 10-12% share in the expanding global market over the next 25 years.

The Policy is expected to provide the required support and directions to strengthen the medical devices industry into a competitive, self-reliant, resilient and innovative industry that caters to the healthcare needs of not only India but also of the world. The National Medical Devices Policy, 2023 aims to place the medical devices sector on an accelerated path of growth with a patient-centric approach to meet the evolving healthcare needs of patients.

The Policy proposes the following:

1. In order to enhance ease of doing research and business and further to balance patient safety, product innovation measures such as creation of a Single Window Clearance System' for Licensing of Medical Devices coopting all the stakeholder departments / organizations is to be implemented.
2. The establishment and strengthening of large medical device parks, clusters equipped with world class common infrastructure facilities in proximity to economic zones with requisite logistics connectivity.
3. Promotion of Research & Development in India and complement the Department of Pharmaceuticals' (the "**Department**") proposed National Policy on R&D and Innovation in the Pharma- MedTech Sector in India. The Policy also aims at establishing Centres of Excellence in academic and research institutions, innovation hubs, 'plug and play' infrastructures and support to start-ups.
4. Along with recent schemes and interventions like Make in India, Ayushman Bharat program, Heal-in-India, Start-up mission, the Policy encourages private investments, series of funding from venture capitalists, and also Public-Private Partnership (PPP).
5. The policy envisages the creation of a dedicated Export Promotion Council for the sector under the Department which will be an enabler to deal with various market access issues.

Sale of medicines under direct supervision of pharmacists

The Drugs Controller General of India ("**DCGI**") has sought strict implementation of the Pharmacy Act, 1947 and the Drugs and Cosmetics Act, 1940 and required drugs controllers of all states as well as the Pharmacy Council of India to ensure that pharmacists are physically present in retail stores and that medicines are sold under their direct supervision.

Drug regulation on par with global standards

NITI Aayog, the primary public policy think tank in India has recommended that Indian standards of drug regulation should be on par with global standards as this promotes ease of doing business and export of quality drugs from India. NITI Aayog has also suggested creating a separate authority to regulate medical devices in the country which is currently being monitored by the DCGI. The recommendations have been made during the ongoing inter-ministerial consultation on the New Drugs, Medical Devices and Cosmetics Bill, 2023.

Public Health emergencies

The Government of India is contemplating the setting up of surveillance units ("**Metro Surveillance Unit**", or "**MSU**") in 20 (twenty) metro cities across India. These MSUs act as rapid response units for management of any disease outbreaks.

Draft cabinet note on the new scheme – Promotion of Research and Innovation in Pharma MedTech sector

A draft cabinet note on the Promotion of Research and Innovation in Pharma MedTech sector ("**PRIP**") has been sent to the Empowered Technology Group for consideration and approval. The PRIP scheme has been conceived to give effect to the announcement made in the Union Budget regarding a new programme for research innovation in the pharmaceutical sector.

Research and Development on Rare Condition Drugs

The Government of India will soon issue a roadmap for encouraging the research and development of orphan drugs – medicines used for the treatment of rare conditions which are often serious or life threatening. With a view to involving the private sector, the Government may offer incentives in the form of faster regulatory approvals and an extended period of exclusivity for such orphan drugs.

Cancellation of manufacturing license of Marion Biotech Pvt Ltd.

The Government of India recommended the cancellation of the manufacturing license of M/s Marion Biotech Pvt Ltd., after the company had been found manufacturing sub-standard cough syrups, which had also caused the death of children in Uzbekistan.

Simpler clearances for changing product mix for API industry

The Indian Drug Manufacturers' Association ("**IDMA**") has requested state drug licensing authorities for simpler time bound clearances and permission to change product mix or capacities for the active pharmaceutical ingredients (API) industry to comply with waste management norms as set out in the Bio-Medical Waste Management Rules, 2016.

Implementation of revised disintegration testing time

The IDMA has represented to the Indian Pharmacopoeia Commission to refrain from the implementation of the British Pharmacopoeia standards for the disintegration testing time for soft gelatin capsules. The IDMA notes that any change in the existing marketed products may cause harm to the health of the patient given that the climatic conditions in India vary from that in Britain, and in India, soft gelatin capsules undergo several changes during transportation. Accordingly, since the products in the Indian market are subjected to extremes of temperature and humidity, the IDMA has recommended that the disintegration testing time should be more than 30 (thirty) minutes for soft gelatin capsules to ensure quality.

Federation of Indian Chambers of Commerce and Industry on e-Pharmacies

In light of the recent show cause notices issued by the regulator to e-pharmacies, the e-Pharmacy Working Group of the Federation of Indian Chambers of Commerce and Industry has in a recent letter to the MOHFW extolled the benefits of e-pharmacies, and has called the MOHFW to promptly notify the draft e-Pharmacy Rules and the new Drugs, Medical Devices and Cosmetics Bill, *in order to eliminate any regulatory ambiguity and to cohere with all the existing regulations, with which the e-Pharmacy is already compliant*.

Prescription by a pharmacist

The MOHFW has in response to a question in the Lok Sabha set out that as writing a prescription is dependent upon the examination of patients and making a diagnosis, the National Medical Commission has not agreed to the proposal put forth by the Pharmacy Council of India for pharmacists to issue prescriptions.

Revision of clinical guidelines in relation to COVID-19

The National Task Force on COVID-19 has revised the clinical guidelines for treatment of persons infected with COVID. The guidelines advise against the use of antibiotics (unless there is a clinical suspicion of bacterial infection) as well as convalescent plasma therapy for the treatment of adult COVID-19 patients in India.

Notice to pharmaceutical companies on bio-resource use

In accordance with provisions of the 'access and benefit sharing' under the Biological Diversity Act, 2002, commercial users of biological resources are required to share the benefits arising out of such resources with the State Biodiversity Board ("**SBB**").

The Government of West Bengal has issued notices to the pharmaceutical companies operating out of the state of West Bengal requiring them to set out the biological resources that such entities are using in their products, and to share a percentage of the revenue with the SBB.

Case Laws

Punishment of doctor for storing small quantities of medicine

In ***S. Athilakshmi v The State. Rep by the Drugs Inspector***[1] the Supreme Court of India ("**Supreme Court**") has held that when a small quantity of medicine has been found in the premises of a registered medical practitioner, it would not amount to sale of medicines across an open counter in a shop, while quashing the criminal proceedings against the medical practitioner under the Drugs and Cosmetics Act, 1940 (the "**Act**").

Upon undertaking an inspection of the premises of appellant S. Athilakshmi, a registered medical practitioner, the drugs inspector found a certain quantity of medicines, lotions, ointments. Alleging that the appellant stocked drugs for sale and sold the drugs without having a valid drug license, which is punishable under section 27(b)(ii) of the Act, an application was moved by the inspector for obtaining a sanction for prosecution from the office of the Director of Drugs Control, Tamil Nadu, which was granted.

The Supreme Court held that the appellant would be governed by Entry 5 to Schedule K of the Act, which granted exemptions to medical practitioners for supply of medicines to their own patients, provided such medicines are not sold over the counter, and hence quashed the criminal proceedings against the appellant.

Medical negligence in case expert committee finding is in favour of doctor

In the recent case of ***Dr. Vijay Singh v The State of Jharkhand***[2], the Jharkhand High Court held that proceeding further on a protest petition when the expert committee finding in a medical negligence case is in favour of the doctor, amounts to abuse of the legal process.

The Jharkhand High Court clarified that whenever a complaint is received against a doctor or hospital by the consumer forum (whether district, state or national) or by the criminal court, then before issuing notice to the doctor or hospital against whom the complaint was made, the consumer forum or the criminal court should first refer the matter to a competent doctor or committee or doctors specialized in the field relating to which the medical negligence is attributed. In the event the doctor or committee reports that there is *prima facie* a medical negligence, should a notice be issued to the concerned doctor/hospital. The Jharkhand High Court further held that "*it is well known that in spite of best efforts made by the doctor sometimes they are not successful, and this does not mean that doctor must be held guilty*". The Jharkhand High Court came to the conclusion that the case of the petitioner is fully covered with the 2

[1] SLP (Crl.) No. 9978 of 2022 (SC)
[2] Cr. M.P. No. 588 of 2013 (Jharkhand HC)

(two) judgments of the Supreme Court in the case of *Martin F. D'Souza V. Mohd. Ishfaq*[3] as well as *Jacob Mathew v. State of Punjab*[4], and hence quashed the criminal proceedings against the petitioner.

Unsuccessful treatment or death of patient does not prove medical negligence

In the case of ***Pink City Heart & General Hospital v Banarsi Devi and Ors.***[5], the National Consumer Disputes Redressal Commission ("**NCDRC**") dismissed the complaint filed by the appellant relating to medical negligence of the hospital on the grounds that the complainant failed to bring on record appropriate medical evidence to prove medical negligence. The NCDRC held that *"every death of a patient cannot, on the face of it, be considered as death due to medical negligence, unless there is material on record to suggest to that effect".*

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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3 Civil Appeal No. 3541 of 2002 (SC)
4 Appeal (Crl.) No 144-145 of 2004 (SC)
5 First Appeal No. 1018 of 2019 (NCDRC)

17 Practices and
24 Ranked Lawyers

16 Practices and
11 Ranked Lawyers

7 Practices and
2 Ranked Lawyers

11 Practices and
39 Ranked Partners
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