November-December 2024 Edition

Introduction

The Indian healthcare sector is one of the shining spots in the Indian economy. Recognising the significance of this sector, the Government of India ("**GoI**") took various steps in 2024 to support the expansion and growth of the healthcare industry at the macro and micro level. The final couple of months of 2024 witnessed some interesting developments, on the legal, regulatory and investment front.

The Ayushman Bharat Digital Mission ("**ABDM**"), a mission aimed at streamlining India's digital healthcare infrastructure by integrating and harnessing the necessary support of government bodies, non- government organizations, healthcare and health tech- oriented companies and other private players in health care and health-tech space (including health insurers and healthcare practitioners) has enabled interoperability of health data within the Indian health ecosystem, supporting the digital health infrastructure of the country. As on November 2024, more than 68,00,00,000 (sixty-eight crore) Ayushman Bharat Health Accounts ("**ABHA**") have been created, approximately 3,50,000 health facilities have registered on the Health Facility Registry, more than 5,00,000 healthcare professionals have registered on the Healthcare Professional Registry ("**HPR**") and more than 45,00,00,000 (forty five crore) health records have been linked with ABHA.

Further, the GoI introduced initiatives to boost the medical device industry and the homeopathic medical practice, resulting in a more streamlined approach towards regulation of medical and healthcare industry. According to news reports, the Indian medical device sector is expected to reach USD 50 (fifty) billion by 2025, supported by various policies and schemes designed to facilitate this growth. Market experts predict that the healthcare sector will reach USD 320 (three hundred twenty) billion by 2028. The initiatives to boost medical industry through *inter- alia* marginal investment schemes are encouraging, especially considering India's potential to leverage investments in the context of creating self- reliant India, with reduced support from imports.

At the regulatory front, the government has introduced stricter penalties for certain offences under for breach of rules the Food Safety and Standards Act, 2006. Further, considering the potential harm of tobacco products, the government has tightened its regulatory grip on the packaging of such products, requiring *inter- alia* clear depiction of warnings concerning use of such products.

Considering public centric regulatory amendments, the Central Drugs Standard Control Organization has been directed by the Ministry of Health and Family Welfare ("**MoHFW**") to ensure prompt clearance of drug samples sent by foreign national regulatory authorities to avoid delays in testing and releasing safe, efficacious, and quality drugs for the population. Further, the Ministry of Ayush has introduced amendments to the procedural aspects including licensing, manufacturing and import process for new homeopathic medicines in India.

To streamline the processes concerning receipt of funds, the Ministry of Social Justice and Empowerment has released a checklist of documents required from NGOs and other organizations for the release of funds under the National Action Plan for Drug Demand Reduction ("**NAPDDR**") scheme.

This edition of the JSA Healthcare Newsletter highlights the above key legal and regulatory developments introduced in November- December 2024, impacting the Indian healthcare sector.

Guidelines for verification of pharmacists profile with the ABHA Number to integrate them with the HPR

As a step forth to assimilate pharmacists with ABDM, the Pharmacy Council of India has issued guidelines to integrate pharmacists with the HPR by verifying their profiles using the ABHA Number. All existing registered pharmacists are required to verify their DIGI-PHARMed profiles with their ABHA Number within 45 (forty-five) days from November 20, 2024. Failure to complete the verification process will result in the deactivation of the pharmacist's profile on the DIGI-PHARMed portal.

Further, new pharmacists are required to verify their accounts with the ABHA Number at the time of registration, as incomplete registrations without ABHA verificationis not acceptable under such guidelines.. Pharmacists without an ABHA Number are required to create one using their AADHAAR before registration.

Additionally, pharmacy institutions are also required to ensure that all faculty members have ABHA-verified profiles. Starting from the 2025–2026 academic session, only ABHA-verified profiles will be considered for standard inspection format applications and other references.

Operational guidelines for the Scheme for Strengthening of Medical Device Industry

To boost the manufacturing of the medical device industry in India and reduce its reliance on imports, the Department of Pharmaceuticals ("**DoP**") has launched the Scheme for Strengthening of Medical Device Industry **("SSMDI")** following consultations and two Meditech Stackathons involving over 100 (one hundred) manufacturers. The SSMDI aims to reduce imports, enhance manufacturing capacity, ensure quality and safety, foster human resource development, and deepen the medical device supply chain in India.

The total outlay for the SSMDI is set at INR 500,00,00,000 (Indian Rupees five hundred crore) for the financial years 2024-25 to 2026-27. It focuses on the following 5 (five) components:

1. Common Facilities for Medical Device Clusters;
2. Marginal Investment Scheme for Reducing Import Dependence;
3. Capacity Building and Skill Development in Medical Device Sector;
4. Medical Device Clinical Studies Support Scheme; and
5. Medical Device Promotion Scheme.

To streamline compliance, the following 2 (two) pre-approved sub-schemes have been integrated to the SSMDI:

1. Assistance to Medical Device Clusters for Common Facilities; and
2. Human Resource Development in the Medical Device Sector.

To operationalize SSMDI, committees/ sub- bodies including Technical Committee, Scheme Steering Committee and Project Management Agency have been set- up for effective implementation of the scheme through assistance of officials and professionals at various levels. The overall outcome of the scheme will be periodically monitored by NITI Aayog.

The Food Safety and Standards (Amendment) Rules, 2024

On October 29, 2024, the MoHFW has notified the Food Safety and Standards (Amendment) Rules, 2024 amending the Food Safety and Standards Rules, 2011. Pursuant to the amendment, the Adjudicating Officer can now hold an inquiry for the purpose of adjudicating offences punishable under Section 61 (*Punishment for false information*) and Section 63 (*Punishment for carrying out a business without licence*) of the Food Safety and Standards Act, 2006.

The Cigarettes and Other Tobacco Products (Packaging and Labelling) Amendment Rules, 2024

On December 3, 2024, MoHFW has notified the Cigarettes and Other Tobacco Products (Packaging and Labelling) Amendment Rules, 2024 amending the Cigarettes and Other Tobacco Products (Packaging and Labelling) Rules, 2008. The amendments are in line with World Health Organization Framework Convention on Tobacco Control. While these may lead to manufacturers/ relevant stakeholders incurring additional costs of production, these have been issued in larger public interest.

The amendments introduce significant changes to enhance public awareness of the health risks associated with tobacco use. A new, enhanced, lucid and cautionary textual warning has been introduced for all tobacco product packages, including text encouraging cessation from tobacco products. Additionally, the inclusion of rotating pictorial warnings with new graphic images depicting the severe and often fatal health consequences of tobacco use has been mandated. These images are required by the amended law to be updated annually to ensure their continued impact and relevance. In order to ensure efficacy of the intended outcome, MoHFW has assured to provide digitally accessible versions of all the relevant health warnings to ensure the availability of the mandated pictorial representations and textual warnings at all times with manufacturers and other relevant stakeholders.

Shipment of drug samples sent by the foreign national regulatory authorities into India for test, examination and analysis

MoHFW has directed all port offices of the Central Drugs Standard Control Organisation to ensure prompt clearance of drug samples sent by foreign national regulatory authorities to avoid delays in testing and releasing safe, efficacious, and quality drugs for the population.

Pursuant to this circular, port offices are instructed to fast-track the clearance process, subject to the following conditions:

1. **Authorised sender**- Drug samples must be sent exclusively by the concerned foreign national regulatory authority.
2. **Undertaking**- Samples must be accompanied by an undertaking stating they have no commercial value and are intended solely for testing, examination, or analysis.
3. **Licensed laboratory**- Analysis must be conducted at a laboratory holding valid permission under Form-37.
4. **Disposal of samples**- Residual samples toned not be returned and must be disposed of by the testing laboratory in accordance with applicable procedures.

The Drugs (Fifth Amendment) Rules, 2024

On October 28, 2024, the Ministry of Ayush has notified the Drugs (Fifth Amendment) Rules, 2024 amending the Drugs Rules, 1945. The amendments introduce significant changes to the licensing, manufacturing and import process for new Ayurveda, Siddha, Unani and homeopathic medicines in India . It also introduces the concept of Sowa-Rigpa drugs.

Pursuant to the amendment, the term "New Homeopathic Medicines" is defined and it establishes a clear process for their important, licensing and manufacture. A new homeopathic medicine is considered as "new" for 5 (five) years following its first approval. An online application system, e-AUSHADHI portal, has been introduced to streamline various approvals.

Checklist for furnishing complete documents for seeking disbursement of funds under the National Action Plan for Drug Demand Reduction

The Ministry of Social Justice and Empowerment has released a checklist of documents required from NGOs and other organisations, such as the Integrated Rehabilitation Centres for Addicts, District De-Addiction Centres, Outreach and Drop In Centres and Community based Peer led Interventions, for the release of funds under the National Action Plan for Drug Demand Reduction ("**NAPDDR**") scheme. In additional to carrying out education/ community engagement based and peer-to-peer awareness around drug and substance use, NAPDDR scheme aims to eradicate drug addition and to regulate and control the consumption of drugs and substance use through central and state action plans including integration of government bodies, non- government organizations, hospitals and addition treatment facilities.

Eligible entities seeking release of funds are advised to submit their proposals as per the checklist, in line with the guidelines of the NAPDDR scheme. Further, NGOs and voluntary organisations receiving financial assistance are encouraged to computerise the records of beneficiaries receiving benefits from the centre.

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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