



March 2023 Edition

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

'One Nation, One Policy' for Organ Donation and Transplantation

The Government of India ("GoI") has, as per a press release issued on March 24, 2023, adopted the 'One Nation, One Policy' for organ donation and transplantation. The policy aims to bring in uniformity and oneness by proposing the removal of the requirement of state domicile for registration of patients requiring organ transplantation from a deceased donor thereby allowing anybody to register in any state for an organ transplant. Further, the new guidelines also allow persons of all ages to be eligible to receive deceased organ donation by removing the present upper age limit of 65 years.

Draft amendments proposed to Medical Devices Rules, 2017

The MoHFW has, on March 1, 2023, issued the draft Medical Devices (... Amendment) Rules, 2023 to further amend the Medical Device Rules, 2017. The proposed amendment enables state governments to establish medical devices testing laboratories in the states for the purposes of testing and evaluation of medical devices. The proposed amendment also empowers state governments to designate any laboratory, accredited by the National Accreditation Body for Testing and Calibration Laboratories and having facilities for carrying out test and evaluation of medical devices, as such a testing laboratory.

New Drugs and Clinical Trials (Amendment) Rules, 2023

The MoHFW has, on March 9, 2023, notified the New Drugs and Clinical Trials (Amendment) Rules, 2023, in terms of which the following non-clinical testing methods for assessing the safety and efficacy of a new drug or investigational new drug have been permitted: (a) cell-based assay; (b) organ chips and micro physiological systems; (c) sophisticated computer modelling; (d) other human biology-based test methods; and (e) animal studies.

Surrogacy (Regulation) Amendment Rules, 2023

The MoHFW has, on March 14, 2023, notified the Surrogacy (Regulation) Amendment Rules, 2023 to amend paragraph 1 (d) under Rule 1 of Form 2 of the Surrogacy (Regulation) Rules, 2022. The amendment has disallowed the use of donor gametes for couples undergoing surrogacy and has mandated the requirement of having both the gametes from couples intending to undergo surrogacy. The amendment has however allowed single woman, whether widow or divorcee, to use donor sperms along with self-eggs to avail surrogacy.

Ayushman Bharat Digital Mission creates longitudinal electronic health record facilitating interoperability of health data

The Ministry of Health and Family Welfare (“**MoHFW**”) has on March 17, 2023 designated premier institutions like AIIMS Delhi, PGIMER Chandigarh and AIIMS Rishikesh as Centres of Excellence for Artificial Intelligence to promote the creation and use of artificial intelligence (“**AI**”) based solutions in healthcare system in India.

The introduction of AI in healthcare aims to achieve the objectives of Ayushman Bharat Digital Mission (“**ABDM**”), which is the MoHFW’s flagship scheme, of building a digitally connected healthcare ecosystem by creating a platform enabling interoperability of health data within the health ecosystem so as to generate a longitudinal electronic health record of every citizen. In addition to the introduction of AI, ABDM also envisages the integration of other cutting-edge technologies like Internet of Things (IoT), blockchains etc. with existing health IT applications with a view to improve the performance of the healthcare services in India.

MoU signed between Ministry of AYUSH and Indian Tourism Development Corporation, Ministry of Tourism

AYUSH has signed a memorandum of understanding (“**MoU**”) with the Indian Tourism Development Corporation (“**ITDC**”) of the Ministry of Tourism to work together for the promotion of ‘Medical Value Travel’ in Ayurveda and other traditional systems of medicine. This collaboration between AYUSH and the Ministry of Tourism aims to promote traditional medicine in India through tourism by supplementing the MoHFW’s initiative of ‘Heal in India’ and ‘Heal by India’.

A national strategy and roadmap for ‘Medical and Wellness Tourism’ has been formulated by the Ministry of Tourism by involving AYUSH, MoHFW, Ministry of Commerce, Ministry of External Affairs, Ministry of Civil Aviation etc. Further, AYUSH has also developed a Central Sector Scheme, namely, Champion Service Sector Scheme for Medical Value Travel. The scheme provides financial assistance in the form of interest subsidy to private investors for establishing super speciality hospitals / day care centres operating on systems recognized under the National Commission for Indian System of Medicine (NCISM) Act, 2020 and The National Commission for Homeopathy (NCH) Act, 2020.

MoU signed between Ministry of AYUSH and Department of ex-servicemen welfare, Ministry of Defence

AYUSH and the Department of Ex-servicemen Welfare (“**DoESW**”) of the Ministry of Defence signed an MoU on March 24, 2023 to integrate ayurveda in Ex-Servicemen Contributory Health Scheme (“**ECHS**”) Polyclinics as an out-patient department (“**OPD**”) service for a period of 5 (five) years. These ayurveda OPD polyclinics will be based at Ambala, Mysore, Ranchi, Nagpur, Bhopal, Bhubaneswar, Chennai, Meerut, Danapur, and Allepey, and will cover all ECHS members on a voluntary basis.

By way of this collaboration, AYUSH will provide technical support and guidance to these polyclinics from time to time and will empanel Ayurveda doctors and pharmacists for their engagement with these polyclinics. The DoESW will, in turn, provide the requisite infrastructure and resources, including administrative, clerical, and multi-tasking staff required for day-to-day working along with other amenities at a suitable location in the respective polyclinics. It will also engage with ayurveda specialists, general duty medical officers and paramedical staff on contractual basis.

Through this MoU, both AYUSH and Ministry of Defence have agreed to form a joint working group comprising of representatives from AYUSH and DoESW to take forward the proposal of establishing Ayurveda OPDs as per the MoU and strengthen their association in providing Ayush health services at various establishments of Ministry of Defence.

MoU signed between Ministry of AYUSH and Ministry of Rural Development for skilling of rural youth and empowering women

The Ministry of Rural Development (“**MoRD**”) has signed an MoU with the Ministry of AYUSH (“**AYUSH**”) on March 16, 2023 to collaborate in the development of skilled personnel by imparting training to rural poor youth and women for Ayush healthcare system under the Deen Dayal Upadhyaya-Grameen Kaushalya Yojana (“**DDUGKY**”), a flagship programme of the MoRD.

The MoU is valid for a period of 3 (three) years and aims to provide training programs, which would be funded as per DDUGKY cost norms, for empowering women’s self-help groups and rural poor youth. As per the MoU, AYUSH will provide its institutes for conducting courses, training & certification programmes of candidates, and will also depute nodal agencies across the country to ensure mobilization, counselling, training, placement and tracking of candidates as per DDUGKY norms in their respective designated states. The MoU aims to formulate a system that will arrange training and orientation of plantation beneficiaries and community level livelihood workers and provide technical assistance in identifying permissible medicinal plantation activities, plant protection and inter-cropping to generate additional streams for income under the schemes of MoRD.

Through this collaboration, both the ministries will also set up a joint working group to identify and work on activities of mutual interest. The MoU is therefore expected to create a synergy and convergence between both the ministries and to enable the fulfilment of a larger goal of community development and poverty alleviation in rural areas.

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



11 Practices and
39 Ranked Partners
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11 Ranked Lawyers



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10 Ranked Practices

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7 Practices and
2 Ranked Lawyers



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