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**JSA Newsletter**  
Healthcare

November 2022 Edition

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

## **Government of India sets up committee to monitor progress of bulk drug parks**

The media has reported that the Department of Pharmaceuticals of the Government of India has set up a high-level committee to monitor the progress of bulk drug parks that are being set up in Andhra Pradesh, Himachal Pradesh and Gujarat. Headed by Mansukh Mandaviya, Union Minister of Chemicals and Fertilizers, the committee's objective apparently will be to give impetus to the domestic production of specific bulk drugs which India is importing in order to reduce import dependence.

As per news reports relating to the setting up of the committee, these 3 (three) states will have to present the details of design, strategy of selection of industrial units, and the list of bulk drugs going to be manufactured in the parks. All this will be done well before the allotment of plots. The reports suggest that the government intends to give preference to units manufacturing such bulk drugs in respect of which India has the highest import dependency rather than those which India is already producing in sufficient quantities. These reports also state that the committee will facilitate the alignment of investments in the bulk drug parks with pharmaceutical industry requirements and public health needs.

## **MOU signed between NHA and NABH to expedite the implementation of ABDM**

The National Health Authority ("NHA") and the National Accreditation Board for Hospitals and Healthcare ("NABH") have signed a memorandum of understanding ("MOU") to expedite the implementation of Ayushman Bharath Digital Mission ("ABDM") by collaborating in the areas of capacity building and creating awareness about their respective initiatives. The Ministry of Health and Family Welfare ("MoHFW") issued a press release on October 18, 2022 to announce the signing of the MOU.

NHA and NABH will mutually create a platform for disseminating information, providing technical support, promoting NABH accreditation and ABDM standards, and providing stakeholder advocacy to achieve the milestones of ABDM. It aims to incorporate ABDM standards in the healthcare system by encouraging a rapid adoption of digital health information system and by developing accreditation standards and ratings for healthcare facilities by both agencies.

NABH, which is a constituent board of Quality Council of India ("QCI"), has an extensive and efficient quality framework and accreditation system for healthcare facilities. As per the MOU, NABH will provide assistance in the onboarding of accredited/certified facilities on ABDM's Health Facility Registry and onboarding of doctors, nurses and other medical staff working in these facilities on the Healthcare Professionals Registry. NHA, in turn, will seek to strengthen and

leverage NABH's reach and presence among the health facilities and healthcare professionals from the public as well as private sector and will encourage them to provide quality healthcare to the masses.

## WHO Global TB Report 2022

The World Health Organisation ("WHO") released the Global Tuberculosis Report 2022 ("Report") on October 27, 2022. Based primarily on data obtained by the WHO from national ministries of health and published every year since 1997, the stated purpose of the Report is to provide a comprehensive and up-to date assessment of the status of the TB epidemic and progress in the response at global, regional and national levels, in the context of global commitments, strategies and targets. The Report in particular details its findings on the impact of the Covid-19 pandemic on the diagnosis, treatment and burden of disease for Tuberculosis ("TB") across the world. One of the most significant findings of the Report is a large drop in the global reported newly diagnosed TB cases in 2020 and 2021. It attributes this to challenges in accessing essential TB services especially during the Covid-19 pandemic, resulting in many people suffering with TB from not getting diagnosed and treated. The burden of drug resistant TB is also estimated to have increased between 2020 and 2021.

Some key findings of the Report relating to India are:

1. India was among the 8 (eight) countries (the others being China, Pakistan, Indonesia, the Philippines, Nigeria and the Democratic Republic of the Congo) which had more than two-thirds of the global total TB patients in 2021. Most people who developed the disease were adult males.
2. India was amongst the top 3 (three) countries accounting for the largest drop in reported TB cases in 2020 and 2021. The number of TB deaths however increased during this period, with India being one of the 4 (four) countries which witnessed the largest increase.
3. India also is the only country in which a national TB prevalence survey has been completed since 2019.

Estimates of TB incidence and mortality in India for 2020 – 21 are interim and subject to finalisation in consultation with the MoHFW.

## MOU signed between FOGSI and NABH to collaborate for improving quality standards for maternal healthcare in India

The Federation of Obstetricians and Gynaecological Societies of India ("FOGSI") has signed an MOU with NABH on August 29, 2022, to work together to improve the quality of maternity services in India and achieve the missions of its flagship initiative 'Manyata' which aims at promoting the adoption and practice of 16 (sixteen) clinical standards based on the WHO standards of quality care. The MOU aims to fulfil the objective of 'One Nation One Standard' by harmonizing the assessment standards of maternity health in India. It establishes a quality-improvement sectoral collaboration that will work towards advancing India's health system by enhancing and standardizing the healthcare quality across all maternity facilities in India.

As per the MOU, NABH and FOGSI will undertake a joint assessment of clinical standards of hospitals and nursing homes having maternal care facilities. The MoU also provides for conducting sensitizing workshops for Maternity Service Providers ("MSPs") that will aim to create a pool of FOGSI specialists to assess facilities for NABH quality accreditation and undertake assessment of MSPs by NABH as per FOGSI's Manyata standards.

The agencies expect that the MoU will enable them in ensuring a consistent, safe, and respectful care for mothers during and after childbirth and therefore complement their efforts to bring a drop in maternal mortality in India, which is amongst the highest in the world.

## Drugs (Eighth Amendment) Rules, 2022

The central government, *vide* its notification dated November 17, 2022 published by the MoHFW, has amended the Drugs and Cosmetics Rules, 1945 (“**Rules**”) to mandate the printing/affixing of bar code or quick response code (QR code) on the primary packaging label on 300 (three hundred) drug formulation products, which are listed in the newly inserted Schedule H2 to the Rules by the manufacturers of these products. However, if the primary packaging label does not have sufficient space, the same will have to be printed or affixed on the secondary package label.

The bar code or QR code is required to include the following data/information, legible with software application to facilitate authentication: (a) unique product identification code; (b) proper and generic name of the drug; (c) brand name; (d) name and address of the manufacturer; (e) batch number; (f) date of manufacturing; (g) date of expiry; and (h) manufacturing licence number.

The amendment comes into effect from August 1, 2023.

## Draft New Drugs and Clinical Trials (Amendment) Rules, 2022

The Central Government, *vide* its notification dated November 22, 2022 published by the MoHFW, has proposed to amend the New Drugs and Clinical Trials Rules, 2019 to allow the following non-clinical testing methods for assessing the safety and efficacy of a new drug or investigational new drug: (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.

The central government has invited objections and suggestions from the general public on the proposed amendment within 15 (fifteen) days of the publication of the said notification.

### 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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14 Practices and  
23 Ranked Lawyers



15 Practices and  
18 Ranked Lawyers



7 Practices and  
2 Ranked Lawyers



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10 Practices and  
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of the Year

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Team of the Year



Among Top 7 Best Overall  
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10 Ranked Practices

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