
February 2023 Edition

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

## Regulatory Updates

### Fixation of retail and ceiling prices of various formulations by National Pharmaceutical Pricing Authority

The National Pharmaceutical Pricing Authority ("**NPPA**") *vide* order dated February 2, 2023 has notified the retail and ceiling prices of various formulations. It also specifies the details of the formulation along with the strength, unit and name of manufacturer and marketing company. All such retail and ceiling pricings are exclusive of goods and services tax.

### Import of high risk food products at specific ports

The Central Board of Indirect Taxes and Customs has *vide* Instruction No. 5 of 2023 – Customs, dated February 8, 2023 instructed that certain high risk food products, including nutraceuticals, health supplements, and foods for special medical or dietary purposes are required to be imported only through 79 (seventy nine) specified ports, with effect from March 1, 2023.

### Issuance of Guidelines for Umbilical Cord Blood Banking, 2023 by Indian Council of Medical Research

The Guidelines for Umbilical Cord Blood Banking, 2023 (the "**Guidelines**") have been issued by the Indian Council of Medical Research. These Guidelines are meant to serve as a guidance document on the quality and ethical aspects of umbilical cord blood collection, processing, banking, and release. The Guidelines are applicable to all stakeholders including umbilical cord blood banks and personnel involved in all its procedures, obstetricians, neonatologists, and transplant physicians along with parents and all individuals providing support services. It may be stated that the said Guidelines are not meant to be construed to replace or overrule but to substantiate the existing regulatory requirements as described in Drugs and Cosmetic Act, 1940, read with corresponding rules and amendments, that are already in place for umbilical cord blood banking.

### Approval of Medical Procurement Authority Act by the Maharashtra Cabinet with respect to single authority for procurement of medicines for state-run hospitals

The Government of Maharashtra in its cabinet meeting of February 14, 2023, has approved the Medical Procurement Authority Act. This paves the way for formation of an independent entity for procurement of medicines in state-run hospitals and all municipal corporations in the State of Maharashtra. The regulatory board of the authority will be headed by the Chief Minister and will constitute 14 (fourteen) members.

### Issuance of Assisted Reproductive Technology (Regulations) Amendment Rules, 2023 by Ministry of Health and Family Welfare

The Ministry of Health and Family Welfare has *vide* notification dated February 24, 2023 issued the Assisted Reproductive Technology (Regulations) Amendment Rules, 2023, by which any person intending to transfer their gametes and embryos for personal use within or outside India is required to apply or furnish declarations in prescribed forms and obtain the prior permission of the National Assisted Reproductive Technology and Surrogacy Board.

## Interesting Reads

### Maintenance of existing maximum retail price

The NPPA has required manufacturers to maintain the existing maximum retail price till April 2023. The manufacturers could subsequently increase the price by up to 10%, based on the National List of Essential Medicines, 2022.

### Show-cause notices against e-pharmacies for non-compliances

The Drugs Controller General of India has served show-cause notices on February 8, 2023 against 20 (twenty) e-pharmacies seeking their explanations on why action should not be taken against them for selling pharmaceutical substances online, in contravention of the Drugs and Cosmetics Act, 1940, and the order of the Delhi High Court in *Dr. Zaheer Ahmed v Union of India*[1]. The notices state that the sale, or stock or exhibit or offer for sale or distribution of drugs through online, internet or other electronic platforms without a licence has potential impact on the quality of drugs and pose risk to public health due to potential misuse of drugs through self-medication and indiscriminate use of drugs.

### Implementation of QR-based code for OPD registration in hospitals

In the annual conference of Apollo Hospital, the Additional CEO of the National Health Authority mentioned that the NHA had implemented a QR-based code for rapid registration of out-patients in more than 300 (three hundred) public hospitals, thereby reducing waiting times to about 4 (four) minutes. The patient can scan a hospital's unique QR code and share their details with the facility. Once their profile is shared, and a token number is issued. According to the token numbers issued to them, the patient can collect their out-patient slips for consultation with a doctor.

### Government launches digital tools developed by NPPA

Indian pharmaceutical companies have been urged by the NPPA to register in the Integrated Pharmaceutical Database Management System ("**IPDMS 2.0**") to build a strong database of businesses and speed up the regulatory approvals process for drug manufacturing in India. IPDMS 2.0 is an integrated responsive cloud-based application developed by NPPA with technical support from the Centre for Advance Computing (C-DAC). It is envisaged to optimise synergies in operations to promote Government's thrust on 'Ease of Doing Business' as it would provide a single window for submissions of various forms as mandated under the Drug Price Control Order (DPCO), 2013. The IPDMS 2.0 aims to

[1] Writ Petition (C) No:11711/2018 (Delhi HC)

create an authentic database of data on goods, costs, manufacturing, and sales of scheduled, non-scheduled formulations and active medicinal ingredients.

## Case Laws

### Centre clarifies surrogacy law provisions before the Supreme Court

In the case of ***Arun Muthuvel v Union of India***[2], certain provisions of India's Surrogacy Regulation Act, 2021, and the Assisted Reproductive Technology (Regulation) Act, 2021, have been challenged before the Supreme Court of India ("**Supreme Court**"). On February 7, 2023, the Supreme Court directed the Government of India (through the National Assisted Reproductive Technology and Surrogacy Board (the "**Board**")) to implement forthwith, those suggestions which are feasible and acceptable by the Board. During the hearing on February 7, 2023, the Government of India in relation to the aforementioned statutes had clarified its position viz., (a) child to be born through surrogacy must be genetically related to the intending couple or intending woman; (b) constitution of a state-level Board in all states and union territories; and (c) constitution of appropriate authorities in all states and union territories for the purposes of the 2 (two) legislations. The government informed the Supreme Court that other than the States of Bihar, Haryana, and Uttar Pradesh, the Board had been constituted in all other states and union territories.

### Liability of partners in relation to manufacture of sub-standard drugs

In ***Hindustan Medical Products v State of Karnataka***[3], the Karnataka High Court held that "*it is well settled and as per the definition and explanation to the Section 34 (of the Drugs and Cosmetics Act, 1940) that Company means including firm and Director including the partners. Normally, as per the definition of Partnership Act, they are individually called as partners and collectively they are called as firm. Therefore, it cannot be said the partners are not responsible for the day to day affairs of the firm*".

It had been alleged by the partners of Hindustan Medical Products that as partners they could not be held liable, and only the technical person could be held liable, in relation to manufacture of sub-standard drugs. Referring the matter back to the trial courts, the Karnataka High Court opined that the partners would have to stand trial, in relation to the allegations of manufacture of sub-standard drugs made against the partnership.

### Delhi High Court directs the Government to release INR 50 million to the All India Institute Of Medical Sciences ("AIIMS")

In ***Master Arnesh Shaw v Union of India***[4], the Delhi High Court has directed the government to immediately release INR 50,000,000 (Indian Rupees fifty million) to AIIMS to ensure that the treatment of children with rare diseases, which has already commenced, is not stopped due to lack of funds.

### Supreme Court simplifies the 2018 guidelines on living will/advance directives

The Supreme Court modified a slew of directives regarding advance medical directives, or living wills, under the 2018 ruling of ***Common Cause v. UOI***[5], that had recognised the right to die with dignity, and had accordingly upheld the legal validity of passive euthanasia. Some of the fundamental changes with respect to previous guidelines, are provided as follows:

[2] W.P. (Civil) No. 756 of 2022 (SC)
[3] CrlP No. 6742/2020 (Karnataka HC)
[4] W.P.(C) 5315/2020 & connected matters (Delhi HC)
[5] WP (C) No. 215 OF 2005 (SC)

| Previous Guidelines | Modifications |
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| The document was to be signed in presence of 2 (two) attesting witnesses and countersigned by the jurisdictional Judicial Magistrate of First Class ("**JMFC**") so designated by the District Judge concerned. | The document after being signed in the presence of 2 (two) attesting witnesses has to be attested by a notary or a Gazetted Officer. |
| The JMFC must keep a copy and forward one to the Registry of the jurisdictional District Court for being preserved. Additionally, the Registry of the jurisdictional District Court must retain the document in digital format. | The provision has been deleted. |
| Only 1 (one) guardian or close relative was to be named, in the document who would be updated with the patient's condition and be involved in the decision making. | More than 1 (one) guardian or close relative can be named, in the document who would be updated with the patient's condition and be involved in the decision making. |
| After receiving the hospital medical board's approval, the treating physician or hospital had to inform the jurisdictional collector, who would then constitute another medical board comprising the chief district medical officer and 3 (three) expert doctors from the fields of general medicine, cardiology, neurology, nephrology, psychiatry, or oncology with experience in critical care and with overall standing in the medical profession of at least 20 (twenty) years. The members of the hospital medical board would not be eligible to be a part of the medical board formed by the collector. | After the primary medical board gives its sanction, the hospital will immediately constitute a secondary medical board comprising a registered medical practitioner nominated by the chief medical officer of the district and at least 2 (two) subject experts with at least 5 (five) years' experience in the concerned speciality who were not part of the primary medical board. This board will provide its opinion preferably within 48 (forty eight) hours of the case being referred to it. |
| The decision of the medical board constituted by the collector had to be conveyed by the chairman, i.e., the chief district officer, to the judicial magistrate, who would then authorise the withdrawal of treatment after visiting the executor at the earliest and examining all aspects. | It is no longer necessary to wait for the judicial magistrate's authorisation. |

## Liability of a retailer in relation to spurious or sub-standard quality drugs

In ***Sundaram Surgicals v Drugs Inspector, Doda***[6] the Jammu and Kashmir High Court has held that a retailer cannot escape liability in relation to spurious or sub-standard quality drugs, merely because he has obtained the same from a licensed dealer. A retailer can seek discharge only if he shows that he has acquired the drug from a duly licensed manufacturer, distributor or dealer and that he did not know and could not, with reasonable diligence, ascertain contravention of the provisions of the section and further that the drug or the cosmetic was properly stored and remained in the same state as and when he acquired it. The burden to prove the aforesaid 3 (three) conditions would always be upon the concerned dealer.

[6] CRMC No. 396/2018 (Jammu and Kashmir HC)

## 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.

**This Newsletter has been prepared by:**

**Sidharrth Shankar**
Partner

**Ayisha Mansoor**
Principal Associate

**Arjun Krishnamoorthy**
Principal Associate

17 Practices and
24 Ranked Lawyers

16 Practices and
11 Ranked Lawyers

7 Practices and
2 Ranked Lawyers

11 Practices and
39 Ranked Partners
**IFLR1000 APAC Rankings 2022**

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Banking & Finance Team
of the Year

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Fintech Team of the Year

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Restructuring & Insolvency
Team of the Year

Among Top 7 Best Overall
Law Firms in India and
10 Ranked Practices

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13 winning Deals in
IBLJ Deals of the Year

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10 A List Lawyers in
IBLJ Top 100 Lawyer List

Banking & Financial Services
Law Firm of the Year 2022

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Dispute Resolution Law
Firm of the Year 2022

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Equity Market Deal of the
Year (Premium) 2022

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Energy Law Firm of the Year 2021

**Ranked #1**
**The Vahura Best Law Firms to**
**Work Report, 2022**

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Top 10 Best Law Firms for
Women in 2022

For more details, please contact km@jsalaw.com


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