May 2023 Edition

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

Regulatory updates:

Export sample of cough syrup to be tested by government approved laboratories

The Directorate General of Foreign Trade, *vide* Notification No. 06/2023 dated May 22, 2023 ("**Notification**") has amended the ITC (HS) Export Policy. With effect from June 1, 2023, the amendment mandates that cough syrups may be exported, subject to the export sample being tested by Government approved laboratories and production of a Certificate of Analysis issued by such laboratories, as specified in the said Notification. This direction has been issued following global concerns over the quality of cough syrups exported by Indian companies.

Constitution of state allied and healthcare councils

The Ministry of Health and Family Welfare ("**MOHFW**") has issued the National Commission for Allied and Healthcare Professions 5th (Removal of Difficulties) Order, 2023 and directed all state governments and union territories to constitute state allied and healthcare councils within 2 (two) years and 6 (six) months from the date of commencement of the National Commission for Allied and Healthcare Professions Act , 2021 i.e. on or before November 22, 2025.

Retail price of new drugs

The Drugs (Prices Control) Amendment Order, 2023 sets out that the retail price of a new drug (or that which contains molecules or components that have either become off-patent or about to become off-patent) will be calculated by reducing 50% of the price arrived at under paragraph 4 of the Drugs (Prices Control) Order, 2013, and if the new drug is not available in the domestic market, the price will be determined by a Standing Committee of Experts.

Notification of standards for medical devices

The Bureau of Indian Standards has notified the Indian standards in relation to particular requirements for basic safety and essential performance of critical care ventilators.

Scheme for assistance to medical device clusters for common facilities

The Department of Pharmaceuticals ("**DoP**") of the Government of India ("**GoI**") has released detailed guidelines dated May 9, 2023 for the scheme with respect to "Assistance to Medical Device Clusters for Common Facilities", which supplements the recently notified National Medical Device Policy, 2023 and aims to strengthen the existing infrastructural framework for medical devices clusters (including establishing more testing laboratories for medical devices).

For a detailed analysis, please refer to JSA Prism of May 26, 2023.

Interesting reads:

Approval by cabinet for signing of Project Collaboration Agreement between Department of Health Research and the World Health Organisation

The MOHFW issued a press release on May 17, 2023 regarding the Union Cabinet being apprised of the signing of Project Collaboration Agreement ("**PCA**") between Department of Health Research ("**DHR**") and World Health Organization ("**WHO**"). The PCA was signed by WHO on October 10, 2022 and was subsequently signed by DHR on October 18, 2022. The said collaboration intends to promote research and innovation, develop and disseminate relevant training programmes, and increase global awareness of the availability of high quality affordable assistive technology.

Signing of MOA between Ministry of AYUSH and Indian Council of Medical Research

The MOHFW issued a press release on May 11, 2023 regarding the Memorandum of Agreement ("**MOA**") signed between Indian Council of Medical Research ("**ICMR**") and the Ministry of AYUSH ("**AYUSH**"). The MOA envisages cooperation and collaboration between ICMR and AYUSH for exploring the areas of synergy for integrative health research and strengthening research capacity particularly in the area of integrative medicine. Integrative medicine refers to the use of complementary and alternative medical practices such as ayurveda, yoga, naturopathy, unani, siddha, and homoeopathy. The MOU aims to integrate modern research with traditional knowledge to strengthen ayurveda's credibility on the basis of scientific evidence.

Case laws

Establishment of a committee to implement the National Policy for Rare Diseases, 2021

In a petition filed by the petitioners who are mostly children suffering from rare diseases claiming that medicines and therapies are exorbitantly expensive, the Delhi High Court in ***Arnesh Shaw and Ors. V. Union of India***[1] constituted a 5 (five) member committee ("**Committee**") to implement the National Policy for Rare Diseases, 2021 ("**Policy**"). This will be undertaken in close coordination among the medical community, therapy providers and governmental organizations. The mandate of the Committee includes:

1. procurement of therapies & drugs and creation of associated logistical framework for administration of treatment for patients with rare diseases;
2. recommending necessary steps for the indigenisation of therapies, medicines for rare diseases and identify the manner in which the same can be made accessible to the lakhs of patients who, as per the Policy, are suffering from rare diseases;
3. undertaking a periodic review of the Policy and recommending the changes needed in the Policy to the Ministry of Health and Family Welfare, if deemed necessary.

[1] 2023/DHC /003423 [Delhi HC]

Timeline fixed for holding of the interviews towards kidney transplant process

In the case of ***Amar Singh Bhatia & Anr. v. Sir Ganga Ram Hospital & Ors.***[2], plea was moved by a man seeking organ donation, and challenging the delay on the part of Sir Ganga Ram Hospital to take a decision on the kidney transplant which the petitioner required. The issue raised in the plea is that there are no prescribed timelines for holding the interview by the authorisation committee under Transplantation of Human Organs and Tissues Rules, 2014 ("**Transplantation Rules**"), once the requisite documentation is submitted.

The court observed that Rule 23(1) of the Transplantation Rules provides that the authorisation committee should state in writing its reason for rejecting or approving the application of the proposed living donor. Rule 23(4) of the Transplantation Rules further provides that the decision should be displayed on the notice board and website of the hospital or institution immediately, within 24 (twenty four) hours and Rule 23(3) Transplantation Rules requires that the decision has to be taken within 24 (twenty four) hours of the authorization committee holding its meeting for such purpose. Insofar as Rule 23(1) of the Transplantation Rules is concerned, there is no timeline fixed for holding the interviews.

Taking note that the Transplantation Rules have been enacted by the Union Government under Section 24 of the Transplantation of Human Organs & Tissues Act, 1994, the court directed MOHFW to file an affidavit on this issue and indicating the reasonable timeline that should be followed by hospitals, authorisation committees and for the screening process to hold interviews and conveying the decisions to the applicants.

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.

[2] W.P.(C) 3590/2020 and CMAPPL. 12775/2020 [Delhi HC]

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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

Banking & Finance Team
of the Year

Fintech Team of the Year

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

Dispute Resolution Law
Firm of the Year 2022

Equity Market Deal of the
Year (Premium) 2022

Energy Law Firm of the Year 2021

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

Top 10 Best Law Firms for Women in 2022

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