July-August 2024 Edition

This edition of the JSA healthcare newsletter focuses on the key developments undertaken in the Indian healthcare ecosystem in July and August 2024.

Regulatory updates

Launch of provision for instant (tatkal) issuances of licenses/registrations in certain categories of food businesses

The Food Safety and Standards Authority of India ("**FSSAI**"), *vide* notification dated July 1, 2024, has enabled instant issuances of licenses/registrations under the Food Safety and Standards (Licensing and Registration of Food Businesses) Regulations, 2011, for specific categories. These include wholesalers, distributors, retailers, transporters, storage without atmospheric control, importers, food vending agencies, direct sellers and merchant-exporters. It is subject to key changes (and conditions) with respect to the existing procedure, such as:

1. it will be only applicable for prescribed Kind of Businesses ("**KoB**") and certain food product categories within the KoB;
2. for proprietorship firms, the digital verification will be done through Goods and Services Tax ("**GST**") and AADHAAR and for partnership/registered firms through corporate identification number/GST and AADHAAR;
3. the applicant will be required to declare that: '*He/she does not possess the valid license/registration at the same premises or his/her license/registration has not been suspended or cancelled by the authorities in past 3 (three) months*';
4. the applicant will be required to upload photographs of the unit, specifically including images of the entrance/front facing of the unit;
5. the validity of instant license/registration will be 1 (one) year and it can be renewed post that as per the renewal procedure; and
6. the applicants will be required to pay the entire annual fee for license/registration during filing of application.

The instant issuance of license/registration (*except for the partnership/registered firms requiring digital verification through GST and AADHAAR*) is being rolled out in the States/Union Territories of Assam, Delhi, Gujarat, Jammu and Kashmir, and Kerala from June 28, 2024.

Display of nutritional information labelling of total sugar, salt and saturated fat

FSSAI, in its 44th meeting on July 6, 2024, approved the proposal to amend the Food Safety and Standards (Labelling and Display) Regulations, 2020 with respect to displaying nutritional information regarding total sugar, salt and saturated fat in bold letters and relatively increased font size on labels of packaged food items.

Validity of FSSAI recognised food testing laboratories

FSSAI, *vide* notification dated July 11, 2024, has issued a list of FSSAI recognised laboratories along with the validity of their National Accreditation Board for Testing and Calibration Laboratories accreditation and their respective contact details. These laboratories carry out the analysis of food samples taken under the Food Safety and Standards Act, 2006 and rules and regulations made there under.

Re-operationalisation of Food Safety and Standards (Licensing and Registration of Food Business) Amendment Regulations, 2021

FSSAI had approved the draft Food Safety and Standards (Licensing and Registration of Food Business) Regulations, 2018 ("**FSS 2018 Regulations**") on September 21, 2017, pursuant to which they were notified for comments from stakeholders. Pending finalisation of the FSS 2018 Regulations, FSSAI had issued and operationalised the Food Safety and Standards (Licensing and Registration of Food Business) Amendment Regulations, 2021 to ensure food safety and fair practices in food business operations. Since the FSS 2018 Regulations are yet to be finalised and notified, FSSAI, *vide* a direction dated July 19, 2024, has re-operationalised the Food Safety and Standards (Licensing and Registration of Food Business) Amendment Regulations, 2021 with effect from May 11, 2024.

Omission of Regulation 7(4) of the Food Safety and Standards (Fortification of Foods) Regulations, 2018

FSSAI, *vide* a direction dated July 19, 2024, has omitted Regulation 7(4) of the Food Safety and Standards (Fortification of Foods) Regulations, 2018. Accordingly, packages of food, fortified with iron can no longer carry the following statement: "*People with thalassemia may take under medical supervision and persons with sickle cell anaemia are advised not to consume iron fortified food products*".

Re-operationalisation of certain provisions of the Draft Food Safety and Standards (Food Product Standards and Food Additives) Amendment Regulations, 2021

FSSAI, *vide* a direction dated May 30, 2022, had operationalised certain provisions of the draft Food Safety and Standards (Food Product Standards and Food Additives) Amendment Regulations, 2021 with respect to the permissible limits of total dissolved solids, calcium and magnesium in packaged drinking water. The final amendment regulations have been approved by FSSAI but are yet to be notified. To allow Food Business Operators ("**FBOs**") to formulate packaged drinking water, FSSAI, *vide* a direction dated July 26, 2024, has re-operationalised the said provisions of the amendment regulations with effect from July 1, 2024.

Clarification regarding selling/marketing of fruit juices with non-standardised ingredients

FSSAI has noted that few manufacturers are adding non-standardised ingredients such as 'deionized apple juice concentrate' in their fruit juices which is not a permitted ingredient under various food safety and standards regulations such as the Food Safety and Standards (Advertising and Claims) Regulations, 2018 and Food Safety and

Standards (Labelling and Display) Regulations, 2020. Consequently, FSSAI, *vide* advisory dated July 31, 2024, has advised the FBOs to obtain approval of such non specified food/ingredients under the Food Safety and Standards (Approval for Non-Specific Food and Food Ingredients) Regulation, 2017.

Extension of enrolment of non-food production units for collection of used cooking oil from FBO

FSSAI, *vide* its circular dated August 5, 2024, has extended the validity of the provisional enrolment of the prescribed 50 (fifty) non- food production units[1] for collection of used cooking oil from FBOs up to July 31, 2025, or till the registration mechanism in the State/Union Territories gets devised.

Applications for registration and import of cosmetics through SUGAM on-line portal

The Central Drugs Standard Control Organisation ("**CDSCO**") through its SUGAM on-line portal[2] receives various applications for registration and import of cosmetics (including applications for post approval changes).To streamline the application process, CDSCO, *vide* circular dated August 9, 2024, has decided to restrict the number of products per application to a maximum of 50 (fifty). However, multiple applications are allowed. The said restriction is implemented with effect from August 16, 2024.

Advisory for all medical colleges and institutions for ensuring safe work place environment

The National Medical Commission ("**NMC**"), *vide* public notice dated August 13, 2024, issued an advisory for all medical colleges and institutions requesting them to develop a policy for safe work environment within the college and hospital campus for all the staff members including faculty, medical students and resident doctors. The policy should ensure adequate safety measures at OPD, wards, casualty, hostels and other open areas in the campus and residential quarters. Further, any incident of violence against the medical students should be promptly investigated by the college management and an first information report should be lodged with the police. A detailed action taken report on any incident of violence should invariably be sent to the NMC within 48 (forty-eight) hours of the incident.

Selling/marketing of reconstituted fruit juices as '100% Fruit Juice'

FSSAI, *vide* its advisory dated August 14, 2024, has extended the deadline provided in its advisory dated June 3, 2024,. FSSAI has now required all FBOs to exhaust all existing pre-printed packaged reconstituted fruit juices labelled as "100% Fruit Juice" by December 31, 2024 (*earlier this was August 31, 2024*). Further, products manufactured by FBOs before December 31, 2024, are allowed to be sold in the market across all channels until the end of their shelf life.

[1] Non-food production units refer to company or production units involved in preparation of non-food products such as biodiesel, candles, soaps, lubricant, etc. in which used cooking oil is used as an ingredient.

[2] SUGAM portal is an online web portal where applicants can apply for no objection certificates, licenses, registration certificates, permissions and approvals under the Drugs and Cosmetics Acts, 1940. It provides an online interface for applicants to track their applications, respond to queries and download the permissions issued by CDSCO. It also enables CDSCO officials to process the applications online and generate the permissions online and generate management information system reports.

Sensitisation of food testing laboratories mapped on food import clearance system portal

FSSAI has noted that the food testing laboratories whilst testing of import samples have been making inadvertent mistakes while uploading test reports of import samples on the Food Import Clearance System ("**FICS**") portal.[3] This creates unnecessary hindrances in the clearance of import consignments. To address this, FSSAI, *vide* its advisory dated August 16, 2024, has directed the laboratories mapped on the FICS portal to conduct due diligence on the following:

1. the sample must be tested and the test reports must be generated and uploaded on FICS portal within 5 (five) days as stipulated under Regulation 9 (12) of Food Safety and Standards (Import) Regulations, 2017;
2. the entries such as test parameters, food product category, FSSR limits, result string must be verified before final submission of test reports on FICS portal. The test result, i.e., 'Pass/Fail' status must be verified with the test report uploaded on FICS portal of the relevant sample;
3. before final submission of the test report, it must be ensured that the wrong test report is not uploaded and the test report uploaded is of the respective sample;
4. test reports must be uploaded in FORM-2 on FICS portal as per Food Safety and Standards (Import) Regulation, 2017 with NABL symbol;
5. the samples which are not covered under the NABL scope of accreditation of the laboratory must not be accepted;
6. only the validated and accredited methods must be adopted for testing of food samples by the laboratory;
7. the test report should be signed by a food analyst duly appointed as per the requirement of Rule 2.1.4 (1) of the Food Safety and Standards Rules, 2011; and
8. in case of any delay in completion of testing of the import samples, the laboratory must inform it to the authorised officer as mentioned under Regulation 9 (13) of Food Safety and Standards (Import) Regulations, 2017.

Jan Vishwas (Amendment of Provisions) Act, 2023

The Ministry of Health and Family Welfare ("**MoHFW**"), *vide* notification dated August 19, 2024, has appointed December 31, 2024, as the date on which the provisions of the Jan Vishwas (Amendment of Provisions) Act, 2023 with respect to the Pharmacy Act, 1948 ("**Pharmacy Act**"), will come into force.

Some of the key provisions with respect to the Pharmacy Act that would be amended under the Jan Vishwas (Amendment of Provisions) Act, 2023, are detailed below:

Section	Existing Provision	Amendment
Section 18(2)	As per Section 18(2), the Central Council may, with the approval of the Central Government by notification in the Official Gazette make regulations consistent with purpose of the Pharmacy Act and such regulations must provide for specific procedures, powers and duties.	Insertion of new sub-sections (i) and (j) for framing of regulations for holding inquiry and penalty under Section 43Aand form and manner of preferring an appeal under Section 43A respectively. Section 43A is a new provision which has been inserted for adjudication of penalties.

[3] The FICS portal is an online food regulatory portal which is integrated with the customs ICEGate (i.e Indian Customs Electronic Commerce/Electronic Data Interchange Gateway) portal to facilitate trade, provides an opportunity to importers to file an application for easy clearance of food consignments.

Section	Existing Provision	Amendment
Section 26A(3)	Under Section 26A (3), any person that obstructs an Inspector in the exercise of his powers, must be punishable with imprisonment of up to 6 months or with fine up to INR 1,000, or with both.	The punishment of imprisonment is proposed to be removed. The penalty for obstructing an inspector while exercising powers in line with the Pharmacy Act, enhanced to INR 100,000.
Section 41(1)	Any person whose name is not entered in the register of pharmacists, falsely pretends that it has been entered, must be punishable with fine of up to INR 500 on first conviction, and on continuing contravention with imprisonment of up to 6 months or with a fine of maximum INR 1,000 or both.	The first conviction is punishable with maximum fine INR 1,00,000 and subsequent contravention is punishable with imprisonment up to 3 months or with maximum fine up to INR 2,00,000 or with both imprisonment and fine.
Section 42(2)	Dispensing by unregistered person is punishable with maximum 6 months imprisonment, or with fine up to INR 1,000, or with both.	Dispensing by unregistered person is punishable with maximum 3 months imprisonment, or with fine up to INR 200,000, or with both fine and imprisonment.
Section 43A		A new provision (Section 43A) has been inserted for adjudication of penalties under Section 26A. The President of the State Council is authorised as an adjudicating officer for holding inquiry and imposing penalties.

Withdrawal of advisory on selling/marketing of milk and milk products such as ghee, milk in the name of Al and A2

FSSAI, *vide* its order dated August 21, 2024, had instructed all e-commerce FBOs claiming to sell their milk and milk related products in the name of A1 and A2 under FSSAI license number and/or registration certificate number, to remove such claims from their websites. However, FSSAI *vide* its order dated August 26, 2024, has withdrawn the aforesaid advisory.

Re-operationalisation of certain provisions of the Draft Food Safety and Standards (Health Supplements, Nutraceuticals, Food for Special Dietary Use, Food for Special Medical Purpose and Prebiotic and Probiotic Food) Amendment Regulations, 2022

FSSAI, *vide* a direction dated March 29, 2022, overhauled the Food Safety and Standards (Health Supplements, Nutraceuticals, Food for Special Dietary Use, Food for Special Medical Purpose, Functional Food and Novel Food)

Regulations, 2016, and framed the draft Food Safety and Standards (Health Supplements, Nutraceuticals, Food for Special Dietary Use, Food for Special Medical Purpose and Prebiotic and Probiotic Food) Regulations, 2022 ("**Draft 2022 Regulations**"). Pending finalisation of the Draft 2022 Regulations, FSSAI had operationalised certain provisions with effect from April 1, 2022. Since these are yet to be finalised, FSSAI, *vide* a direction dated August 30, 2024, has re-operationalised the said provisions of the Draft 2022 Regulations with effect from July 1, 2024.

Case laws

Supreme Court upholds the Delhi High Court decision against Sun Pharma for overpricing medicine

The Supreme Court of India ("**Supreme Court**"), in the case of ***Sun Pharmaceutical Industries Ltd. vs. Union of India and Others***,[4] has upheld the recovery demand issued by the National Pharmaceutical Pricing Authority against Sun Pharmaceutical Industries Limited for selling overpriced drugs. The Supreme Court also stated that the purpose of Drugs (Price Control) Order, 1995 is to control prices of medicinal drugs for the common man, and it cannot be subjected to a narrow interpretation.

Supreme Court directs Centre regarding implementation of National Commission for Allied and Healthcare Professions Act, 2021

The Supreme Court, in the case of ***Joint Forum of Medical Technologists of India (Jfmti) and Others vs. Union of India and Others***,[5] has directed the Union Government and the respective State Governments to take necessary steps to implement the provisions of the National Commission for Allied and Healthcare Professions Act, 2021, on or before October 12, 2024. Further, the Secretary of MoHFW was directed to convene an online meeting within a period of 2 (two) weeks from the date of this order, with all the State secretaries of MoHFW to lay down a road map for implementing the provisions of the National Commission for Allied and Healthcare Professions Act, 2021.

Formation of 'National Task Force' by the Supreme Court for medical professionals' safety

The Supreme Court has issued an order[6] in the *suo motu* case taken over the rape and murder of a trainee doctor at the RG Kar Medical College Hospital, Kolkata, ordering the formation of a 'National Task Force' to give recommendations on the modalities to be followed all over the country to ensure the safety and well-being of medical professionals.

National Consumer Disputes Redressal Commission: If a doctor follows an acceptable practice, they are not liable for negligence

The National Consumer Disputes Redressal Commission, in the case of ***Sri Balaji Action Medical Institute vs. Tilak Raj Sikri***,[7] held that a lack of care or an error in judgment does not automatically prove negligence. If the doctors have followed an acceptable practice they are not liable for negligence, even if a better alternative exists.

[4] 2024 LiveLaw (SC) 487
[5] W.P.(C) No. 983/2023
[6] SMW (Crl) No 2 of 2024
[7] F.A. No. 1882/2018

Interesting Reads

Standard operating procedure for prescription writing

The Employee State Insurance Corporation ("**ESIC**") has formulated the Standard Operating Procedure ("**SOP**") for prescription writing to enhance healthcare quality and patient safety while achieving therapeutic goals within the ESIC. The SOP serves as a comprehensive guide for ESIC doctors using the Dhanwantri module, ensuring standardised, clear, and patient specific prescriptions.

Union Ministers of State for Health and Family Welfare, Shri Prataprao Ganpatrao Jadhav and Smt. Anupriya Singh Patel, unveil 3 (three) initiatives

The initiatives aim to improve the quality of healthcare services and promoting the ease of doing business in India. The Union Ministers have launched, a virtual 'National Quality Assurance Standards' assessment for Ayushman Arogya Mandirs; a dashboard which will help national, state and district health institutions and facilities in quickly monitoring compliance with respect to Indian public health standards and taking actions accordingly; and a spot food licence and registration initiative for food vendors.

Research update on the new strains of communicable diseases

The Prime Minister's Science, Technology, and Innovation Advisory Council has reviewed the ongoing activities for pandemic preparedness across agencies and recognised the need for a unified effort in pandemic preparedness through the initiative of National One Health Mission ("**NOHM**"), to address the gaps and enhance coordination among multiple sectors. The mission is a collaborative effort of 13 (thirteen) ministries/departments to realise the objectives of the NOHM, which is steered by the Office of the Principal Scientific Advisor to the Government of India along with other key stakeholders.

Series of digital initiatives launched to streamline pharmaceutical regulations

CDSCO has launched a series of digital initiatives aimed at revolutionising the pharmaceutical regulatory framework in India. These initiatives, showcased at the 'iPHEX 2024' event, are designed to enhance transparency, improve efficiency, and ensure the highest standards of safety and quality in the pharmaceutical sector. The key initiatives include:

1. **National Single Window System ("NSWS")**: The NSWS aims to provide a unified platform for all regulatory approvals at the national level, minimising the need for multiple interfaces and ensuring a more streamlined process for the industry. While the system is currently partially implemented for medical devices and clinical trials, a phased rollout is planned for other licenses;
2. **Online National Drug License System**: Branded as the 'One Nation-One Drug Licensing System', this initiative offers a digital portal managed by CDSCO for uniform drug licensing across all States and Union Territories. It standardises requirements and interpretations, maintains a comprehensive database of licenses, and enables prompt verification, ensuring no discrepancies or anomalies in the licensing process; and
3. **Track and Trace System**: This system is being introduced to ensure the traceability of Active Pharmaceutical Ingredients ("**APIs**") and top formulations. Quick response (QR) codes or barcodes will be used for all APIs imported or manufactured in the country, starting with the top 300 (three hundred) brands of formulations. Future phases will extend this to all remaining formulations, vaccines, and narcotic drugs.

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:

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18 Practices and
25 Ranked Lawyers

7 Ranked Practices,
16 Ranked Lawyers

Elite – Band 1 -
Corporate/ M&A Practice
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3 Band 1 Practices
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4 Band 1 Lawyers,1 Eminent Practitioner

12 Practices and
42 Ranked Partners
IFLR1000 APAC Rankings 2023

Banking & Finance Team of the Year

Fintech Team of the Year

Restructuring & Insolvency Team of the Year

14 Practices and
38 Ranked Lawyers

20 Practices and
22 Ranked Lawyers

Ranked Among Top 5 Law Firms in India for ESG Practice

Recognised in World's 100 best competition practices of 2024

Among Top 7 Best Overall Law Firms in India and
11 Ranked Practices
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11 winning Deals in IBLJ Deals of the Year
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12 A List Lawyers in IBLJ Top 100 Lawyer List

Asia M&A Ranking 2024 – Tier 1

Employer of Choice 2024

Energy and Resources Law Firm of the Year 2024

Litigation Law Firm of the Year 2024

Energy - Law Firm of the Year (APAC)

7 Practices and
3 Ranked Lawyers

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