jsa
advocates & solicitors

Knowledge Management

Semi-Annual Healthcare Sector Compendium 2024

July – December 2024

Semi-Annual Healthcare Sector Compendium 2024

Introduction

This Compendium consolidates all key developments, notifications, judicial precedents and other updates in the Healthcare sector, during the calendar period from July 2024 till December 2024.

Please *click here* to access the Semi-Annual Healthcare Compendium – January 2024 to June 2024.

Regulatory updates

Jan Vishwas (Amendment of Provisions) Act, 2023

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

Some of the key amendments relating to the Pharmacy Act 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.
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 (six) months or with fine up to INR 1,000 (Indian Rupees one thousand), 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 1,00,000 (Indian Rupees one lakh).
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 (Indian Rupees five hundred) on first conviction, and on continuing contravention with imprisonment of up to 6 (six) months or with a fine of maximum INR 1,000 (Indian Rupees one thousand) or both.	The first conviction is punishable with maximum fine INR 1,00,000 (Indian Rupees one lakh) and subsequent contravention is punishable with imprisonment up to 3 (three) months or with maximum fine up to INR 2,00,000 (Indian Rupees two lakh) or with both imprisonment and fine.
Section 42(2)	Dispensing by unregistered person is punishable with maximum 6 (six) months imprisonment, or with fine up to INR 1,000 (Indian Rupees one thousand), or with both.	Dispensing by unregistered person is punishable with maximum 3 (three) months imprisonment, or with fine up to INR 200,000 (Indian Rupees two lakh), 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.

New Drugs and Clinical Trials (Amendment) Rules, 2024.

MoHFW, *vide* notification dated September 19, 2024, announced significant amendments to the New Drugs and Clinical Trials Rules, 2019 ("**NDCT Rules, 2019**"). The latest changes, encapsulated in the New Drugs and Clinical Trials (Amendment) Rules, 2024 (**"NDCT Rules, 2024**") intend to streamline the approval process for new drugs and clinical trials, improve patient safety protocols, and ensure compliance with global standards. Key changes in the NDCT Rules, 2024 are as follows:

1. **Definition for Clinical Research Organisations ("CROs")**: The NDCT Rules, 2024 has introduced a definition for CROs which means the sponsor or a body, commercial or academic or of other category, owned by an individual or an organisation having status of legal entity by whatsoever name called, to which the sponsor may, delegate or transfer in writing, some or all of the tasks, duties or

obligations regarding clinical trial or bioavailability or bioequivalence study.

2. **Registration of CROs**: CROs are required to obtain registration from the Central Licensing Authority ("**CLA**") (as defined in rule 2(i) of the NDCT Rules, 2019) before conducting any clinical trials or bioavailability and bioequivalence studies involving new or investigational drugs on human subjects.

   CROs must submit their registration applications to the CLA using Form CT-07B along with the prescribed fee of INR 5,00,000 (Indian Rupees five lakh). However, centres that are already registered for conducting bioavailability or bioequivalence studies are deemed to be registered for these purposes under the NDCT Rules, 2024.

3. **Grant of registration**: Upon submission of the necessary documents and information *via* Form CT-07B, the CLA will review the application and conduct enquiries for a period of 45 (forty-five) working days and do either of the following:

   a) grant an approval: The approval will be granted if the application meets all criteria and the CLA will grant registration using Form CT-07C;

   b) reject the application: The application may be rejected if the application does not meet the requirements by providing written reasoning. In cases of rejection, applicants have the right to request a reconsideration of their application within 60 (sixty) days from the date of rejection, accompanied by the appropriate fee and any additional required documentation. Furthermore, aggrieved applicants can appeal against the decision to the Central Government within 45 (forty-five) days, with the government set to respond within 60 (sixty) days of receiving the appeal; and

   c) request for rectification: If there are deficiencies, the CLA will notify the applicant, who will then have a specified period to rectify these issues. Post-rectification, the CLA will make a final decision within 90 (ninety) days from the receipt of the corrected application.

   The registration for CROs, once granted under Rule 38C of the NDCT Rules, 2024, is valid for 5 (five) years from the date of its grant, unless suspended or cancelled earlier. To renew this registration, organisations must apply using Form CT-07B along with specified documents before the current registration expires. If this renewal application is submitted before the expiration date, the existing registration remains valid until a decision is made on the renewal. The CLA will review the renewal application and can either renew the registration using Form CT-07C or request rectifications, following the same procedures under rule 38C of the of the NDCT Rules, 2024.

4. **Conditions for registration**:

   a) CROs must maintain facilities and qualified staff as outlined in the Ninth Schedule to perform their functions;

   b) they can initiate clinical trials or bioavailability or bioequivalence studies only after receiving protocol approval from an Ethics Committee ("**EC**") and permission from the CLA;

   c) if a clinical trial site or bioavailability or bioequivalence center lacks its own EC, it can initiate a study after getting protocol approval from an EC at another site or an independent EC registered under Rule 8. The approving EC must be responsible for the study and be located within the same city or within a 50 (fifty) kilometer radius of the trial site or center;

   d) the CLA must be informed about any EC approvals for clinical trials or bioavailability or bioequivalence studies;

   e) all clinical trials and bioavailability or bioequivalence studies must be registered with the Clinical Trial Registry of India before the enrolment of the first subject;

   f) studies must adhere to the approved protocols, Good Clinical Practices Guidelines, and relevant regulations;

   g) if a study is terminated early, reasons must be promptly communicated to the CLA. Additionally, any serious adverse events occurring during the study must be reported to the CLA within 14 (fourteen) days of their occurrence, following specific procedures and formats outlined in the regulations;

h) in cases of injury, disability, or death during a study, the Clinical Research Organisation must provide appropriate medical management and compensation as outlined in Chapter VI. Details of the compensation paid must be reported to the CLA within 30 (thirty) days of receiving the order. Further, any changes in the constitution or ownership of the CRO must be reported within 30 (thirty) days;

i) CROs are required to maintain all study-related data, records, and documents for 5 (five) years post-study completion, or for at least 2 (two) years after the expiration date of the drug batch studied, whichever is later;

j) CROs must allow inspections by any officer authorised by the CLA, with or without prior notice, to review any records or documents related to clinical trials. The CLA also reserves the right to impose additional conditions justified in writing, on specific clinical trials to ensure they meet targeted objectives and standards concerning study design, subject population, subject eligibility, assessments, conduct and treatment of such specific study; and

k) other requirements for the registration of CROs i.e., particulars and documents required to be submitted along with application for registration are as specified in the Ninth Schedule introduced through the NDCT Rules, 2024.

The NDCT Rules, 2024, aims to enhance the clinical trials landscape in India by providing a structured framework for operation of the CROs. By aligning more closely with international standards and addressing critical concerns around patient safety and regulatory efficiency, these amendments enhance India's position as a leading global hub for clinical trials and ensures the protection of patient interests and meets the expectations of domestic stakeholders.

Food Safety and Standards (Amendment) Rules, 2024

MoHFW, *vide* notification dated October 29, 2024, amended the Food Safety and Standards Rules, 2011 to give power to the adjudicating officer to hold an inquiry for purpose of adjudicating offences punishable under Sections 58 (penalty for contraventions for which no specific penalty is provided), 61 (punishment for false information), and 63 (punishment for carrying out a business without Food Safety and Standards Authority of India ("**FSSAI**") licence) of the Food Safety and Standards Act, 2006.

The Cigarettes and Other Tobacco Products (Packaging and Labelling) Amendment Rules, 2024

On December 3, 2024, MoHFW has notified the Cigarettes and Other Tobacco Products (Packaging and Labelling) Amendment Rules, 2024 amending the Cigarettes and Other Tobacco Products (Packaging and Labelling) Rules, 2008. The amendments are in line with World Health Organisation Framework Convention on Tobacco Control. While these may lead to manufacturers/relevant stakeholders incurring additional costs of production, these have been issued in larger public interest.

The amendments introduce significant changes to enhance public awareness of the health risks associated with tobacco use. A new, enhanced, lucid and cautionary textual warning has been introduced for all tobacco product packages, including text encouraging cessation from tobacco products. Additionally, the inclusion of rotating pictorial warnings with new graphic images depicting the severe and often fatal health consequences of tobacco use has been mandated. These images are required by the amended law to be updated annually to ensure their continued impact and relevance. In order to ensure efficacy of the intended outcome, MoHFW has assured to provide digitally accessible versions of all

the relevant health warnings to ensure the availability of the mandated pictorial representations and textual warnings at all times with manufacturers and other relevant stakeholders.

Shipment of drug samples sent by the foreign national regulatory authorities into India for test, examination and analysis

MoHFW, *vide* circular dated December 9, 2024, has directed all port offices of the Central Drugs Standard Control Organisation to ensure prompt clearance of drug samples sent by foreign national regulatory authorities to avoid delays in testing and releasing safe, efficacious, and quality drugs for the population.

Pursuant to this circular, port offices are instructed to fast-track the clearance process, subject to the following conditions:

1. **Authorised sender**: Drug samples must be sent exclusively by the concerned foreign national regulatory authority.
2. **Undertaking**: Samples must be accompanied by an undertaking stating they have no commercial value and are intended solely for testing, examination, or analysis.
3. **Licensed laboratory**: Analysis must be conducted at a laboratory holding valid permission under Form-37.
4. **Disposal of samples**: Residual samples toned not be returned and must be disposed of by the testing laboratory in accordance with applicable procedures.

The Drugs (Fifth Amendment) Rules, 2024

On October 28, 2024, the Ministry of Ayush has notified the Drugs (Fifth Amendment) Rules, 2024 amending the Drugs Rules, 1945. The amendments introduce significant changes to the licensing, manufacturing and import process for new Ayurveda, Siddha, Unani and homeopathic medicines in India . It also introduces the concept of Sowa-Rigpa drugs.

Pursuant to the amendment, the term 'New Homeopathic Medicines' is defined and it establishes a clear process for their important, licensing and manufacture. A new homeopathic medicine is considered as 'new' for 5 (five) years following its first approval. An online application system, e-AUSHADHI portal, has been introduced to streamline various approvals.

Checklist for furnishing complete documents for seeking disbursement of funds under the National Action Plan for Drug Demand Reduction

The Ministry of Social Justice and Empowerment has released a checklist of documents required from NGOs and other organisations, such as the Integrated Rehabilitation Centres for Addicts, District De-Addiction Centres, Outreach and Drop In Centres and Community based Peer led Interventions, for the release of funds under the National Action Plan for Drug Demand Reduction ("**NAPDDR**") scheme. In additional to carrying out education/ community engagement based and peer-to-peer awareness around drug and substance use, NAPDDR scheme aims to eradicate drug addition and to regulate and control the consumption of drugs and substance use through central and state action plans including integration of government bodies, non- government organisations, hospitals and additional treatment facilities.

Eligible entities seeking release of funds are advised to submit their proposals as per the checklist, in line with the guidelines of the NAPDDR scheme. Further, NGOs and voluntary organisations receiving financial assistance are encouraged to computerise the records of beneficiaries receiving benefits from the centre.

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

FSSAI, *vide* notification dated July 1, 2024, 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) was rolled out in the States/Union Territories of Assam, Delhi, Gujarat, Jammu and Kashmir, and Kerala, June 28, 2024, onwards.

Subsequently, FSSAI, *vide* notification dated September 11, 2024, has extended this provision nationwide excluding the States/Union Territories of Chandigarh, Himachal Pradesh, and Meghalaya. The provision will be implemented in these States/Union Territories after incorporating State-specific requirements. Further, the issuance of licenses/registrations will continue to be subject to the conditions as mentioned above, for the said specific categories.

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, 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, 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 noted that few manufacturers are adding non-standardised ingredients such as 'deionised 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, 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.

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

FSSAI, *vide* its advisory dated August 14, 2024, extended the deadline provided in its advisory dated June 3, 2024. FSSAI has 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.

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.[2] 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, limits under various food safety and standards regulations, 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.

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

FSSAI, *vide* its order dated August 21, 2024, 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**").

[2] 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.

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.

Uniform Code for Marketing Practices in Medical Devices 2024

On March 12, 2024, the Department of Pharmaceuticals ("**DoP**") introduced the Uniform Code for Pharmaceutical Marketing Practices, 2024 bringing changes to the regulatory framework on pharmaceutical marketing practices. Subsequently, DoP, *vide* notification dated September 6, 2024, has issued the Uniform Code for Marketing Practices in Medical Devices, 2024 ("**UCMPMD**") to curb unethical practices by medical device companies while promoting and marketing medical devices. Some of the key provisions of the UCMPMD are as follows:

1. **Claims and comparisons**: All product claims must be in accordance with the terms of the document submitted for obtaining product registration. Comparisons of medical devices must be factual, fair and capable of substantiation and not disparaging of other companies' products, services or promotions.
2. **Text and audio-visual presentation**: Certain minimum information must be provided on all promotional materials such as name and address of the manufacturer/importer and warnings and precautions for use. The names and photographs of Healthcare Professionals ("**HCPs**") must not be used in promotional materials.
3. **Medical Representatives ("MRs")**: The term MR is defined to include personnel retained by way of contract with third parties. MRs cannot employ any inducement or subterfuge to gain an interview or pay for access with an HCP. Companies are responsible for the activities of MRs and must include a clause in the employment contract with an MR to ensure compliance with the UCMPMD.
4. **Evaluation samples and demonstration products**: The UCMPMD also prescribes conditions regarding evaluation samples (such as free evaluation sample must not be provided to anyone other than HCPs) and demonstration products (which should be solely for demonstration purposes and not patient use).
5. **Continuing medical education and research**: The medical device industry must engage with HCPs for continuing medical education and professional development through a well-defined, transparent, and verifiable set of procedures. Events in foreign locations are prohibited except for advanced clinical training in exceptional cases. Any study or research should have approval from the competent authority such as ICMR and DCGI.
6. **Relationship with HCPs**: No gift or pecuniary advantage or benefit in kind should be offered or provided for personal benefit of any HCP or family member by any medical device company or its agent. Providing travel and hospitality facilities are also prohibited unless the person is a speaker or participant at a training participants for which specific approval is obtained from DoP.
7. **Complaints**: All the Indian Medical Device Associations should upload the UCMPMD on their website along with the detailed procedure for lodging of complaints, which will be linked to the UCPMP portal of the DoP. All complaints related to the breach of the UCMPMD should be addressed to the 'Ethics Committee for Marketing Practices in Medical Device', 'Chief Executive Officer', and 'Name of Association'. Complaints must be made within 6 (six) months of the alleged breach, with another 6 (six) months for reasonable delay that can be explained in writing. The respondent company must submit its comments and documents within 30 (thirty) days of receipt of notice from the committee. The committee must give its decision within 90 (ninety) days of receipt of complaint.
8. **Penalties**: Once it is established that a breach of the UCMPMD has been made by an entity, the committee can propose one of the following

actions against the erring entity: (a) to suspend or expel the entity from the respective Association; (b) to reprimand the entity and publish full details of such reprimand; (c) to require the entity to issue a corrective statement in the same media which was used to issue textual or audio-visual promotional material; (d) to ask the entity to recover money or items, given in violation of the UCMPMD, from the concerned person/s; and (e) in cases where disciplinary, penal, or remedial action lies within the domain of any agency or authority of the Government, the committee may send its recommendations to such agency or authority through DoP.

Reduction in testing fee for PAN-India surveillance

FSSAI exclusively conducts PAN-India surveillance programs on food products to gather data for food safety monitoring, risk assessment, identifying hotspots of adulteration, and setting standards. These nationwide surveillance activities are carried out extensively, with samples collected from both the organised and unorganised sectors across all districts in the 36 (thirty six) States/Union Territories. FSSAI, *vide* order dated September 11, 2024, has reduced the testing fee for all food categories by 50% for PAN-India surveillance.

Modification to the guidelines for the scheme on strengthening of pharmaceuticals industry

DoP, *vide* notification dated September 17, 2024, amended the guidelines for the scheme on Strengthening of Pharmaceuticals Industry by amending the sub-scheme on Revamped Pharmaceutical Technology Upgradation Assistance Scheme. . The key changes are as follows:

1. incentives of pharmaceutical units under the scheme are revised to INR 2,00,00,000(Indian Rupees two crore) (earlier this was INR 1,00,00,000 (Indian Rupees one crore)) while the average turnover criteria remain the same;
2. expenditure incurred on production equipment items will also be considered for calculation of subsidy amount to pharmaceutical units;
3. the requirement for a detailed gap analysis for online application for the sub-scheme is removed and replaced with a simple gap analysis; and
4. the subsidy amount that can be released to applicants is modified. Earlier, 50% of the eligible amount could be released to the applicant within 30 (thirty) days of obtaining requisite documents, which was subject to an upper limit of INR 50,00,000 (Indian Rupees fifty lakh) for the first instalment and INR 1,00,00,000 (Indian Rupees one crore) for the second and final instalment. This is revised to INR 1,00,00,000 (Indian Rupees one crore) and INR 2,00,00,000 (Indian Rupees two crore) respectively.

Modification to the Production Linked Incentive Scheme for Bulk Drugs

DoP, *vide* corrigendum dated September 25, 2024, amended the term 'Successor-in-interest' to include a wholly owned subsidiary of an applicant. Prior to the amendment, the term 'Successor-in-interest' was defined to mean the new or reorganised entity formed after the merger, de-merger, acquisition, transfer of business or significant change in ownership of an applicant. Pursuant to the amendment, the transfer of business to any entity including the wholly owned subsidiary of the applicant is permitted.

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[3] 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.

Guidelines for verification of pharmacists profile with the Ayushman Bharat Health Account Number to integrate them with the healthcare professional registry

As a step forth to assimilate pharmacists with Ayushman Bharat Digital Mission, the Pharmacy Council of India has issued guidelines to integrate pharmacists with the healthcare professional registry by verifying their profiles using the Ayushman Bharat Health Account ("**ABHA**") Number. All existing registered pharmacists are required to verify their DIGI-PHARMed profiles with their ABHA Number within 45 (forty-five) days from November 20, 2024. Failure to complete the verification process will result in the deactivation of the pharmacist's profile on the DIGI-PHARMed portal.

Further, new pharmacists are required to verify their accounts with the ABHA Number at the time of registration, as incomplete registrations without ABHA verification is not acceptable under such guidelines. Pharmacists without an ABHA Number are required to create one using their AADHAAR before registration.

Additionally, pharmacy institutions are also required to ensure that all faculty members have ABHA-verified profiles. Starting from the 2025–2026 academic session, only ABHA-verified profiles will be considered for standard inspection format applications and other references.

Operational guidelines for the Scheme for Strengthening of Medical Device Industry

To boost the manufacturing of the medical device industry in India and reduce its reliance on imports, DoP, on November 8, 2024, launched the Scheme for Strengthening of Medical Device Industry **("SSMDI")** following consultations and 2 (two) Meditech Stackathons involving over 100 (one hundred) manufacturers. The SSMDI aims to reduce imports, enhance manufacturing capacity, ensure quality and safety, foster human resource development, and deepen the medical device supply chain in India.

The total outlay for the SSMDI is set at INR 500,00,00,000 (Indian Rupees five hundred crore) for the financial years 2024-25 to 2026-27. It focuses on the following 5 (five) components:

1. common facilities for medical device clusters;
2. marginal investment scheme for reducing import dependence;
3. capacity building and skill development in medical device sector;
4. medical device clinical studies support scheme; and
5. medical device promotion scheme.

To streamline compliance, the following 2 (two) pre-approved sub-schemes have been integrated to the SSMDI:

1. assistance to medical device clusters for common facilities; and
2. human resource development in the medical device sector.

[3] 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.

To operationalise SSMDI, committees/ sub- bodies including Technical Committee, Scheme Steering Committee and Project Management Agency have been set- up for effective implementation of the scheme through assistance of officials and professionals at various levels. The overall outcome of the scheme will be periodically monitored by Niti Aayog.

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 a 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.

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.

Kerala High Court rules in the favour of nurse in the case of malicious medical negligence cases filed against them

The Kerala High Court, in the case of ***Celinamol Mathew vs. State of Kerala***[7], has opined that nurses in Government service and in private hospitals should

[4] 2024 LiveLaw (SC) 487
[5] W.P.(C) No. 983/2023
[6] SMW (Crl) No 2 of 2024
[7] CRL.MC NO. 5401 OF 2018

also get protection like the doctors and that private complaints should not be entertained by courts against nurses unless the complainant gives prima facie evidence in the form of expert opinion to support their case of medical negligence. Further, the court stated that nurses should be given moral support by the society and Government. They should be allowed to work without fear of any prosecution and let them be known as Indian nursing nightingales.

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

The National Consumer Disputes Redressal Commission ("**NCDRC**"), in the case of ***Sri Balaji Action Medical Institute vs. Tilak Raj Sikri,***[8] 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.

NCDRC has held that expert medical evidence is crucial for determining medical negligence

The NCDRC, New Delhi, in the case of ***Chief Medical Officer Nehru Satabdi Central Hospital and Ors. vs. Puja Sahu***[9], set aside the orders by the District and State Commission by stating that the thumb amputation done by the hospital resulted due to the thread tied by the complainant's parents. The complainant who was admitted to the hospital to get a treatment for a snake bite was brought in with a thread tied to his thumb. Since the thread was tied by the parents of the complainant and not the hospital and since no expert opinion established hospital's negligence, the hospital could not be held responsible.

[8] F.A. No. 1882/2018

[9] Revision Petition No. 1353 OF 2022 (against the order dated July 22, 2022, in Appeal No. 156/2000 of the State Commission Orissa)

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.

The authors of this Compendium are:

Sidharrth Shankar
Partner

Prakriti Jaiswal
Partner

Gaurav G Arora
Partner

Dhruv Malhotra
Principal Associate

Aditi Richa Tiwary
Associate

18 Practices and 41 Ranked Lawyers	7 Ranked Practices, 21 Ranked Lawyers	12 Practices and 50 Ranked Lawyers	14 Practices and 12 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 2025	
Among Top 7 Best Overall Law Firms in India and 11 Ranked Practices --- 11 winning Deals in IBLJ Deals of the Year --- 11 A List Lawyers in IBLJ A-List - 2024	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 --- Innovative Technologies Law Firm of the Year 2023 --- Banking & Financial Services Law Firm of the Year 2022	**Ranked #1** **The Vahura Best Law Firms to Work** **Report, 2022** --- Top 10 Best Law Firms for Women in 2022	
			7 Practices and 3 Ranked Lawyers

For more details, please contact km@jsalaw.com

www.jsalaw.com

Ahmedabad | Bengaluru | Chennai | Gurugram | Hyderabad | Mumbai | New Delhi