September-October 2024 Edition

This edition of the JSA healthcare newsletter focuses on the key developments undertaken in the Indian healthcare ecosystem in September and October 2024. Some of the major developments include introduction of the Uniform Code for Marketing Practices in Medical Devices 2024, which aims to curb unethical practices by medical device companies while promoting and marketing medical devices and the amended the New Drugs and Clinical Trials Rules, 2019 ("**NDCT Rules**") that streamline the approval process for new drugs and clinical trials and align the procedural compliance more closely with international standards.

Regulatory updates

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.

Nationwide extension of provision for instant (tatkal) issuance of license/ registration in certain categories of food businesses

The Food Safety and Standards Authority of India ("**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 in the States/Union Territories of Assam, Delhi, Gujarat, Jammu and Kashmir, and Kerala. 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 prescribed under the primary notification dated July 1, 2024, for specific categories such as wholesalers, distributors, retailers, transporters, storage without atmospheric control, importers, food vending agencies, direct sellers, merchant exporters, petty retailers of snacks/tea shops and hawkers (itinerant/mobile food vendors).

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, has 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 now revised to INR 1,00,00,000 (Indian Rupees one crore) and INR 2,00,00,000 (Indian Rupees two crore) respectively.

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

The Ministry of Health and Family Welfare ("**MoHFW**"), *vide* notification dated September 19, 2024, has notified the New Drugs and Clinical Trials (Amendment) Rules, 2024 ("**NDCT Rules Amendment**") amending the NDCT Rules. They come into effect on and from April 1, 2025. It incorporates provisions relating to the registration of Clinical Research Organisations ("**CROs**"). Some of the key amendments are as follows:

1. **Definition of CRO**: The term CRO is defined to mean 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**") before conducting any clinical trials or bioavailability and bioequivalence studies involving new or investigational drugs on human subjects. However, centres that are already registered for conducting bioavailability or bioequivalence studies under the NDCT Rules are deemed to be registered as CROs.
3. **Validity of registration:** The registration for CROs is valid for 5 (five) years from the date of its grant, unless suspended or cancelled earlier.

Validity of FSSAI recognised food testing laboratories

FSSAI, *vide* notification dated September 24, 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.

Modification to the Production Linked Incentive Scheme for Bulk Drugs

DoP, *vide* corrigendum dated September 25, 2024, has 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.

Food Safety and Standards (Amendment) Rules, 2024

MoHFW, *vide* notification dated October 29, 2024, has 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 FSSAI licence*) of the Food Safety and Standards Act, 2006.

Case laws

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***[1], has opined that nurses in Government service and in private hospitals should 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 has held that expert medical evidence is crucial for determining medical negligence

The National Consumer Disputes Redressal Commission, New Delhi, in the case of ***Chief Medical Officer Nehru Satabdi Central Hospital and Ors. vs. Puja Sahu***[2], 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.

Interesting reads

Ambitious reforms in healthcare and education for a resilient future

The Government has unveiled a series of groundbreaking initiatives designed to strengthen the nation's healthcare and education sectors. The programs focus on improving healthcare accessibility, medical education, research, and technological advancement. Some of the major initiatives include the Ayushman Bharat Pradhan Mantri Jan Arogya Yojana for senior citizens and launching of innovative platforms like the U-WIN Portal for digitised vaccination services. Further, initiatives like the establishment of the National Medical Register Portal, the creation of 75,000 (seventy five thousand) new medical seats, the Vigyan Dhara scheme introduced to promote scientific research, innovation, and technological development and other policy reforms in cancer treatment and biotechnology reflect a long-term vision to create a self-reliant and resilient nation.

Inauguration of various health infrastructure projects

With an aim to strengthen India's healthcare infrastructure and providing quality healthcare services across the country, Prime Minister Narendra Modi inaugurated and laid the foundation stone of several health infrastructure projects, and launched various health programmes at an event at All India Institute of Ayurveda on October 29, 2024.

[1] CRL.MC NO. 5401 OF 2018
[2] Revision Petition No. 1353 OF 2022 (against the order dated July 22, 2022, in Appeal No. 156/2000 of the State Commission Orissa)

The total outlay of these projects amounts to more than INR 12,855 crore (Indian Rupees twelve thousand eight hundred fifty-five crore).

Unethical and false presentation by Entod Pharmaceuticals on PresVu eye drops

Entod Pharmaceuticals had made several unapproved claims for its PresVu eye drops stating that it could reduce the dependency on reading glasses for individuals suffering from presbyopia, which is an age-related vision condition. The Directorate General of Health Services under the Central Drugs Standard Control Organisation has identified that the company has several misleading claims basis which it has suspended Entod Pharmaceuticals Limited's licence to manufacture and market Pilocarpine Hydrochloride Ophthalmic Solution USP 1.25% w/v, branded as PresVu.

Healthcare Practice

JSA provides a full range of transactional and advisory services in the healthcare sector. We represent clients in the entire spectrum of the health care system, including, hospital networks and individual hospitals, managed care organisations, health insurers, pharmaceutical and biotechnology companies, medical device manufacturers; and major financial investors in the sector. These include domestic as well multinational clients. Our clients in the sector range from start-ups to industry leaders. We also represent the leading trade associations representing these industries, namely, Centre for Scientific & Industrial Research, Centre for DNA finger printing & Diagnostics, Institute of Microbial Technology, All India Institute of Medical Science-Department of Biotechnology, National Institute of Health & Family Welfare, etc.

JSA also has substantial experience in matters relating to regulation of foods, drugs, medical devices, cosmetics, product packaging, and dangerous chemicals. Our attorneys advise manufacturers on Indian labelling questions, national rules for testing and review of new products, reporting of safety information, and proceedings relating to product withdrawals. We regularly advise clients on regulatory standards governing advertising, the distinction between advertising and labelling and the differing regulatory standards that apply to each, and the roles of the states and self-regulatory mechanisms. JSA has been actively involved in advising clients with respect to regulation of nutrition and health claims in food advertising.

We also have extensive experience in litigating cases in courts and administrative agencies in the healthcare sector.

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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
50 Ranked Lawyers

14 Practices and
38 Ranked Lawyers

20 Practices and
22 Ranked Lawyers

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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
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of the Year 2024

Innovative Technologies Law Firm of the Year 2023

Banking & Financial Services
Law Firm of the Year 2022

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7 Practices and
3 Ranked Lawyers

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