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# Knowledge Management

## Semi-Annual Healthcare Sector Compendium 2024

January – June 2024

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## Introduction

This Compendium consolidates all key developments pertaining to the Healthcare sector which were circulated as JSA Newsletters/Prisms from January 2024 till June 2024.

## Regulatory updates

### Good manufacturing practices and requirements of premises, plant and equipment for pharmaceutical products

The Government of India ("**GOI**"), on December 28, 2023, notified the revised Schedule M to the Drugs Rules, 1945 ("**Schedule**"), setting out the Good Manufacturing Practices ("**GMP**"). The Schedule requires that:

1. every license holder to evolve appropriate methodology, systems and procedures which must be documented for inspection and reference; and
2. the manufacturing premises must be used exclusively for the manufacture of drugs.

Salient features of the Schedule are briefly discussed below:

### Pharmaceutical quality system

The Schedule introduces the concept of a Pharmaceutical Quality System ("**PQS**") placing responsibility on the manufacturer to ensure the quality of the drugs, and further ensure that a patient does not suffer harm owing to inadequate safety, quality, or efficacy. All manufacturers are required to put in place a comprehensive PQS which includes GMP and Quality Risk Management ("**QRM**") systems. The PQS is required to be documented and a quality manual should be retained. The role of senior management in ensuring such PQS is also clearly defined with the senior management being held ultimately responsible for any shortcomings or failures. Requirements of a PQS are also specified and include amongst others:

1. designing, qualifying, planning, implementing, maintaining and continuous improvement of the PQS;
2. specifications to be indicated in writing;
3. managerial responsibilities being set out clearly;
4. processes being in place to ensure that manufacture, supply and use of each material in the manufacturing are verified;
5. no pharmaceutical product is sold or supplied before certification by authorised persons;

6. the products are stored / distributed in a manner that does not harm the shelf-life; and
7. all deviations and short-comings are reported, investigated, and recorded.

## QRM

The Schedule calls for the establishment of a QRM system and defines it as a *systematic process for the assessment, control, communication and review of risks to the quality of* the drug. Any evaluation of the risk is to be undertaken based on scientific knowledge and experience with the process, and must have as the end, ultimate protection of the patient from any risks owing to lack of quality.

## Product quality review

The Schedule includes specific requirements in relation to periodic quality reviews of pharmaceutical products. Such specific requirements, include the review of:

1. the raw materials, the packing materials and the review of the supply chain;
2. all batches that did not meet the established specifications, including investigating and understanding the reasons for such failure;
3. all changes made to the processes and analytical methods;
4. in-process controls; and
5. all quality related product returns, recalls, complaints.

The manufacturer is required to evaluate the results of the product quality review and take any corrective or preventive actions under the PQS. The procedures for corrective or preventive actions to be adopted are required to be documented and the effectiveness of these procedures is to be verified during any self-inspections.

## GMP for pharmaceutical products

While the original Schedule M did cover GMP in relation to practices being adopted, there was no specific requirement in relation to the products per se. The Schedule defines GMP to mean those practices that ensure that the drugs are manufactured according to the quality standards appropriate to their intended use. The Schedule classifies, amongst others, the following as GMPs:

1. clarity and unambiguity in relation to the manufacturing process, including systematic reviews;
2. provision of necessary resources including, qualified suitably trained personnel; appropriate equipment and space for manufacture; appropriate containers and labels; suitable storage and transport;
3. provision of clear, precise and written instructions and procedures;
4. ensuring that the procedures are carried out in a proper manner and by qualified and trained personnel; and
5. maintenance of records during manufacture to show that the steps required by the defined procedures and instructions have all been followed, and retention of such records in a comprehensible and accessible form, to ensure that a complete history of a batch are easily traceable.

## Qualification and validation

While the original Schedule M did include requirements for product process validation, the Schedule also includes detailed requirements in relation to the validation of equipment being used in the manufacturing process.

## Complaints

The Schedule adds a new section in relation to management of complaints and adverse reactions. All complaints in relation to defective drugs are to be reviewed and any corrective actions undertaken. A designated person (along with qualified and sufficient supporting staff) is responsible for handling complaints and deciding on the corrective measures to be taken. All procedures detailing the actions to be undertaken, including the need to consider a recall, should be available in written format. Any complaint concerning a defective drug is required to be recorded along with all the original details and thoroughly investigated by the person responsible for quality control. If a defect is identified or suspected in a batch,

any other batch that may contain a reprocessed product from the defective batch is also to be investigated. The Central or State Licensing Authority under the Drugs and Cosmetics Act, 1940 ("**D&C Act**") is required to be informed if the manufacturer considers any actions following the quality concerns around a product. The manufacturer is required to put in place a pharmacovigilance system for the collection, processing and forwarding of reports to the concerned licensing authority for information regarding adverse reactions emerging from the use of a drug.

## Change control

The Schedule introduces change in control management and requires the establishment of a formal change control system to assess all changes that may impact the product and control of the drug. Any proposals to the GMPs are required to be reviewed and approved by the relevant quality units. Any impact of a change on the quality of the Active Pharmaceutical Ingredient or the finished product is required to be evaluated using scientific procedures to justify any change in a validated process. When implementing the approved changes, all documents affected by the changes are required to be revised. After the implementation of a change, the first batch produced is required to be tested.

## Production under loan license or contract and contract analysis

The Schedule introduces new provisions relating to production under a loan license or contract. All arrangements for production under a loan license or contract, including any technology transfers, are required to be in accordance with the license for the concerned drug. Under the contract, the loan licensee must audit the facilities and activities of the manufacturing facility provider. The PQS of the loan licensee will include the control and review of any outsourced activities, and it is the responsibility of the loan licensee to ensure that the suitability and competence of the manufacturing facility provider to successfully carry out the work, as well as ensuring that the manufacturing facility being used has in places a PQS including GMPs and QRS systems. The responsibilities of each party (i.e. the loan licensee and the manufacturing facility provider), along with details of any outsourced activities, and technical arrangements are all required to be in a written contract between the parties. The contract is required to clearly state the manner in which any authorised person, in releasing each batch of drug for sale, exercises full responsibility in relation to their actions.

## Computerised systems

Keeping in mind Digital India, the Schedule also introduces separate provisions regarding the usage of computerised systems. The computerised systems are required to have sufficient controls to prevent unauthorised access or changes to data. Any change in data is recorded, along with details of the previous entry, the time of the change, and the person making the change. In instances where critical data is being entered manually, there is a requirement for an additional check on the accuracy of the data entered, either by a second operator or by the system itself. Changes to the computerised systems are required to be made according to a change procedure and are required to be formally authorised, documented, and tested. Records must be kept of all changes, including modifications and enhancements made to the hardware, software, or any other critical component of the system. A back-up system is required to be provided so that there is no permanent data loss owing to system breakdown or failure.

## Launching of National Single Window System

The Central Drugs Standard Control Organisation ("**CDSCO**"), on January 1, 2024, issued a public notice that, with effect from January 15, 2024, applications in relation to regulatory approvals for medical devices (specifically, the certificate of registration, and licenses to manufacture and import) would only be accepted through online filing at the National Single Window System (NSWS) Portal, and that applications would no longer be accepted in the existing SUGAM portal.[1]

[1] An online platform launched by CDSCO to facilitate the electronic submission of applications, tracking of status, and other regulatory services.

## New guidelines issued for intensive care unit admission and discharge criteria

The Ministry of Health and Family Welfare ("**MoHFW**") introduced guidelines for regulating the admission and discharge criteria for an Intensive Care Unit ("**ICU**"), for hospitals to decide the need of admitting a patient for treatment in an ICU. Altered level of consciousness of recent onset, hemodynamic instability, need for respiratory support, patients with severe acute (or acute-on-chronic) illnesses requiring intensive monitoring or organ support or any medical condition or disease with anticipation of deterioration, patients who have undergone major surgery, among others, have been listed as criteria for ICU admission. Blood pressure, pulse rate, respiratory rate, breathing pattern, heart rate, oxygen saturation, urine output and neurological status among other parameters should be monitored in a patient awaiting an ICU bed.

## CDSCO issues notice regarding pathway for clearance of fixed dose combinations for sale in India

CDSCO had issued a letter on January 15, 2013, requesting all State/Union Territory Drugs Controllers to ask the concerned manufacturers in their State to prove the safety and efficacy of Fixed Dose Combinations ("**FDCs**"), within 18 (eighteen) months which were permitted by the State Licencing Authorities without due approval from the office of Drug Controller General of India ("**DCGI**"). An expert committee was constituted based on the Supreme Court of India ("**Supreme Court**") order dated February 15, 2017, to examine certain FDCs licensed for manufacturing without due approval from DCGI. The expert committee subsequently provided recommendations with respect to 3 (three) specific FDCs.

CDSCO issued a public notice on January 11, 2024, providing a pathway for clearance of such FDCs based on whether (a) manufacturers are holding licenses for such FDCs from State Licensing Authorities prior to October 1, 2012; (b) manufacturers are new manufacturers for the proposed FDCs; and (c) manufacturers are holding licenses from State Licensing Authorities prior to October 1, 2012, and did not apply to DCGI.

## Surrogacy Amendment Rules, 2024

MoHFW, on February 21, 2024, notified the Surrogacy (Regulation) Amendment Rules 2024. Following this amendment, couples can opt for surrogacy, and use donor gametes if either spouse is certified by the District Medical Board as having a medical condition which prevents the spouse from contributing the gamete. The earlier requirement was that the couple undergoing surrogacy was supposed to have both gametes from the intending couple and donor gametes for surrogacy was not permitted.

## Department of Pharmaceuticals new Uniform Code for Pharmaceutical Marketing Practices, 2024

A new Uniform Code for Pharmaceutical Marketing Practices, 2024 ("**New Code**") is notified by the Department of Pharmaceuticals ("**DoP**") on March 12, 2024, as a replacement to the Uniform Code for Pharmaceutical Marketing Practices, 2014 ("**Earlier Code**") bringing changes to the regulatory framework on pharmaceutical marketing practices.

### Key Changes

The following are the key changes brought about in the New Code:

1. **Definition of 'Promotion'**

   There was no definition for the term 'promotion' in the Earlier Code. However, it is defined in the New Code as referring to "*all informational and persuasive activities by manufacturers and distributors, the effect of which is to induce the prescription, supply, purchase and/or use of medical drugs.*"

2. **Brand reminders**

   Brand reminders are anything used by pharma companies to market the brand. This is usually done by providing information about the drug through e-journals, books and dummy device models.

   The New Code permits the use of brand reminders on the basis of the following 2 (two) categories, viz., (a) Informational and education items; and (b) Free samples provided by the companies to the medical professionals.

Informational and education items include books, calendars, diaries, journals including e-journals, dummy device model and clinical treatment guidelines, with value of such items capped at INR 1,000 (Indian Rupees one thousand) per item. It is also mentioned that these items must not have any independent commercial value for the healthcare professionals.

With respect to free samples, the New Code has added the following:

a) in addition to the name and address of the medical representative distributing the sample, the companies must take note of the name and address of the healthcare practitioner to whom the samples of products are distributed;

b) samples are provided only for the purpose of creating awareness about treatment options and for acquiring experience in dealing with the product;

c) in addition to the condition that the sample packs be limited to prescribed dosage for not more than 3 (three) patients, there is a mandate for the company to not offer more than 12 (twelve) sample packs per drug to a healthcare practitioner in a year;

d) the monetary value of samples distributed should not exceed 2% of the domestic sales of the company per year; and

e) the requirement of procuring a signed and dated request for supply of sample packs are removed.

It is also clarified that receipt of brand reminders from pharma companies by healthcare practitioners may not be construed as endorsement activity if it does not amount to recommendation or issuance of a statement by a healthcare professional with respect to use of the respective brand.

3. **Continuing medical education**

Continuing medical education must be through a well-defined, transparent, and verifiable set of guidelines. A framework is established for operation of activities and events for continuing medical education and professional development.

This framework prohibits conduct of events in foreign locations and allows for the events to be conducted in places such as medical colleges, universities, hospitals, professional associations, certain laboratories, colleges/other academic and research institutions and pharma companies.

The pharma companies are required to share details of the events conducted, including the expenditures incurred thereupon, on their website, and may be subject to independent, random, or risk-based audit for this purpose.

The organisers must provide comprehensive details of the procedure followed in selection of participants and speakers, display a statement of their funding sources and expenditures on their website, and may be subject to special audit for this purpose.

4. **Enhanced authority for the ethics committee**

The New Code provides enhanced authority to the overseeing ethics committee, empowering it to forward its recommendations to relevant government agencies through DoP. As an impact, scrutiny by statutory bodies and contravening companies are being accountable under relevant legislations, such as the D&C Act, and associated rules and regulations.

5. **Change from being voluntary in nature**

The Earlier Code, in its introductory paragraph states that, "*This is a voluntary code of Marketing Practices for Indian Pharmaceutical Industry for the present and its implementation will be reviewed after a period of six months from the date of its issue. If it is found that it has not been implemented effectively by the pharma associations/ companies, the Government may consider making it a statutory code.*"

The Earlier Code was widely criticised for lacking teeth since the obligations imposed were voluntary in nature. DoP, in its annual report in FY 2018, stated that after having consulted with the stakeholders including the non-governmental organisations / civil societies, it was desirable that the code be made mandatory in order for it to be implemented effectively.

The New Code has chosen to forego the term 'voluntary' and instead urges the pharma companies to set up an ethics committee for taking

steps to implement the New Code. The language of the New Code brings in increased accountability for the pharma companies. The authority of the ethics committee is enhanced by providing the power to forward their recommendations to relevant government agencies through DoP.

## Conclusion

The New Code represents a step towards a more robust framework for pharma stakeholders. Its emphasis on strict compliance and the power given to pharma companies to send recommendations to statutory authorities takes strides towards its objective of curbing unethical practices in the pharma industry. It remains to be seen however, whether the ethics committee appointed under the pharma code will be effective in its implementation of the New Code.

## CDSCO mandates online safety reporting for medical devices

CDSCO issued a circular dated March 19, 2024, mandating all manufacturers of medical devices/ in-vitro devices to submit periodic safety update reports only on the online portal. The circular further provides that offline mode of submission of application is not accepted after April 1, 2024.

## Notice to all stakeholders for strengthening of private medical devices testing laboratory

CDSCO issued a public notice dated April 3, 2024, inviting applications from existing private labs to register for testing specific medical devices. Applications are invited from private labs that have the facilities to perform various medical device tests that include physical, chemical, microbiological, mechanical, and electrical examinations to expedite the testing process for medical devices. Eligible and interested private labs can submit their applications through Form MD-39, along with the requisite fees, for registration with CDSCO.

## MOHFW amends the pack size rule for retail sale of drugs

MOHFW issued a notification dated March 18, 2024, regarding a modification in the retail pack size rule under Rule 105 of the Drug Rules, 1945 which applies to packaging of tablets (coated or uncoated) and capsules (hard or soft gelatine). This notification is issued after consultation with the Drugs Technical Advisory Board. The amendment permits the packaging of drugs meant for retail sale in multiples of 7 (seven) units when the minimum pack size is greater than 10 (ten) units (in addition to retail sale in multiples of 5 (five) units).

## MOHFW amends punitive clauses under the D&C Act

MOHFW, through the Department of Health and Family Welfare, *vide* notification dated March 28, 2024, notified the effective date of amendments introduced by the Jan Vishwas (Amendment of Provisions) Act, 2023. These amendments alter penalties and punishments outlined in Sections 29, 30, and 32(B) of the D&C Act. The maximum leviable penalty is raised to INR 1,00,000 (Indian Rupees one lakh), a significant increase from the previous limit of INR 5,000 (Indian Rupees five thousand). Further, subsequent offences involving the use of a government analyst's report for advertising of any drug or cosmetic, carries an extended imprisonment period of up to 2 (two) years and/or a fine of up to INR 5,00,000 (Indian Rupees five lakh). Additionally, Section 32B of D&C Act allows compounding of offences under Sections 27(d) and 27A(ii) of the D&C Act, which set out the offence of manufacture and sale of drugs and cosmetics in contravention of the D&C Act. These amendments are set to come into force from December 31, 2024.

## E-commerce platforms advised to ensure appropriate categorisation of food products sold on their websites

The Food Safety and Standards Authority of India ("**FSSAI**") issued a clarification dated March 28, 2024 for all e-commerce food business operators to remove or de-link such beverages from the 'Health Drink' and 'Energy Drink' sections and place the products in appropriate categories as provided under the existing laws**.** FSSAI observed that food products categorised under 'Proprietary Food', specifically dairy based beverage mix, cereal based beverage mix, or malt based beverage, are being marketed on e-commerce

platforms as 'Health Drink' or 'Energy Drink', which is misleading consumers**.** Additionally, there is no definition or standardised category for 'Health Drink' under the Food Safety and Standards Act, 2006 or its related regulations**.**

## Regulations setting minimum standards and rating of undergraduate Ayurveda, and Siddha colleges and attached hospitals

The National Commission for Indian System of Medicine ("**NCISM**",) *vide* notification dated April 26, 2024, published the NCISM (Minimum Essential Standards, Assessment and Rating for Undergraduate Siddha Colleges and Attached Teaching Hospitals) Regulations, 2024 ("**NCISM Regulations**") to ensure quality education and infrastructure for aspiring siddha practitioners. NCISM Regulations establish a comprehensive framework for ensuring the quality and consistency of Siddha medical education in India. The key provisions include:

1. **Minimum essential standard requirements**: NCISM Regulations define the basic infrastructure such as the admission capacity, land requirement, minimum constructed area, faculty, equipment, and facilities required for Siddha colleges and their attached teaching hospitals to operate.
2. **Assessment criteria**: Detailed guidelines for the assessment of colleges are provided. These include the evaluation of academic processes, clinical training, research activities, and the overall educational environment.
3. **Financial transparency**: Separate bank accounts are mandatory for colleges and attached hospitals (non-government institutions).
4. **Technology integration**: An IT cell must be established to manage all information technology needs.
5. **Establishing cells and committees**: Institutions must establish various cells including a student council, grievance redressal cell, pharmacovigilance cell, committee against sexual harassment of women, internal quality assurance cell, human resources cell, and a research innovation and entrepreneurship development cell overseen by the chairperson, along with an academic committee.

Further, NCISM Regulations supersedes (a) the Indian Medicine Central Council (Requirements of Minimum Standard for Under-graduate Siddha Colleges and Attached Hospitals) Regulations, 2016; and (b) the Establishment of New Medical College, Opening of New or Higher Course of Study or Training and Increase of Admission Capacity by a Medical College Regulations, 2019.

## Medical Termination of Pregnancy (Amendment) Rules, 2024

MoHFW, *vide* notification dated June 10, 2024, amended the Medical Termination of Pregnancy Rules, 2003. Under Rule 3B and in Form E of the Medical Termination of Pregnancy Rules, 2003, the word 'mental retardation' is substituted with 'women with intellectual disability'.

## Medical device licence holder under materiovigilance programme of India

CDSCO issued a circular dated May 15, 2024, regarding the Materiovigilance Programme of India ("**MvPI**"). The MvPI is an important program for reporting adverse events, and coordinated analysis related to the medical devices including in-vitro diagnostic devices. In this regard, the license holders are suggested to use the MvPI platform for reporting of any adverse events/serious adverse events associated with the devices to enhance the procedure for identifying risk associated with medical devices.

## Blood centres situated in hospitals

CDSCO, *vide* circular dated May 22, 2024, clarified that the blood centre run by hospital means the blood centre situated in the hospital premises. Further, the applications for grant/renewal of license are accepted by the State drugs department and CDSCO for operation of blood centre/processing of human blood components run by the GOI, Indian Red Cross Society, hospitals, charitable trust or voluntary organisation.

## Regulation of all Class C and D medical devices under licensing regime

CDSCO, *vide* circular dated May 16, 2024, stated that if an existing importer/manufacturer who is already

importing/manufacturing any of the Class C or Class D medical devices, has submitted application on or before September 30, 2023 to the Central Licensing Authority, for the grant of import/manufacturing licence under the provisions of Medical Devices Rules, 2017 ("**MDR 2017**"), the said application must be deemed valid. The importer/manufacturer can continue to import/manufacture the said device(s) for up to 3 (three) months from the date of issue of this circular or till the Central Licensing Authority takes a decision on the said application (whichever is earlier).

## Retention of license/certificates under MDR 2017

CDSCO, *vide* circular dated May 15, 2024, requested all the stakeholders to ensure that the requisite fee payable under the MDR 2017 for manufacturing/import license of medical devices and registration of quality management system certification, may be deposited in appropriate account of the GOI, before the stipulated timeline under MDR, 2017. The stakeholders must also submit the application to the licensing authority in order to maintain continuity of the product in the market.

## Employees' State Insurance Corporation issues revised guidelines and standard operating procedure for home delivery of drugs

The Employees' State Insurance Corporation ("**ESIC**"), *vide* circular dated January 10, 2024, revised the guidelines and Standard Operating Procedure ("**SOP**") relating to home delivery of drugs to ESIC beneficiaries. ESIC medical colleges, on a pilot project basis, are authorised to provide the facility of home drug delivery to ESIC beneficiaries. These services are limited to the districts as decided by the dean/medical superintendent of the concerned hospitals.

1. **Eligibility:** (a) all senior citizens with chronic illness entitled for treatment with ESIC, receiving consultations from the hospital and prescribed for more than 30 (thirty) days; (b) all ESIC beneficiaries, ESIC employees and their dependents, pensioners seeking consultation through e-Sanjeevani; and (c) handicapped and bedridden patients on medication for chronic disease.
2. **Hospital's responsibility:** Hospitals are required to float a bid on the Government e-Marketplace (GeM) portal for procuring doorstep delivery services for drugs, including packaging, collection and electronic notifications to the beneficiary *via* SMS/WhatsApp regarding dispatch and delivery confirmation. The medical stores' in-charge are to act as nodal officers to monitor smooth functioning of the delivery process. Further, each hospital is required to adopt its own SOPs basis the process flow requirement and local needs, guidance for the vendor, pharmacist, other stake holders and grievance redressal system.
3. **Vendor's responsibility:** The vendor must ensure that the delivery of the drugs should be done through one time password based/signature of the authorised recipient. The vendor is responsible for sending an SMS/WhatsApp notification to the beneficiary intimating: (a) parcel tracking number along with the link of tracking webpage; and (b) delivery of drug packet information. Additionally, vendors are required to ensure maintenance of cold chain as and when required for certain drugs.

## Re-operationalisation of the regulations governing health supplements, nutraceuticals, special dietary food and medical purpose and prebiotic and probiotic food

While FSSAI is finalising the provisions of draft FSS (Health Supplements, Nutraceuticals, Food for Special Dietary Use, Food for Special Medical Purpose, and Prebiotic and Probiotic Food) Regulations, 2022 ("**Heath Supplements Regulations**"), it has, *vide* direction dated June 5, 2024, decided to re-operationalise the provisions of the Health Supplements Regulations from April 1, 2024. These regulations are applicable to:

1. health supplements;
2. nutraceuticals;
3. food for special dietary use;
4. food for special medical purpose; and
5. prebiotic food and probiotic food.

## Mandatory Ayushman Bharat Health Account ID for patient registration

The National Medical Commission, *vide* public notice dated June 4, 2024, has mandated that all medical colleges are required to ensure that patients visiting for outpatient department/inpatient department/emergency services are registered with an Ayushman Bharat Health Account ("**ABHA**") ID in addition to the hospital's registration number. The authentication of patients and clinical material using ABHA ID is crucial for decisions regarding college assessments, such as increasing under-graduate/post graduate seats, establishing new colleges, and renewing permissions/recognitions to admit students.

## Master Circular on reforms in health insurance

The Insurance Regulatory and Development Authority of India, on May 29, 2024, issued the Master Circular on health insurance business, repealing 55 (fifty five) circulars. Key aspects of the master circular are as follows:

1. wider choice to be provided by the insurers by making available products/add-ons/riders by offering diverse insurance products catering to all ages, regions, occupational categories, medical conditions/ treatments, all types of hospitals and health care providers to suit the affordability of the policyholders/prospects;
2. introduction of customer information sheet which is provided by the insurer along with every policy document, which explains the basic features of insurance policies in simple words; and
3. customer to be provided with the flexibility to choose products/add-ons/riders as per his/her medical conditions/specific needs.

## Centre withdraws the powers of States for issuing no objection certificate for export of drugs

CDSCO, *vide* an order dated April 30, 2024 has withdrawn the power of State Governments to issue no-objection certificates for the manufacture of unapproved/banned/new drugs solely for export amid the heightened global scrutiny of Indian drugs. This power currently remains solely with CDSCO, and the existing players can file fresh applications for the no-objection certificates from May 15, 2024, via online mode through CDSCO zonal offices.

## CDSCO drafts norms to report adverse effects of vaccines

CDSCO on May 29, 2024, released "Guidance for industry on Pharmacovigilance requirements for Human Vaccines' directing the manufacturers and importers of vaccines to report Serious Adverse Events (SAEs) in India and distributing countries within 15 (fifteen) days to CDSCO. After a vaccine is approved, requirement of stringent follow-up is essential, to monitor vaccine safety in routine use through phase IV-post marketing trials, practice management system, observational or non-interventional study for active surveillance, including assessment of Adverse Events Following Immunisation (AEFI) and Adverse Events of Special Interest (AESI).

## CDSCO mandates adherence to Bureau of Indian Standards for medical devices

CDSCO, *vide* circular dated May 29, 2024, has mandated that medical device manufacturers and in-vitro diagnostic testing laboratories comply with the Bureau of Indian Standards ("**BIS**") for product testing. The circular was issued in consonance with the observation that the testing of the medical devices which have BIS Standards available has not be carried out as per the standards.

## Self-certificate for advertisement

On June 3, 2024, the Ministry of Information and Broadcasting in line with the directions issued by the Supreme Court issued press release requiring a self-declaration certificate to be submitted before publishing or broadcasting any content effective from June 18, 2024. The advertising agencies are required to file their self-declaration certificates through the Broadcast Seva Portal and print and digital media must submit the same *via* the Press Council of India's portal.

## Case laws

### Supreme Court orders presence of company director and endorser in contempt proceedings over misleading advertisements

In the case of ***Indian Medical Association & Anr. vs. Union of India***[2], the Supreme Court ordered both the director of the company and the endorser of the offending advertisement to appear for contempt proceedings concerning misleading advertisements. The business in question is a major Indian ayurvedic medicine manufacturer caught in the crosshairs for advertising false claims. The Supreme Court was prima facie of the opinion that the endorser, along with the director, had violated provisions under Section 3 and 4 of the Drugs and Magic Remedies (Objectionable Advertisements) Act, 1954, read with Rule 6 of the corresponding rules. The Court had previously granted 3 (three) weeks for the director to respond to the contempt notice, which went unanswered. Following this lack of response, a notice was ordered to be issued against the endorser to show cause as to why contempt proceedings should not be initiated against him.

### Supreme Court agrees to hear plea against fixed rate for hospitals and seeks response from the GOI

The Supreme Court[3] in ***All India Ophthalmological Society & Anr. vs. Union of India,*** sought a reply from the GOI after it agreed to hear a plea by an association of doctors and hospitals that questioned GOI's move to prescribe uniform fee for private hospitals. The matter is stated for hearing on September 10, 2024. The hospital associations have said that standardised rates for medical procedures should not be implemented without a proper analysis of costing, requirements and expertise of doctors.

### Cognisance of offence under the D&C Act cannot be taken based on a police inspector's complaint

The Supreme Court, its order in ***Rakesh Kumar vs. The State of Bihar & Anr.***[4], held the proceedings against the appellant under the D&C Act initiated based on the police inspector's complaint, have been deemed legally invalid. The Supreme Court has also reversed and set aside the order of the Patna High Court which refused to quash the proceedings against the accused.

### Fundamental right to health includes customer's right to be made aware of quality of products

The Supreme Court, in the case of ***Indian Medical Association and Anr. vs. Unions of India and Ors.,***[5] held that the fundamental right to health encompasses the right of a consumer to be made aware of the quality of products being offered for sale by manufacturers, service providers, advertisers and advertising agencies. To protect this right, the Supreme Court directed that henceforth, before an advertisement is printed/aired/displayed, a self-declaration must be submitted by the advertiser/advertising agency on the lines contemplated in Rule 7 of the Cable Television Networks Rules, 1994.

### Punjab and Haryana High Court rules implanting poor quality pacemaker as 'cheating'

The High Court of Punjab and Haryana, in the case of ***Max Super Speciality Hospital and Anr. vs. State of Punjab and Anr.***[6], ruled that the incident goes beyond gross medical negligence. The court highlighted that the petitioners conspired to commit cheating by implanting a pacemaker costing INR 45,000 (Indian Rupees forty-five thousand) instead of one costing INR 4,50,000 (Indian Rupees four lakhs fifty thousand) as consented by the patient's family.

### Jharkhand High Court emphasises quality over pricing, while assigning tenders of medical devices

The High Court of Jharkhand, in the case of ***Hosco Pvt. Ltd. vs. Jharkhand Medical & Health Infrastructure Development & Procurement Corporation Ltd and Ors.***[7], dismissed the writ application. The court emphasised that the price of a product such as

[2] Writ Petition (Civil) No. 645/2022
[3] Writ Petition(s)(Civil) No(s). 214/2024
[4] 2024 LiveLaw (SC) 264
[5] W.P.(C) No. 645/2022
[6] 2024 LiveLaw (PH) 80
[7] 2024 LiveLaw (Jha) 41

defibrillators, alone cannot be the determining criteria in awarding a tender, as the quality of the product in addition to meeting other specification as per the respective tender documents, should be taken into consideration while making such selection. Additionally, the court ruled that a tenderer without technical qualifications cannot challenge the tender process. The judgment highlighted the importance of product quality and adherence to tender specifications.

## Complaint of medical negligence may not be entertained unless supported by credible opinion given by another doctor

The High Court of Jharkhand, in the case of ***Dr. Suman Kumar Pathak vs. the State of Jharkhand and Ritesh Kumar Sinha,***[8] has quashed the criminal proceedings against the petitioner citing the need for credible medical evidence to support claims of negligence. The court emphasised that mere allegations without expert medical opinion are insufficient for criminal prosecution. The judgment referenced the Supreme Court's guidelines in the Jacob Mathew case, highlighting the need for caution in prosecuting medical professionals for negligence.

## Madras High Court observes that to person should be denied of quality medical treatment

In ***B Anantha Lakshmi and S Kiruthika vs. the State of Tamil Nadu,***[9] while adjudicating the bond period of post graduate doctors, the Madras High Court observed that any poor person who is unable to afford paid treatment can in no way be treated differently. A life is a life, and it has its value. No person should be denied quality treatment on economic grounds. The court dismissed the petitions, stating that the petitioners must fulfil the bond conditions as agreed, emphasising the importance of serving the poor and needy in government hospitals. The court upheld the bond conditions, requiring the petitioners to complete their service period in government hospitals.

## Bombay High Court emphasised on the importance of preventing confusion in medicinal products, citing potential health risks

***Glenmark Pharmaceuticals Limited***[10] sought an injunction against Gleck Pharma for using the trademark "XIGAMET," claiming it was deceptively similar to their trademark "ZITA-MET". The court granted the ad-interim injunction, restraining Gleck Pharma from using "XIGAMET" due to the likelihood of confusion between the 2 (two) trademarks, especially given the medicinal nature of the products.

## Not every death in hospital indicates medical negligence unless proven otherwise

The National Consumer Disputes Redressal Commission ("**NCDRC**") in ***Hridylal Sahu vs. Dr. Roshan Upadhyay and Anr.***[11] held that not every death occurring in a hospital setting can automatically be considered medical negligence based on an assumption of inadequate medical care. It was further held that in order to prove medical negligence, concrete evidence has to be submitted.

## Unsuccessful treatment or differing opinions does not equate to medical negligence

NCDRC, in the case of ***Jagdish K Sharma vs. Medanta, the Medicity,***[12] dismissed a complaint against Medanta Hospital and ruled that an unfavorable outcome of treatment alone or a divergence in professional opinion does not amount to negligence on the part of the medical professionals as long as they're acting as per the accepted practice.

[8] Cr.M.P. No. 2866 of 2016 dated June 18, 2024
[9] WP N 6432 and 6434 of 2024 dated April 30, 2024
[10] Glenmark Pharmaceuticals Ltd. vs. Gleck Pharma (OPC) Pvt. Ltd IP Suit (L) No 30149 of 2023
[11] F.A. No. 2482/2017
[12] C.C. No. 1934/2018

## 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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