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Checking the Pulse

Recent Legal Developments in the Indian Healthcare and Pharma Sector

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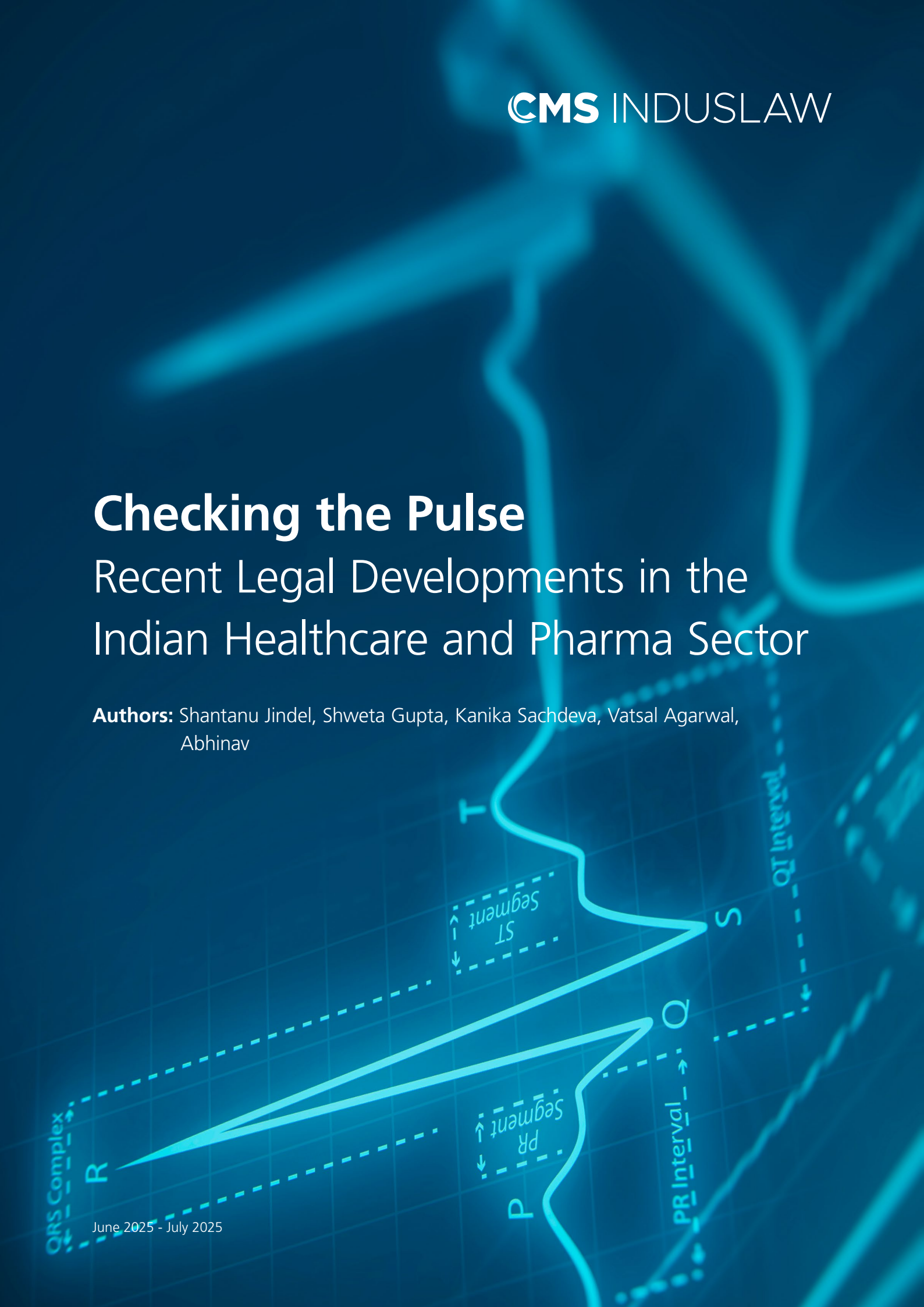

June 2025 - July 2025

Introduction

In the past couple of months, the healthcare and pharmaceutical sectors have undergone significant regulatory and policy shifts, highlighting a sustained focus on transparency, quality assurance, and industry facilitation. A key development during this period has been the introduction of the Pharmacy Council of India (Manner of Holding Inquiry and Imposition of Penalty) Regulations, 2025, bringing long-needed procedural clarity to disciplinary proceedings under the Pharmacy Act, 1948. This move aims to harmonise the framework for conducting inquiries and levying penalties across state pharmacy councils and plug long-standing procedural gaps.

On the pharmaceutical front, the Central Drugs Standard Control Organisation has mandated exclusive use of the Online National Drugs Licensing System portal for procurement of World Health Organisation Good Manufacturing Practices Certificate and Certificate of Pharmaceutical Products – an important step toward digitization and simplification of compliance processes. In parallel, medical device reforms, from eased sterilisation norms to updated skill development guidelines, reflect a push for operational efficiency and capacity-building.

In this edition of 'Checking the Pulse', we delve into the key updates pertaining to the months of June 2025 and July 2025.

Government Initiatives

Pharmacy Council of India notifies inquiry and penalty regulations on violations of provisions under Pharmacy Act, 1948

On June 10, 2025, the Pharmacy Council of India ("**PCI**") notified the Pharmacy Council of India (Manner of Holding Inquiry and Imposition of Penalty) Regulations, 2025 ("**New Regulations**") to provide clarity on the manner of holding inquiry and imposing penalty for any violations under the Pharmacy Act, 1948 ("**Pharmacy Act**").[1]

Pertinently, although Section 18(i) of the Pharmacy Act empowers PCI to formulate regulations governing the manner of holding inquiry and imposition of penalty for violation of the Pharmacy Act, there was no procedural clarity in this regard prior to the notification of the New Regulations. The New Regulations aim to fill in this void and bring consistency in the inquiry mechanism across all state pharmacy councils.

The step-wise procedure prescribed under the New Regulations is outlined below:

(a) **Eligibility to File Complaint:** Any person can file a complaint in Form-I (specifically set out in the New Regulations) through electronic means or speed post or in person, to the adjudicating officer regarding contravention of the provisions of the Pharmacy Act.

(b) **Issuance of Show Cause Notice:** The adjudicating officer, as authorised under Section 43A of the Pharmacy Act, shall issue a show cause notice to the person against whom the complaint has been filed. If the adjudicating officer is satisfied that an inquiry should be held in the matter, the adjudicating officer can even proceed to issue a notice of appearance to the person (against whom allegations have been made) to appear either themselves or through a representative. The onus has been entrusted on the person in receipt of the afore-mentioned notice to explain as to why an inquiry should not be initiated against him. This explanation ought to be furnished within the time specified in the notice, being not less than 7 (seven) days from the date of service of the notice. Further, the New Regulations require the notice to clearly specify the alleged violation committed.

(c) **Modes of Service of Notice or Order:** Notices or orders under the New Regulations may be served on a person by delivering them directly to the individual or their authorized representative, sending them electronically or by registered/ speed post to their current or last known residential or business address. If these methods are not viable, they can also be served by affixing them to a prominent part of the premises where the person resides, last resided, carried on business or worked for gain.

1. The New Regulations can be accessed here: https://pci.gov.in/documents/1298/Gazette.pdf

(d) **Authority to Issue Ex-Parte Order:** If the person against whom the complaint has been filed fails, neglects, or refuses to appear before the adjudicating officer, the adjudicating officer may proceed with the inquiry in his absence after recording the reason for doing so.

(e) **Manner of Taking Evidence:** The adjudicating officer shall give an opportunity to the accused person to produce documents and evidence in Form-III (specifically set out in the New Regulations) as he may consider relevant to the inquiry. The evidentiary process underpinning the scenario herein is not bound by the provisions of the Bharatiya Sakshya Adhiniyam, 2023. The adjudicating officer is also conferred with the authority to summon and secure the attendance of any person with knowledge of the matter, or to require the production of documents deemed relevant to the proceedings.

(f) **Imposition of Penalty:** If the adjudicating officer, after examining the evidence produced, is satisfied that the person accused has committed the contravention, he may, by an order in writing, impose such penalty under the Pharmacy Act, as he considers reasonable. The order shall specify the provision of Pharmacy Act in respect of which contravention has been committed and shall also specify the reasons for imposition of the penalty.

(g) **Timeline for Completion of Proceedings:** The adjudicating officer must complete the proceedings within 6 (six) months from the issuance of the notice pursuant to a complaint.

(h) **Filing and Processing of Appeals:** Any person aggrieved by an order of the adjudicating officer under the New Regulations may prefer an appeal to the appellate authority in Form-IV (specifically set out in the New Regulations). Such appeal shall be filed within a period of 45 (forty-five) days from the date of receipt of the order from the adjudicating officer. The appeal may be admitted even after the expiry of the afore-stated period, if the appellant satisfies the appellate authority that he had sufficient cause for not preferring the appeal within the prescribed period.

The appeal must be filed with a copy of the adjudicating officer's order, a clear statement of facts, grounds of appeal and details of the alleged contraventions. It is to be submitted in triplicate, either in person, through an authorized representative or by registered/ speed post or electronic means. The appellate authority will subsequently serve a copy of the appeal on the respondent, who must file a reply within 30 (thirty) days of receiving the copy. As per the New Regulations, the appellant authority is required to dispose of the appeal within 90 (ninety) days from the date of filing of the appeal.

Central Drugs Standard Control Organisation streamlines the application process for procurement of World Health Organisation Good Manufacturing Practices Certificate and Certificate of Pharmaceutical Products

On June 25, 2025, the Central Drugs Standard Control Organisation ("**CDSCO**") directed drug controllers across India to ensure that manufacturing units operating in their respective jurisdictions submit applications for procurement of: (a) World Health Organisation ("**WHO**") Good Manufacturing Practices Certificate ("**WHO-GMP**"); and (b) Certificate of Pharmaceutical Product ("**COPP**") exclusively through the Online National Drugs Licensing System portal ("**ONDLS Portal**").[2]

The WHO-GMP certificate serves as an indicator of a pharmaceutical manufacturer's compliance with the quality assurance standards recommended by the WHO. This certification is a mandatory prerequisite for obtaining a COPP, which is a product-specific certificate, required for the registration and marketing of pharmaceutical products in India.

Before applying for the grant of WHO-GMP certificate, the applicants are required to get the details of their license and product approved on the ONDLS Portal. The ONDLS Portal serves as a single window platform for online processing of various applications for issuance of manufacturing and sales licenses including blood banks, market standing certificate etc., and post approval changes.

2. The notice can be accessed here: https://cdsco.gov.in/opencms/resources/UploadCDSCOWeb/2018/UploadCircularFile/Circular%20for%20COPP%20through%20ONDLS%20portal.pdf

This digitalization initiative replaces the earlier, more cumbersome process of manual submissions. Under the erstwhile framework, applicants were required to submit supporting documents such as manufacturing license copy, product lists, site master file, compliance related undertakings etc., in physical form to the Drug Controller General of India ("**DCGI**") for procurement of the afore-mentioned certificates. The manual submission process was not only time-consuming but also prone to inconsistencies and lacked a digital tracking mechanism.

By moving the entire application process for procurement of WHO-GMP and COPP to the ONDLS Portal, the CDSCO aims to streamline the licensing application and approval process and enhance the ease of doing business in India. By digitizing the licensing application and approval process, substantially reducing the paperwork, and eliminating redundancies, the centralized online system is expected to facilitate improvement in tracking of applications. Further, the air is sanguine for provision of a uniform platform for stakeholders across the country to strike a balance between ease of doing business in India and aligning the regulatory framework with global best practices.

Free Trade Agreement between India and the United Kingdom grants zero-duty access to generic drugs and medical devices

In a welcome move for industry stakeholders in the country, India and the United Kingdom ("**UK**") entered into a Free Trade Agreement ("**FTA**") on July 24, 2025, with the aim of eliminating regulatory and import barriers and promoting long-term collaboration.[3] The FTA sets out several crucial changes with respect to the pharmaceutical and medical devices industries, which have been discussed in detail below:

(a) **Complete Removal of Tariffs on Import of Indian Medical Devices:** For Indian exporters, the FTA envisions a complete removal of the 2% (two percent) to 6% (six percent) tariff rates currently applicable on a wide range of products, including surgical instruments, diagnostic equipment, ECG machines, and X-ray systems. This is expected to lower input costs for Indian exporters and improve price competitiveness in the medical devices sector in the UK. India's export of medical devices to UK was valued at USD 37 Million (United States Dollars Thirty-Seven Million) in 2024, which is expected to see a significant rise once these changes come into effect.

(b) **Reduction of Tariffs on Import of UK Medical Devices:** Export of medical devices by the UK to India shall attract significantly reduced import duties henceforth. The current tariffs, which stand at approximately 15% (fifteen percent), are slated to be reduced to around 3% (three percent).[4] This reduction will make UK-made advanced medical technology more accessible and affordable for the Indian healthcare sector. The FTA outlines a phased implementation where tariff reductions are staggered over several years, with specific timelines for different categories of medical equipment.

(c) **Complete Exemption from Customs Duty on Pharmaceutical Exports:** The FTA offers greater regulatory certainty and zero-duty guarantees for active pharmaceutical ingredients, bulk drugs, and finished formulations. This is likely to accelerate the entry of cost-effective generics and biosimilars into the UK market, India's largest pharmaceutical export destination in Europe. Although pharmaceuticals account for only 56 (fifty-six) tariff lines constituting to be 0.6% (zero point six percent) of the total, the sector holds substantial strategic and economic value in global trade. It is poignant to note that despite India currently exporting USD 23.31 Billion (United States Dollars Twenty-Three point Three One Billion) worth of pharmaceuticals worldwide, and the UK importing nearly USD 30 Billion (United States Dollars Thirty Billion) worth of pharmaceuticals, Indian exports to the UK remain below USD 1 Billion (United States Dollars One Billion). This highlights the significant untapped potential, and the zero tariff provisions under the FTA are expected to combat this issue and strengthen the competitiveness of Indian generics in the UK, thereby creating considerable opportunities for growth.

(d) **Mutual Recognition of Regulatory Frameworks:** On the regulatory front, there is a push to promote good regulatory practices and enhance bilateral cooperation. In furtherance of these objectives, the FTA requires both UK and India to ensure that their

3. The FTA can be accessed here: https://www.commerce.gov.in/international-trade/trade-agreements/india-united-kingdom-comprehensive-economic-and-trade-agreement/
4. The relevant news article can be accessed here: https://www.ndtv.com/world-news/tariffs-on-uk-products-in-india-to-drop-from-15-to-3-under-new-trade-deal-8940121

regulations are made accessible, and that interested stakeholders are provided a reasonable opportunity to comment on proposed major regulatory measures. Further, the FTA envisions measures like retrospective reviews, regulatory impact assessments and information exchanges as means to enhance bilateral trade and investment between the countries by fostering a transparent environment while recognizing each country's unique development and sovereign right to regulate.

Industry stakeholders have hailed this decision, emphasizing on the FTA's potential to significantly enhance India's market access in UK and expand collaborations through partnerships, joint research, and technology transfer. Additionally, with the UK reducing its dependence on Chinese imports in the post-Brexit and post COVID-19 landscape, Indian manufacturers are well placed to become a preferred, cost-effective supply source. The zero-duty pricing advantage for medical devices under the FTA strengthens India's competitive edge, opening new avenues for market expansion and long-term trade partnerships.

Ministry of Health and Family Welfare notifies the Cosmetics (Amendment) Rules, 2025

On July 29, 2025, the Ministry of Health and Family Welfare ("**MoH&FW**") notified the Cosmetics (Amendment) Rules, 2025 ("**Amendment Rules**") to bring several changes in the procedural framework prescribed under the Cosmetics Rules, 2020 ("**Cosmetics Rules**").[5] The introduction of these amendments signals an intention to create a more streamlined and comprehensive regulatory framework by decentralizing the licensing process, simplifying export norms, and simultaneously strengthening enforcement powers at the state level.

The salient features of the Amendment Rules have been discussed in detail below:

(a) **Clarity regarding the Expressions 'Use Before' and 'Date of Expiry':** The Amendment Rules has added an explanation to Rule 3(w) of the Cosmetics Rules in order to clarify the following: (i) the expression 'use before' means that the cosmetic should be used before the first day of the specified month; and (ii) the expression 'date of expiry' means that the cosmetic expires on the last day of the specified month.

(b) **Central Drugs Laboratory to Function as Sample Testing and Appellate Laboratory:** Rule 11 of the Cosmetics Rules earlier required the Central Government to establish or designate a separate Central Cosmetics Laboratory for conducting sample testing and analysis and serve as an appellate laboratory. The Amendment Rules has done away with this requirement and instead the Central Drugs Laboratory, which is already established under the D&C Act, has been designated to perform the functions of the Central Cosmetics Laboratory under the Cosmetics Rules.

(c) **Revised Conditions for License/ Loan License for Manufacturing:** Pursuant to the Amendment Rules, the State Licensing Authority ("**SLA**"), which is the regulatory authority responsible for licensing and enforcement at the state level, has now been designated as the approving authority for laboratories to carry out requisite tests for procurement of licenses. Earlier, this role was played by the Central Licensing Authority ("**CLA**"). Moreover, the licensees have been mandated to keep record of the details of each batch of cosmetics manufactured, including the raw materials used therein, and to maintain such records for a duration of either 3 (three) years or 6 (six) months following the expiry of product, whichever is later.

(d) **Cancellation or Suspension of License:** Rule 31A has been newly inserted in the Cosmetics Rules. The provision empowers the SLA to cancel or suspend a license if the licensee fails to comply with any of the conditions of license or the provisions of the D&C Act and rules made thereunder. Those aggrieved by an order passed under Rule 31A can appeal to the State Government within 90 (ninety) days of receipt of the cancellation or suspension order, and the decision of the State Government upon hearing the appeal shall be final.

(e) **Labelling Requirements for Export of Cosmetics:** The Amendment Rules has relaxed the requirements under Rule 34(10) of the Cosmetics Rules. The labelling of cosmetics meant for export now only needs to comply with the laws of the

5. The Amendment Rules can be accessed here: https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MTI5ODY=

importing country. Previously, the specific labelling requirements listed in the erstwhile provision such as name of the cosmetic, date of expiry, name and address of the manufacturer, etc. needed to be adhered to.

(f) **Confiscation Framework Expanded to Include Spurious Cosmetics:** The Amendment Rules has widened the scope of Rule 53(2) of the Cosmetics Rules, which deals with confiscation of cosmetics, implements, machinery, etc. in case any person contravenes the provisions of the D&C Act and rules made thereunder, including the manufacturing of 'adulterated' or 'misbranded' cosmetics. Pursuant to the Amendment Rules, 'spurious cosmetics' (as defined under Section 17D of the D&C Act) have now been included within the framework alongside 'adulterated' and 'misbranded' cosmetics.

(g) **Change in Nomenclature:** The Amendment Rules has changed the nomenclature for certain terms under the Cosmetics Rules to ensure consistency. The key changes include: (i) the substitution of 'controlling office' with 'controlling authority' under Rule 6 of the Cosmetics Rules; (ii) the substitution of 'licenses' with 'approval' under Rule 60 of the Cosmetics Rules; (iii) the substitution of 'premises licensed' with 'approved premises' under Rule 61 of the Cosmetics Rules; and (iv) the substitution of 'withdrawal of Power of Attorney' with 'withdrawal of authorization' under Schedule I of the Cosmetics Rules.

Policy Proposals

The Drugs Consultative Committee approves proposed amendments to the Drugs and Cosmetics Rules, 1945

The Drugs Consultative Committee ("**DCC**"), in its 66th (sixty-sixth) meeting held on June 17, 2025,[6] endorsed the Central Government's proposal for amendments under the Drugs and Cosmetics Rules, 1945 ("**Drugs Rules**"), with respect to the following:

(a) **Grant of Manufacturing Licenses for Stem Cell Derived Products, Gene Therapy Products and Xenografts:** The proposal contemplates the amendment of erstwhile forms under the Drugs Rules, which are currently being used for granting manufacturing permission for vaccine and r-DNA products, to include stem cell derived and gene therapy products and enable manufacturers to apply for manufacturing license in relation to these products with the SLA and CLA.

The forms proposed to be amended are: (i) Form 27D (Application for grant or renewal of a licence to manufacture for sale or for distribution of Large Volume Parenterals ("**LVPs**") excluding those specified in Schedule X); (ii) Form 27DA (Application for grant or renewal of loan license to manufacture for sale or for distribution of LVPs); (iii) Form 28D (License to manufacture for sale or distribution of LVPs); and (iv) Form 28DA (Loan license to manufacture for sale or distribution of LVPs).

(b) **Exemption from the Requirement of Obtaining Sale License for Liquid Antiseptics:** With respect to the sale of liquid antiseptics, the proposed amendment seeks to exempt: (i) traders of liquid antiseptics for household use from obtaining wholesale license; and (ii) traders of hospital grade antiseptics from obtaining retail sale license, by way of inclusion of these variants of liquid antiseptics in Schedule K of the Drugs Rules as Entry No. 39 and Entry No. 39A respectively.

Schedule K of the Drug Rules provides a list of drugs which can be sold or traded without the requirement of procuring a sale license and serves as an exception to the licensing requirements prescribed under Chapter IV of the Drugs and Cosmetics Act, 1940 ("**D&C Act**").

Pertinently, the exemption is not intended to be absolute, and will only be granted if the following conditions are satisfied: (i) the liquid antiseptics for which exemption is sought should have been manufactured by licensed manufacturers; (ii) they should not contain any substance specified in Schedules G, H, H1 or X of the Drugs Rules; and (iii) they should have been sold in the original sealed containers of the licensed manufacturer. In addition to these conditions, for hospital grade liquid antiseptics, the drugs should have been purchased from a licensed wholesaler or a licensed manufacturer for grant of exemption from procurement of sale license.

6. The minutes of the 66th meeting of the DCC can be accessed here: https://cdsco.gov.in/opencms/resources/UploadCDSCOWeb/2018/UploadCommitteeFiles/Minutes%20of%2066th%20DCC%2017.06.2025.pdf

(c) **Removal of Exemption for Alcoholic Preparations Containing Greater than 30 (thirty) ml of Alcohol under Schedule K:** The DCC accepted the proposal for removal of the exemption granted under Schedule K of the Drugs Rules for alcoholic preparations containing greater than 30 (thirty) ml of alcohol. Instead, the DCC has recommended inclusion of such alcoholic preparations in Schedule H1, meaning that sale licenses and due prescriptions would be required for their sale and purchase. Further, the Bar Code/ QR Code labelling has been mandated on labels of vaccines, anti-microbials, narcotics and psychotropic substances covered under the Narcotic Drugs and Psychotropic Substances Act, 1985 ("**NDPS**").

(d) **Incorporation of WHO Guidelines on Good Distribution Practices under Schedule M:** The DCC agreed to incorporate guidelines on good distribution practice aligned with the Technical Report Series of the WHO ("**WHO TRS**") into the Drugs Rules following stakeholder consultation. It also approved amending Schedule M of the Drugs Rules to align Grade A microbial contamination limits with WHO TRS 1044 Annex II and endorsed implementation of the WHO National Regulatory Authority's market surveillance recommendations with the DCGI to issue standard operating procedures and formats to states and union territories.

Concerns of consumer labelling will be taken up by a sub-committee that would examine aspects like expiry date eligibility, continuous printing of medicine names, use of symbols for generics, and even the potential regulation of packaging material suppliers, signaling that meaningful improvements in medicine labelling and packaging may soon be on the horizon.

Medical Devices

Department of Pharmaceuticals updates operational guidelines in relation to the Capacity Building and Skill Development sub-scheme for medical devices

The Department of Pharmaceuticals ("**DoP**") introduced key changes to the operational guidelines for the sub-scheme 'Capacity Building and Skill Development for Medical Devices' (the "**Sub-Scheme**"), which forms a key component of the 'Scheme for Strengthening of Medical Device Industry' (the "**Scheme**"). These changes were made by way of an addendum issued on June 9, 2025 (the "**Addendum**").[7]

The Scheme is aimed at making India self-reliant and competitive in the medical devices sector, and in order to facilitate this, the Sub-Scheme has been designed to create a skilled workforce of engineers and technicians capable of designing, producing, and testing high-quality medical devices. In this regard, vocational training is delivered by providing financial assistance to academic and training institutions, which are tasked with establishing and running dedicated diploma courses, certificate programmes, and other skill development initiatives. The financial support from the DoP is comprehensive and covers: (a) non-recurring grants for setting up necessary infrastructure and equipment; and (b) recurring, per-student financial aid that is disbursed to institutions to facilitate vocational training.

To support these objectives, the Sub-Scheme has been allocated a total of INR 1,000 Million (Indian Rupees One Thousand Million). A key component of this funding is the support of up to INR 210 Million (Indian Rupees Two Hundred Ten Million) for postgraduate courses at Central Government institutions. Furthermore, institutes approved by the National Council for Vocational Education and Training will receive per-candidate financial assistance of INR 25,000 (Indian Rupees Twenty-Five Thousand) for diploma courses and INR 10,000 (Indian Rupees Ten Thousand) for short-term courses.

CDSCO exempts loan license requirement for sterilisation of medical devices through third parties

The CDSCO, through a public notice dated June 24, 2025, relaxed the requirement of procuring loan licence for medical device manufacturers who outsource sterilisation activities to third-party facilities.[8] The CDSCO has permitted manufacturers to engage sterilisation services through mutual third-party agreements, provided that the concerned sterilisation facility is duly licensed under the Medical Device Rules, 2017.

This regulatory relaxation is aimed at simplifying compliance requirements and improving ease of doing business for medical device manufacturers across India.

7. The Addendum can be accessed here: https://pharma-dept.gov.in/sites/default/files/Corrigendum%20dated%209.6.2025.pdf
8. The notice can be accessed here: https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MTI4NDk=

The earlier regime required manufacturers to obtain a loan licence under the Form MD-5, even if the sterilisation process was conducted externally at a licensed unit. This change is expected to reduce paperwork and speed up the time to market for medical devices, as it eliminates a significant administrative step.

Pertinently, while a loan license is no longer required, manufacturers must now submit documentary evidence of the mutual agreement and the sterilization facility's license to the licensing authority. Details of aspects like mutual agreement between the manufacturer of the device and the sterilization site, quality management system document of the manufacturer like plant master file and device master file mentioning the details of the outsourced activity may be incorporated in the documentary evidence. A crucial new requirement is that the label of the medical device must include the license number of the facility where it was sterilized. This is intended to enable traceability and accountability in the supply chain, maintaining a focus on product quality and patient safety.

The move has been widely welcomed by industry stakeholders and particularly by small manufacturers who often lack in-house sterilization capabilities. The exemption has been viewed as a progressive step that will enhance operational flexibility and efficiency without compromising on the quality and safety of medical devices and reduce compliance burdens. This is expected to lead to a more robust and competitive medical devices manufacturing ecosystem in India.

Government of Uttar Pradesh launches new scheme to promote medical device manufacturing; aims to become a leading hub for healthcare manufacturing

On July 16, 2025, the Yamuna Expressway Industrial Development Authority launched a dedicated scheme to promote manufacturing of medical device manufacturing in the Greater Noida area.[9] The scheme forms a key part of the State Government's broader vision to transform Uttar Pradesh into a leading hub for world-class healthcare manufacturing, with the medical device park contemplated under this scheme being positioned as the largest of its kind in India.

As part of this initiative, 21 (twenty-one) industrial plots shall be allocated to manufacturers in high-growth medical technology segments, including cancer care, radiology, imaging, in-vitro diagnostics, implants, electronic medical devices, cardio-respiratory equipment, and renal devices. Manufacturers will also benefit from having access to shared scientific facilities such as a common IT facility, an artificial intelligence/ machine learning zone, electronics testing and calibration labs, and a 3D design and prototyping lab.

Strategically located in Greater Noida, these plots benefit from robust connectivity through proximity to major infrastructure projects, including the Noida International Airport (Jewar), the proposed international film city, the F1 MotoGP Track, the electronics manufacturing cluster, the MSME hub, and the apparel-handicraft and toy park.

For strengthening the state's position as a premier hub for healthcare manufacturing, this initiative is oriented towards promoting investment and innovation in the medical devices sector. It is aimed at curating dedicated training and capacity building programs for creating a skilled workforce tailored to industry requirements and for establishment of medical device parks cum dedicated clusters to foster an ecosystem for manufacturers. By incentivizing technology transfer, research and development, and collaboration with domestic and international players, the strategic goal of this endeavor is to position the state of Uttar Pradesh as a leading destination for healthcare manufacturing in India.

With planned infrastructure enhancements such as the Eastern Peripheral Expressway expected to further improve logistics and freight connectivity, the initiative is anticipated to attract substantial investment, create employment opportunities, and establish a comprehensive ecosystem for the development and production of cutting-edge medical technologies in the region.

9. The brochure can be accessed here: https://www.yamunaexpresswayauthority.com/web/wp-content/uploads/2025/06/MDP-BROCHURE-JUNE-2025-2.pdf

Notable Judgements

Hon'ble High Court of Delhi directs Drugs Controller General of India to review plea regarding safety and licensing of weight-loss drugs and seek expert consultation

The Hon'ble High Court of Delhi ("**Delhi HC**") has directed the DCGI to examine regulatory concerns raised in a public interest litigation ("**PIL**") challenging the approval and sale of weight-loss drug combinations in India.[10]

The PIL has been filed in response to CDSCO's recent decision to approve certain drugs for weight-loss purposes without requiring large-scale clinical trials specific to Indian demographics or mandating post-marketing surveillance. In particular, the PIL has raised an objection to the approval of Glucagon-like peptide-1 receptor agonist drugs Semaglutide, Tirzepatide and Liraglutide, for cosmetic weight loss purposes, claiming that these drugs have not undergone adequate India-specific trials or safety data. The PIL has further highlighted the international scrutiny that these drugs have attracted due to potential risks such as cancer, organ damage, and neurological complications.

In view of this, the Delhi HC has instructed the DCGI to consult medical experts, stakeholders, and drug manufacturers before taking any regulatory decision. The DCGI has been asked to pass a reasoned decision within 3 (three) months, after considering expert advice and inputs from industry stakeholders.

This judgment is material because it addresses a significant regulatory and public health concern relating to the approval and sale of certain weight loss drug combinations, allegedly without sufficient India-specific trials or supporting data. The decision of the Delhi HC in this regard has the potential to influence future regulatory practices concerning licensing, clinical trial requirements and market availability of such drugs, thereby impacting industry compliance, patient safety, and pharmaceutical governance in India.

Hon'ble High Court of Madras provides clarification on import requirements for ayurvedic drugs

The Hon'ble High Court of Madras ("**Madras HC**") has clarified that while no licence is required for importing ayurvedic drugs into India, such drugs must conform to the standards prescribed for similar drugs manufactured domestically.[11] In this regard, the Madras HC held that imported consignments comprising ayurvedic drugs must be tested in a laboratory accredited by the CDSCO, under the supervision of the relevant SLA.

This direction was issued by the Madras HC while disposing of the petition filed by Axeon Marketing India, an importer of 'Axe Brand Medicated Oil' from Singapore, challenging notices issued for alleged violations under the D&C Act. The petitioner had argued that import licensing provisions do not apply to ayurvedic drugs, relying on the import policy that allows

10. The copy of the judgement can be accessed here: https://delhihighcourt.nic.in/app/showlogo/1751466241_cf2f65e9314f8c02_594_87732025.pdf/2025
11. The copy of the judgement can be accessed here: https://www.legalitysimplified.com/wp-content/uploads/2025/07/display_pdf.pdf

their entry under the 'free' category. Further substantiating on this point, the petitioner contended that CDSCO has framed guidelines permitting the import of ayurvedic drugs subject to the manufacturer's test report and samples being examined followed by issuance of no objection certificate. Further, it was certified by the Health Sciences Authority, Singapore that the manufacturer maintained adequate level of compliance with the Pharmaceutical Inspection and Convention/ Cooperation Scheme Guide to Good Manufacturing Practices for Medicinal Products.

However, the customs department contended that in the absence of specific licensing provisions, such imports are effectively prohibited. To substantiate the contention, arguments vindicated that ayurvedic drugs come under the ambit of D&C Act. The doctrine of *casus omissus* was reiterated to emphasize that courts should abstain from prescribing licensing norms or rules in the light of absence of such provisions or rules by exercising judicial review.

The court rejected the argument posed by the customs department and held that compliance with domestic quality norms is sufficient to allow the import of these drugs. The Madras HC further clarified that all testing costs shall be borne by the importer. This is a material ruling of the Madras HC since it clarifies the applicability of the D&C Act to ayurvedic drugs, highlights the absence of specific import licensing provisions for such products and directs a time bound regulatory pathway for their clearance. This is a precedent for interim regulation while signaling the need for legislative or rule making action as a move that could shape future import controls, industry compliance obligations and public health safeguards for ayurvedic drug sector.

Delhi HC refuses to grant interim injunction against Sun Pharma's use of 'Pruease' trademark

The Delhi HC has refused to grant an interim injunction against Sun Pharmaceutical Industries ("**Sun Pharma**") from selling 'Pruease' tablets, in a trademark infringement plea filed by RSPL Health Private Limited ("**RSPL**"), which markets sanitary products under the brand 'Pro-ease'.[12] The court held that there was no likelihood of confusion between the marks, as the goods were distinct and operated in separate trade channels.

The division bench of the Delhi HC hearing the matter observed that RSPL had failed to establish a *prima facie* case and noted Sun Pharma's clarification that it had no intent to use the 'Pruease' mark for hygiene or sanitary products. The court also took note of Sun Pharma's withdrawal of its opposition to RSPL's trademark applications in the relevant category.

Sun Pharma submitted that the mark 'Pruease' was derived from the active ingredient 'prucalopride', with the addition of the word 'ease' to indicate relief from constipation. The court accepted this explanation and held that the adoption of the mark appeared bona fide and consistent with industry practice. The counsel for the appellant underscored that the appellant was authorized to expand the use of the trademark to allied and cognate goods such as pharmaceuticals for treatment of ailments like menstrual cramps and related use due to which the respondents cannot be allowed to adopt a deceptively similar mark. It was also submitted that the respondents erred in using the mark for allied and cognate goods in addition to medicine for giving relief to constipation.

The counsel for the respondent contended that the distinct nature of goods eliminated the possibility of confusion and that there was no intent of using the mark for sanitary pads/ napkins or like goods in addition to which respondents had also sought deletion of 'hygiene and sanitary preparation' from the goods classification for its application for seeking registration of the mark.

The court stressed on satisfaction of 'trinity test' for grant of interim injunction which includes, showing a good prima facie case, balance of convenience in favor and irreparable harm during failure to grant interim order. The decision came in response to RSPL's appeal challenging a lower court order that had ruled in favour of Sun Pharma. The Delhi HC reaffirmed that despite both marks falling under class 5 (five), the goods were not allied or cognate, and no confusion or deception was likely to occur in the course of business. It noted that adoption of the impugned mark by the respondents was bona fide since the first 3 (three) alphabets were derived from the chemical compound, with the term 'ease' incorporated at the back end for reflecting the ultimate use of the medicine. Accordingly, the court found no merit in the appeal and dismissed the same.

12. The copy of the judgement can be accessed here: https://delhihighcourt.nic.in/app/showFileJudgment/NAC12062025FAOC652025_133939.pdf

This ruling is material since it brings forth the importance of thorough assessment of trademark claims before restricting business activities. The decision emphasizes the need for clear evidence of infringement or likelihood of confusion to protect brand rights while simultaneously balancing the interests of fair competition and innovation in the pharmaceutical industry.

Hon'ble Supreme Court of India exempts stem cell banking services from service tax; recognises them as healthcare services

In a significant judgment, the Hon'ble Supreme Court of India ("**SC**") has held that stem cell banking services, including enrolment, collection, processing, and storage of umbilical cord blood stem cells, qualify as "healthcare services" and are therefore exempt from levy of service tax under the Finance Act, 1994.[13] Relying on Entry 2 of Notification No. 25/2012-ST dated June 20, 2012 ("**2012 Notification**"),[14] and Entry 2A of Notification No. 4/2014-ST dated February 17, 2014 ("**2014 Notification**"),[15] the SC noted that healthcare services provided by clinical establishments, including cord blood banks, were exempt from the levy of service tax.

The appellant argued that "health care services" were always exempted under the Finance Act, 1994 and the expression "any service" used therein should be construed liberally to include diagnosis, treatment, or care of illness, injury, deformity, abnormality or pregnancy. In response, it was contended by the respondent that mutual trust and confidence existed between the department and the appellant regarding compliance with the service tax provisions based on which appellant was required to maintain statutory records under the Service Tax Rules. This was breached and the appellant had failed to pay the service tax for the relevant period. The respondent further stated that the services provided by the appellant did not fall under the ambit of "healthcare services" since the exemption under the 2012 Notification did not cover activities of enrolment, collection, processing and storage of umbilical cord blood stem cells.

The division bench of the SC hearing the matter interpreted the term 'healthcare services' broadly. It reasoned that the collection and preservation of stem cells, while preventive in nature, have potential curative applications for future illnesses. This view was further supported by a prior clarification provided by the MoH&FW, which had classified stem cell banking as a healthcare service through an office memorandum dated May 22, 2013. The court thus held that the appellant's services fell under the scope of "health care services" and was exempt from the levy of service tax.

This ruling of the apex court is material since the exemption of stem cell banking services from service tax, recognizing them as healthcare services, marks a significant step in aligning taxation policy with the evolving healthcare sector. This decision not only reduces the financial burden on patients and providers but also encourages the growth and accessibility of advanced medical services. By acknowledging stem cell banking as an essential healthcare service, the ruling promotes innovation and investment in life-saving technologies, ultimately benefiting public health and medical research in India.

13. The copy of the judgement can be accessed here: https://api.sci.gov.in/supremecourt/2024/47253/47253_2024_9_1505_62294_Judgement_14-Jul-2025.pdf
14. The 2012 Notification can be assessed here: https://iiaonline.in/notification/ST25-2012.pdf
15. The 2014 Notification can be accessed here: https://worldtradescanner.com/04-ST-17.02.2014.htm

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