Newsletter

REGULATORY BRAINBOX

OMC MEDICAL
Regulatory Services

Medical Devices Regulatory Consultancy

JUNE NEWSLETTER 2025

How we can help?

- Authorised Representative services across the globe
- EU MDR/FDA/ROW
- Translation services
- Local country listing

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OMC MEDICAL
Regulatory Services

REGULATORY SERVICES

Our mission is to support our clients in launching their products in various markets.

Who we are?

OMC Medical is primarily based in the UK with offices around the globe offering regulatory support to medical device manufacturers and distributors

- ✓ EU MDR and IVDR compliance
- ✓ Global language translation
- ✓ Global product registrations and Maintenance
- ✓ Product/Process compliance
- ✓ Labelling and Unique Device Identification
- ✓ Clinical evaluation and CRO Services
- ✓ Post-market surveillance
- ✓ Authorised Representative Services - EU, Swiss, UK and ROW.,
- ✓ Importer services - EU, Swiss
- ✓ Internal and External Auditing services
- ✓ Regulatory Staffing
- ✓ Regulatory Training

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MEDICAL PRODUCTS

COSMETICS

EUROPEAN UNION (EU)

EU and Canada Strengthen Health Emergency Preparedness through New Cooperation Agreement | 24 June 2025

The European Commission's Health Emergency and Preparedness Response Authority (HERA) and Canada's Health Emergency Readiness Canada (HERC) have signed a five-year Administrative Arrangement to enhance cooperation on medical countermeasures for serious cross-border public health threats. This collaboration, a result of the EU-Canada Summit on 23 June and the Health Policy Dialogue held on 9 September 2024, aims to reinforce international efforts in pandemic prevention, containment, and response.

The partnership focuses on three priority areas:

- Advancing research and innovation
- Addressing challenges in commercialisation and scale-up
- Strengthening supply chain resilience

The agreement underscores the shared commitment of the European Commission and Canada to coordinate and prepare effectively for future health emergencies through ongoing dialogue and mutual initiatives.

New MDCG Guidelines Enhance Clarity on MDR/IVDR Compliance with AI and Software Tools | June 2025

The European Commission's Medical Device Coordination Group (MDCG) has released a series of critical guidance documents in June 2025, offering clarity on the intersection of medical device regulation, AI, software classification, and in vitro diagnostic studies. Here's a summary of what's new:

Guidelines	Overview
FAQ on Interplay between the Medical Devices Regulation & In vitro Diagnostic Medical Devices Regulation and the Artificial Intelligence Act (June 2025) MDCG 2025-6	This guidance is for manufacturers, notified bodies, and authorities on handling overlapping requirements under the MDR, IVDR, and the AI Act. It introduces the concept of Medical Device Artificial Intelligence (MDAI) and outlines how AI in healthcare should be classified, assessed, and monitored. Key focus areas include quality management, lifecycle monitoring, performance evaluation, and data governance to ensure safety and ethical compliance.
Questions & Answers regarding performance studies of in vitro diagnostic medical devices under regulation (EU) 2017/746 (June 2025) MDCG 2025-5	This Q&A document provides practical guidance on conducting performance studies for in vitro diagnostic (IVD) medical devices under Regulation (EU) 2017/746. It covers study types, submission pathways, safety reporting, ethical considerations, required documentation, and transitional provisions, offering key support for manufacturers and sponsors.
Qualification and classification of software - Regulation (EU) 2017/745 and Regulation (EU) 2017/746 (June 2025) MDCG 2019-11 rev.1	The updated guidance now includes Annex XVI products—software without a medical purpose but still regulated under the MDR. It clarifies: • When software qualifies as a medical device • How it should be classified under MDR and IVDR The revision helps developers and regulators interpret EU law as digital health tools evolve.

Guidance on the safe making available of medical device software (MDSW) apps on online platforms (June 2025) MDCG 2025-4	This guidance ensures that medical software apps distributed online continue to meet the rigorous standards imposed by EU medical device law, without being undermined by digital channel foibles. It bridges overlapping legal frameworks and reinforces trust in digital health tools by clarifying who does what—and when—for patient safety, regulatory clarity, and market consistency.

For stakeholders across the medical device and digital health sectors, these documents represent a significant step forward in harmonizing EU rules and offering actionable regulatory clarity.

MHRA Tightens eCTD Submission Requirements to Align with ICH Standards | 17 June 2025

The MHRA now mandates stricter compliance with eCTD specifications to improve the quality of submissions. In line with ICH guidelines, companies must include historical sequences when updating documents not stored in the MHRA's database. Missing sequences trigger error messages, affecting both existing and new submissions.

To resolve this, companies are required to provide the necessary historical or missing sequences. The MHRA will inform affected companies but cannot correct the issue itself—companies must update their dossiers accordingly.

Submissions with errors will remain in the validation phase until the issue is resolved. The MHRA will propose a timeline for correction, though companies may request adjustments if the timeframe is not feasible. This initiative supports future enhancements like automated validation and self-notification through RegulatoryConnect.

BRAZIL

Stricter Controls for GLP-1 Agonist Drugs Begin in Brazil | 23 June 2025

Starting June 23, pharmacies and drugstores across Brazil must retain prescriptions for GLP-1 agonist drugs such as Ozempic, Mounjaro, and Wegovy.

These medications, commonly used to treat type 2 diabetes and obesity, are now subject to stricter regulations under Anvisa's Normative Instruction IN 360/2025. The rule, published in April 2025, was introduced following numerous reports of adverse events linked to off-label use.

Under the new requirements, prescriptions must be issued in duplicate, and sales are only permitted with the pharmacy retaining one copy. Prescriptions are valid for up to 90 days from the date of issuance.

Anvisa Prohibits Compounding Pharmacies from Handling Intradermal Fillers and Related Medical Devices | 16 June 2025

In November 2023, Anvisa issued Resolution-RE 4,424/2023, banning compounding pharmacies from manufacturing, distributing, or using intradermal fillers and similar medical devices. These products, including hyaluronic acid and PMMA, are implantable and high-risk, requiring sterile conditions and certified good manufacturing practices.

The decision follows inspections revealing unregulated production. Anvisa stresses that only registered products from authorized manufacturers should be used, and compounding pharmacies are not allowed to produce custom-made devices unless they comply with specific regulations under RDC 925/2024.

Anvisa Participates in BRICS Medical Products Regulatory Authorities Meeting to Strengthen International Cooperation | 14 June 2025

On June 12–13, Anvisa participated in the BRICS Medical Products Regulatory Authorities Meeting in Brasília, Brazil. The event aimed to enhance technical dialogue and align regulatory strategies in the medical devices sector. The program featured institutional presentations, discussions on strategic priorities, collaborative proposals, and a side event with industry representatives. A technical document summarizing the outcomes was drafted for submission to BRICS Health Ministers.

Key topics included access to health technologies, pharmaceutical innovation, and standard harmonization. Anvisa highlighted Brazil's regulatory framework, particularly in health surveillance and medical device regulation. The meeting supported international cooperation and experience exchange among BRICS nations.

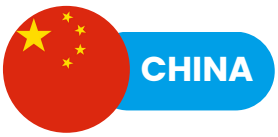
BRICS—originally comprising Brazil, Russia, India, China, and South Africa—continues to grow as a platform for strategic collaboration among Global South countries, focusing on key global issues.

ANVISA Cancels Non-Compliant IVD Device Notifications Following Risk Classification Updates | 09 June 2025

ANVISA has canceled in-vitro diagnostic (IVD) device notifications that failed to comply with RDC 830/2023, which updated risk classification criteria.

The regulation required manufacturers to reclassify products based on health risk by June 1, 2024, possibly shifting from notification (Class I/II) to registration (Class III/IV). Affected products include those related to notifiable diseases, antibiotic resistance, and transplant suitability.

Cancellations result from missed deadlines, not product quality issues, reinforcing ANVISA's role in ensuring regulatory compliance and public health protection.



NMPA Reviews 2024 QMS for Vaccine and Drug Manufacturing Oversight | 16 June 2025

The NMPA held its 2024 annual review of the Quality Management System (QMS) for vaccine regulation and pharmaceutical manufacturing inspection on June 9. The system was deemed effective and aligned with international standards like WHO and PIC/S. Departments reported on system performance, identified issues, and proposed improvements.

The NMPA emphasized enhanced national coordination, continuous system optimization, and strengthening regulatory capabilities to support the pharmaceutical sector's high-quality development.

China Updates Policy on Domestic Production of Imported Medical Devices | 11 June 2025

China's NMPA has revised its 2020 policy to ease domestic production of Class II and III imported medical devices. Now, foreign-invested enterprises established by or sharing the same actual controller as the overseas registrant can apply for registration in China.

Key changes include:

- Use of original overseas registration dossiers with proof of compliance to Chinese standards.
- Requirement for notarized authorization from the overseas registrant.
- Quality system verification to ensure equivalence between domestic and overseas production.
- Priority review for innovative devices produced domestically.

The update supports regulatory reform and encourages high-quality local manufacturing.

China Expands eCTD Implementation Scope for Drug Applications Starting January 2025| 11 June 2025

To support the growth of digital drug regulation and streamline application processes, China will expand the use of the Electronic Common Technical Document (eCTD) format starting January 27, 2025. This extension includes:

- Chemical Drugs:
  - Clinical trial applications for Class 1 to 5.
  - Marketing authorization applications for Class 2, 3, 4, and 5.2.
- Biological Products:
  - Clinical trial applications for Class 1 to 3 preventive and therapeutic biological products.
  - Marketing authorization applications for Class 2 and 3.

Applicants must follow current eCTD technical document requirements and are encouraged to use online transmission for dossier submissions. Operational guidelines can be found on the Center for Drug Evaluation's official website.

Costa Rica Implements Regulation for Medicinal Cannabis Products| 23 June 2025

Costa Rica's Ministry of Health announced that Executive Decree No. 44917-S, establishing Technical Regulation RTCR 515:2024 for cannabis-based medicinal products, took effect on June 22, 2025.

The regulation allows for the sanitary registration of THC-containing medicinal cannabis products via the Register It platform. Permitted products include dried cannabis and pharmaceutical forms like tablets and creams, excluding sterile products. Registered items will be available in pharmacies with a digital prescription.

A separate regulation for therapeutic cannabis products is under development and will soon be open to public consultation.

FINLAND

Fimea Launches 2025 Market Surveillance Campaign Targeting Software-Based Medical Devices | 18 June 2025

Fimea will conduct a market surveillance campaign in 2025 targeting software-based medical devices in Finland. The initiative begins with a survey sent to software operators to assess regulatory awareness and compliance. The campaign aims to identify non-compliant products, guide manufacturers, and enforce MDR and IVDR requirements. It focuses on software used for diagnosis, treatment planning, or monitoring, ensuring proper CE marking and risk classification. The findings will support regulatory development and improve oversight of medical software in the EU market.

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INDIA

Regulatory Body Approves New Guidelines for Outsourced Sterilization of Medical Devices Under MDR 2017 | 24 June 2025

In a move aimed at streamlining regulatory processes for medical device manufacturers, Indian authorities have decided that a separate loan license will no longer be required when outsourcing sterilization to licensed third-party facilities—subject to specific conditions under the Medical Device Rules (MDR), 2017.

The decision follows stakeholder concerns and was finalized after a detailed review by a sub-committee formed by the Drugs Consultative Committee (DCC). The sub-committee concluded that if the final product is released from the original manufacturer's site and all quality control checks are conducted by the manufacturer, then a loan license is not necessary. Instead, the activity can be conducted through a mutual third-party agreement, provided the sterilization facility holds a valid license under MDR-2017.

Recognizing sterilization as a critical activity, the committee also recommended that the license number of the sterilization site must appear on the device label. To support this, an amendment to Rule 44 of the MDR-2017 has been proposed to incorporate labeling requirements specific to outsourced sterilization.

Furthermore, manufacturers will be required to submit documentary evidence—such as mutual agreements and Quality Management System documents (e.g., Plant Master File and Device Master File)—to the Licensing Authority before obtaining a manufacturing license.
These recommendations were endorsed during the 6th DCC meeting in December 2024 and subsequently approved by the Drugs Technical Advisory Board (DTAB) in its 92nd meeting held in April 2025. Authorities have instructed manufacturers to take note of the revised requirements and ensure compliance.

SAHPRA Trains with EDA to Boost Regulatory Capacity | 04 June 2025

The South African Health Products Regulatory Authority (SAHPRA) recently completed a three-day training programme hosted by the Egyptian Drug Authority (EDA) in Cairo. The initiative supports SAHPRA's goal of reaching Maturity Level 3 under the WHO's Global Benchmarking Tool for medicines regulation.

The training, part of a 2023 cooperation agreement, focused on improving regulatory governance, transparency, and performance across key SAHPRA units. This marks a significant step in strengthening regulatory collaboration and capacity within Africa.

SINGAPORE

Singapore Launches SHARE Portal to Streamline Medical Device Regulatory Submissions | 23 June 2025

HSA has officially launched a new digital platform, **SHARE (Singapore Health Product Access and Regulatory E-System)**, to handle medical device product registration and licence submissions. The portal will replace the existing ***MEDICS system***, reflecting the country's continued efforts to modernize and simplify regulatory processes for businesses.

Starting **14 July 2025**, companies can access SHARE using *Corppass* to perform various e-services, including:

- **Product registration for Class B, C, and D** medical devices (new submissions, change notifications, cancellations, and retentions)
- **Product notifications for Class A devices** (new, amendment, and cancellation)
- **Dealer licences** (new, amendment, cancellation, and renewal)
- **Special Access Route** submissions
- **Change of registrant** applications
- Requests for **Free Sale Certificates** and **Export Certificates** for medical devices.

The transition to SHARE will take place over several key dates:

Period	Activity
27 June 2025	MEDICS has stopped accepting new application submissions (IR responses for ongoing applications will still be processed)
4 July 2025	All changes to existing applications in MEDICS, including IR responses, must be completed by 5:00 PM. Changes after this will not be migrated to SHARE

Period	Activity
4–13 July 2025	Cut-over period — MEDICS will be decommissioned and inaccessible.
14 July 2025	SHARE goes live, and all new submissions must be made via the new system. Any pending IRs from MEDICS will be transferred to SHARE

For login setup and further guidance, businesses are encouraged to refer to the published FAQ on HSA website.

AUSTRALIA

TGA Investigates Sunscreen SPF Accuracy Following CHOICE Report | 04 June 2025

The Therapeutic Goods Administration (TGA) is reviewing a CHOICE report that found some sunscreens sold in Australia failed to meet their claimed SPF ratings. Sunscreens classified as therapeutic goods must meet strict standards, including truthful labelling and evidence-backed SPF claims.
The TGA will investigate and take regulatory action if needed but does not comment publicly on ongoing cases. Despite some products showing SPF 30 in tests, the TGA confirms this still offers "High protection."

All sunscreens must comply with Australian and international testing standards, though variability in SPF results is known due to human-based testing methods. The TGA may outsource SPF testing to accredited labs and continues to support advances in more consistent in-vitro methods.

BRAZIL

Anvisa Issues Safety Verification Manual for Hair Ointment Registration | 06 June 2025

On June 4, 2025, Brazil's health authority Anvisa released a Manual for the Verification of Skin and Eye Safety of Hair Ointments to guide companies in preparing documentation for product registration. This follows RDC No. 814/2023, which reclassified hair ointments from notification to mandatory registration due to incidents of serious eye injuries.

The manual outlines requirements to demonstrate skin and eye safety, a key part of the registration dossier as specified in Article 4 of the resolution.

. It covers:

1. In vitro eye irritation tests using internationally validated methods aligned with IATA, requiring products to be classified as “No Category” under the UN GHS.
2. Clinical skin compatibility studies assessing irritation, sensitization, photoallergy, and phototoxicity.
3. Ingredient safety dossiers, especially addressing impurities like 1,4-dioxane and ethylene oxide.
4. Comprehensive safety assessment reports, signed by both the company’s technical manager and legal representative.

The manual aims to standardize safety evidence and ensure regulatory compliance in light of increased product scrutiny.

Updated Guidelines on NCI Notification: Acceptable Evidence of Safe Use & Edible Ingredient Histories | 25 June 2025

The revised Guidelines for Research and Determination of Safe Consumption History of New Cosmetic Ingredients (Trial) detail the acceptable forms of evidence for two specific NCI notification situations in China:

- **Situation 3 & 4:** Ingredients can be notified based on safe use in marketed cosmetics for over 3 years. Evidence must include sales of at least 10,000 units over 3 years (or 100,000 units if using indirect data). Consumer usage data is now only required for whitening/spot-lightening ingredients.

- **Situation 5:** Ingredients with a proven history of safe edible use may also qualify. The guidelines now define acceptable sources (e.g., official ingredient lists, universities), and require additional toxicological evaluation for higher-risk ingredients. Edible use history alone cannot replace skin safety testing for whitening agents.

The changes aim to support ingredient innovation while ensuring safety.

China Releases Nine New Draft Cosmetic Standards for Public Consultation | 24 June 2025

On June 24, 2025, China's National Institutes for Food and Drug Control (NIFDC) published nine draft standards for cosmetics, inviting public comments until July 15, 2025.

These drafts aim to enhance the technical regulatory framework for cosmetic ingredients and testing. Key documents include general principles for physicochemical testing, methods for detecting cannabidiol (CBD) and other components, toxicokinetics, and safety testing methods like the LLNA: BrdU-FCM.

Standards also address technical requirements for biotechnology-derived and plant-origin ingredients, and specific ingredient standards for **Centella Asiatica Extract**, **Copper Tripeptide-1**, and **Acetyl Hexapeptide-8**.

This initiative reflects China's ongoing efforts to expand its relatively limited cosmetic standards and improve oversight of ingredient safety and efficacy.

NMPA Updates Management of Used Cosmetic Raw Materials Catalogue| 23 June 2025

The NMPA has updated the management of the Catalogue of Used Cosmetic Raw Materials to support innovation and ensure safety. The catalogue is now split into two parts:

- **Catalogue I:** Revised version of the 2021 list, with name standardization and removal of historical usage limits.
- **Catalogue II:** Includes new raw materials approved after a 3-year safety monitoring period (e.g., N-acetylneuraminic acid and β-alanylhydroxyprolyldiaminobutyric acid benzylamine).

A dynamic update mechanism has been introduced, and future updates will be published directly on the NMPA website instead of through formal announcements.

MACAU

Macao Bans Mercury-Added Products in Line with Minamata Convention | 23 June 2025

Macao has announced a ban on the import, export, and transshipment of 14 mercury-added products, aligning with global efforts to reduce mercury pollution under the Minamata Convention on Mercury. The new measure, outlined in Chief Executive's Order No. 109/2025, was issued on June 16, 2025, and will come into effect on January 1, 2026.

The ban includes mercury-added cosmetics, particularly skin-lightening soaps and creams, which are identified as hazardous to human health and the environment. Exemptions will be made for eye cosmetics that use mercury as a preservative—only when no safe and effective alternatives exist—as well as for products used in research, calibration of instruments, or as reference standards.

The Minamata Convention, first adopted in Japan on October 10, 2013, is a global treaty designed to protect human health and the environment from the adverse effects of mercury. Macao's adoption of this directive marks another step toward its commitment to international environmental standards.

INDONESIA

Indonesia Tightens Oversight of Imported Cosmetics with New Testing Rules | 04 June 2025

Indonesia's Food and Drug Supervisory Agency (BPOM) released a new draft regulation aimed at enhancing the safety and quality oversight of imported cosmetic products.

This initiative introduces stricter requirements for Certificates of Analysis (CoA) that must accompany cosmetic imports, aligning with BPOM Regulation No. 27/2022 as amended by No. 28/2023, and relevant presidential and agency regulations issued between 2017 and 2025.

The CoA must now include mandatory test results for heavy metals—such as lead (Pb), mercury (Hg), and arsenic (As)—and microbial contamination. For products with multiple batches, additional details including dosage form and organoleptic properties (appearance, smell, texture) must be specified. The CoA is valid for one year from its issuance date.

Specific test parameters vary based on the product category and Harmonized System (HS) Code. For instance:

Product Type	HS Code	Required Tests	Rinse Type
Creams, Lotions, Oils	3304.99.30	Pb, Hg (if applicable), Microbial	Non-Rinse
Foot Care Products	3304.99.30	Pb, US metal (if talc), Microbial	
Skin Freshener	3304.99.90	Hg, Microbial	
Massage Cream/Oil	3304.99.30	Microbial; oils: Pb & Microbial	

Product Type	HS Code	Required Tests	Rinse Type
Acne Preparations	3304.99.20	Hg, Microbial	Non-Rinse
Foundation & Concealers	3304.99.30	Pb, Hg, As, Microbial	
Face & Body Powders	3304.91.00	US metal, Microbial	

This regulatory move seeks to enhance consumer safety, support regulatory compliance among businesses, and improve BPOM's capacity to monitor cosmetic imports effectively. The regulation takes effect immediately upon enactment.

List of ISO standards updated in June 2025

- ISO 9917-1:2025 -Dentistry — Water-based cements — Part 1: Acid-base cements
- ISO 20127:2025 - Dentistry — Physical properties of powered toothbrushes
- ISO/TS 20721:2025 - Implants for surgery — Absorbable implants — General guidelines and requirements for assessment of absorb able metallic implants
- ISO 10993 23:2021/Amd 1:2025 - Biological evaluation of medical devices — Part 23: Tests for irritation — Amend ment 1: Additional in vitro reconstructed human epidermis models
- ISO 14644-5:2025 - Cleanrooms and associated controlled environments — Part 5: Operations
- ISO 80369-6:2025 - Small bore connectors for liquids and gases in healthcare applications — Part 6: Connectors for neural applications
- ISO/IEC TS 17012:2024 - Conformity assessment — Guidelines for the use of remote auditing methods in auditing management systems