Newsletter

REGULATORY BRAINBOX

OMC MEDICAL
Regulatory Services

Medical Devices Regulatory Consultancy

AUGUST 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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UNITED STATES OF AMERICA (USA)

FDA Launches Daily Publication of Adverse Event Data to Enhance Transparency | 22 August 2025

The U.S. Food and Drug Administration has begun publishing data from the FDA Adverse Event Reporting System (FAERS) on a daily basis. This marks a major advancement in modernizing the agency's safety monitoring infrastructure and underscores its commitment to transparency and real-time public health protection. FAERS serves as the main database for adverse event reports, serious medication errors, and product quality complaints related to prescription drugs and biologics, with reports submitted by healthcare professionals, consumers, and manufacturers.

The change is part of the FDA's broader data modernization strategy aimed at streamlining reporting systems, increasing reporting frequency, and improving the early detection of safety signals.

FDA Launches PreCheck Program to Strengthen U.S. Pharmaceutical Supply Chain | 07 August 2025

The U.S. Food and Drug Administration (FDA) has introduced FDA PreCheck, a new program designed to reduce America's reliance on foreign drug manufacturing and strengthen the domestic pharmaceutical supply chain. Currently, over half of pharmaceuticals distributed in the U.S. are produced overseas, with only 11% of FDA-approved active pharmaceutical ingredient (API) manufacturers based in the U.S.

Developed in response to Executive Order 14293, FDA PreCheck streamlines regulatory review for domestic drug production and supports the development of new manufacturing sites. The program features a two-phase approach:

1. Facility Readiness Phase – Provides enhanced FDA communication during facility design, construction, and pre-production, supported by a facility-specific Drug Master File (DMF).
2. Application Submission Phase – Focuses on improving efficiency in application review through pre-application meetings and early feedback on the Chemistry, Manufacturing, and Controls section.

To further engage stakeholders, FDA will hold a public meeting on September 30, 2025, titled "Onshoring Manufacturing of Drugs and Biological Products." The event will present the draft framework, encourage stakeholder feedback, and explore solutions to challenges in domestic drug manufacturing.

Swissdamed UDI Devices Module Goes Live |18 August 2025

Swissmedic has expanded swissdamed, Switzerland's national medical devices database, with the launch of the UDI Devices module. This new feature allows the registration of medical devices, in vitro diagnostic devices, and systems and procedure packs. While registration is currently **voluntary**, it will become **mandatory from 1 July 2026** for all devices placed on the Swiss market.

A transitional period runs until the end of 2026, except for devices linked to serious incident reporting, field safety corrective actions, or trend reporting, which must be registered immediately from July 2026. Registration requirements apply to Swiss manufacturers, authorised representatives, and assemblers of systems and procedure packs.

For more information, see: Swissdamed Device Module Goes Live: What Manufacturers and Stakeholders Need to Know

EU and Switzerland Extended Use of Electronic Instructions for Use | 08 August 2025

The EU adopted Implementing Regulation (EU) 2025/1234, which broadened the scope of medical devices eligible to provide electronic instructions for use (eIFU). Effective from 16 July 2025, this regulation extended the option of eIFU to all medical devices, their accessories, and Annex XVI products without a medical purpose, provided they were intended for professional users. Devices for lay users still had to supply paper instructions. Manufacturers were also required to register the web address of their eIFU in the Eudamed UDI database.

The regulation repealed the previous framework under Regulation (EU) 207/2012, which had applied only to certain legacy devices. Switzerland aligned with the new EU rules, meaning the updated requirements under Regulations (EU) 2021/2226 and 2025/1234 applied directly without amendments to the Swiss Medical Devices Ordinance (MedDO).

ANMAT Implements New Import Notice Requirement for Class I and II Medical Devices | 06 August 2025

Argentina's National Administration of Drugs, Foods and Medical Devices (ANMAT) has enacted Provision 4446/25, effective immediately. Under this rule, authorized companies must submit an Import Notice within 48 hours of nationalizing imports of Class I and II medical devices. This applies only to registered products—including finished products, bulk or semi-finished goods in primary packaging, refurbished devices, and registered product samples.

The notice is submitted via the "Bonita" system under the module Import Notice of Medical Products Class I and II and will serve as an affidavit. The process is non-tariffed. ANMAT will verify the submitted documentation but no longer requires prior authorization for these imports.

Nevertheless, companies remain responsible for compliance with applicable regulations, and late or inaccurate filings may lead to sanctions.

Key points:

- Exemptions: Imports of spare parts for Class I/II products do not require an Import Notice.
- Still require prior authorization: Class III/IV devices, in vitro diagnostic (IVD) products, temporary imports, and unregistered product samples (any class).
- Direct users (healthcare institutions, non-profits): Must continue using TAD for all risk classes.
- Quality obligations: Companies must perform all required quality tests and controls under Mercosur rules, though they are not required to release the goods but must maintain records of release.

India Drafts New Evaluation Protocols for TB Diagnostic Devices, Seeks Public Feedback | 26 August 2025

India's drug regulator and health research body have released draft standard protocols for evaluating in-vitro diagnostic (IVD) devices for tuberculosis (TB) and are inviting public comments until **September 7, 2025**.

The protocols aim to create a uniform framework for assessing nucleic acid amplification-based TB tests before market approval under the Medical Devices Rules, 2017. They set out methods for testing:

- Analytical accuracy – including sensitivity, specificity, and reproducibility.
- Clinical performance – through multi-centre studies comparing new kits with established reference methods.
- Drug-resistance detection – particularly for multidrug-resistant TB.

Evaluations must be carried out in NTEP-approved laboratories with strict safeguards on data handling and patient privacy.

Officials said the final protocols will provide a benchmark for manufacturers and testing labs, supporting regulatory approvals and improving the reliability of TB diagnostics across India.

Stakeholders including manufacturers, laboratories, and clinicians can send feedback in the prescribed format before the deadline.

Malaysia and Singapore Launch Pilot for Medical Device Regulatory Reliancel | 09 August 2025

Malaysia's Medical Device Authority (MDA) and Singapore's Health Sciences Authority (HSA) have signed an MoU to strengthen regulatory cooperation and launched a six-month pilot Medical Device Regulatory Reliance Programme.

From September 1, 2025 to February 28, 2026, the pilot will streamline approvals for Class B, C, and D medical devices by relying on each other's assessments, cutting review times and reducing duplication.

In Malaysia, review timelines could be shortened from 60 to 30 working days, while in Singapore, approvals may be up to 30% faster. Regulators will evaluate the results after the pilot to consider a full rollout.

SFDA Signs MoU with AAMI to Advance Medical Device Standards and Innovation | 20 August 2025

The Saudi Food and Drug Authority (SFDA) has signed a Memorandum of Understanding (MoU) with the Association for the Advancement of Medical Instrumentation (AAMI) to enhance cooperation in the medical devices sector.

The agreement focuses on emerging technologies, including artificial intelligence and biotechnology, to support innovation in diagnosis and treatment. It also covers the development of standards, exchange of technical and scientific information, expert consultations, and collaboration on educational programs, joint events, and international committees.

The partnership reflects the SFDA's strategy to strengthen global collaboration in advancing medical device policies and technical capabilities. It also supports the goals of Saudi Arabia's Health Sector Transformation Program, part of Vision 2030.

EUROPEAN UNION (EU)

EU to Enforce TPO Ban in Cosmetics from September 2025 | 07 August 2025

The European Union will ban Trimethylbenzoyl Diphenylphosphine Oxide (TPO) in cosmetics from September 1, 2025, after classifying it as a Category 1B reproductive toxicant under the CLP Regulation.

The ban covers all sales, distribution, and professional use of products containing TPO, with no grace period for existing stock. Nail salons and retailers must withdraw affected items before the deadline, while manufacturers are required to reformulate products.

The measure, enacted under the EU Cosmetics Regulation, aims to ensure consistency across member states and protect consumers from potential health risks.

BRAZIL

Brazil Bans Animal Testing for Cosmetics | 01 August 2025

Brazil has enacted a nationwide ban on animal testing in cosmetics, covering both finished products and ingredients. The law requires companies to adopt alternative testing methods recognized internationally, ensuring product safety without animal use.

The move brings Brazil in line with global cruelty-free practices already adopted in the EU, India, and Mexico, while boosting its position in ethical cosmetics regulation. Industry experts say the change will drive innovation in non-animal testing technologies and strengthen consumer confidence in cruelty-free products.

Brazil Enforces New Cosmetovigilance Rules Requiring Adverse Event Reporting | 11 August 2025

Brazil's Collegiate Board Resolution (RDC) 894/2024 officially comes into effect, introducing Good Practices of Cosmetovigilance for cosmetic companies.

Under the new regulation, manufacturers must report serious adverse events linked to cosmetic products through Anvisa's official system, Notivisa (professional). Companies and designated employees are required to be registered in advance via Anvisa's company registration portal.

Anvisa has published a step-by-step guide for company registration to support the process. Companies encountering difficulties can seek assistance through the agency's service channels.

The health authority emphasized that cosmetovigilance is a critical tool to protect consumers and ensure continuous monitoring of risks associated with cosmetic use. Effective implementation, it said, depends on active collaboration from the regulated sector.

INDIA

BIS Revises Cosmetic Ingredient Standards: IS 4707 (Part 2 & 3) | 27 August 2025

The Bureau of Indian Standards (BIS) has announced revisions to IS 4707 (Part 2 and Part 3), which lay down the specifications for permitted, restricted, and prohibited ingredients in cosmetics.

These updates align Indian regulations more closely with global best practices and are expected to strengthen consumer safety and product compliance.

- IS 4707 (Part 2) specifies the list of permitted colorants, preservatives, UV filters, and other ingredients that may be used in cosmetic formulations.
- IS 4707 (Part 3) details the prohibited and restricted substances, ensuring that harmful chemicals are excluded or controlled within safe limits.

The revisions also update testing and labeling requirements, giving manufacturers clearer guidance for compliance under the Drugs and Cosmetics Rules, 1945.

According to BIS, the move will help streamline regulatory oversight, enhance product quality standards, and ensure safer cosmetic options for Indian consumers.

The revised standards are now in effect, and cosmetic manufacturers are expected to align their formulations and labels accordingly.

India Notifies 2025 Amendments to Cosmetics Rules | 01 August 2025

The government has issued the Cosmetics (Amendment) Rules, 2025, tightening standards for labeling, licensing, and enforcement in the cosmetics sector.

The changes clarify expiry labeling, designate the Central Drugs Laboratory as the Central Cosmetics Laboratory, and require manufacturers to maintain detailed batch records. A new rule empowers authorities to suspend or cancel licenses, while export products must comply with destination-country regulations.

The amendments also ban sending samples by courier and formally add “spurious cosmetics” to enforcement provisions. Officials said the updates aim to improve consumer safety and align with global practices.

South Korea Abolishes Government Certification for Natural and Organic Cosmetics | 01 August 2025

South Korea has officially scrapped its government-led certification system for natural and organic cosmetics, effective August 1, 2025.

The reform, introduced through amendments to the Cosmetics Act, eliminates separate categories for “natural” and “organic” products. Instead, such items will now be regulated under the broader classification of functional cosmetics.

The change means companies can no longer market products with government-backed natural or organic claims. Existing certifications remain valid until expiry, but no new approvals will be issued.

Authorities say the move aims to reduce regulatory burdens and bring South Korea in line with global practice, where private bodies typically oversee natural and organic product standards.

South Korea Issues New Guideline on Labeling of Natural and Organic Cosmetics | 18 August 2025

South Korea has released a new guideline outlining requirements for the labeling of natural and organic cosmetics. The measure aims to bring greater clarity and consistency to how such products are marketed, helping consumers make informed choices and ensuring fair practices in the cosmetics industry.

The guideline sets out standards for the use of “natural” and “organic” claims, aligning product labeling with international best practices while addressing the country’s regulatory needs.

Industry stakeholders are expected to adapt their labeling in compliance with the new rules.

Malaysia Launches MyHALALINGREDIENTS to Streamline Halal Certification | 15 August 2025

Malaysia has launched MyHALALINGREDIENTS, a new digital system aimed at improving the efficiency and transparency of the country’s halal certification process. The platform, introduced on August 15, 2025, is part of the government’s wider digitalization efforts under the MADANI framework.

MyHALALINGREDIENTS functions as a centralized database for recording and assessing ingredients used in the halal industry. Integrated with the existing MYeHALAL platform, it reduces reliance on physical paperwork and speeds up application reviews.

Key Benefits for Stakeholders

- Simplified registration through online submission on MYeHALAL.
- Faster reviews, avoiding repeated evaluation of identical ingredients.
- Stronger supply chain oversight to safeguard halal integrity and product safety.
- Shorter processing times across all halal certification schemes.

Authorities expect the system to enhance regulatory efficiency while supporting Malaysia's position as a global leader in the halal industry.

China Signals Stricter Oversight of Cosmetics and New Ingredients | 25 August 2025

China's National Medical Products Administration (NMPA) has indicated upcoming changes to its cosmetic regulations, with a stronger focus on new cosmetic ingredients (NCIs) and post-market safety monitoring.

The reforms, building on the Cosmetic Supervision and Administration Regulation (CSAR), aim to tighten requirements for safety data and risk assessments while enhancing adverse event reporting and enforcement. Officials also signaled moves toward international alignment and greater use of digital regulatory tools.

For cosmetic companies, the changes mean higher compliance obligations, particularly for products using innovative ingredients. However, clearer approval pathways are expected to improve regulatory certainty and consumer trust.

SOUTH AFRICA

South Africa Proposes Nationwide Ban on Plastic Microbeads | 19 August 2025

South Africa's Department of Forestry, Fisheries and the Environment has released draft regulations to ban the use, production, distribution, sale, import, and export of plastic microbeads and products containing them. The proposal is now open for public comment until September 7, 2025.

Issued under the National Environmental Management Act, 1998, the draft rules target microbeads—solid plastic particles smaller than 5 mm—commonly used in cosmetics, personal care products, toiletries, pesticides, and similar goods.

If finalized, the regulations will enforce a comprehensive ban and introduce monitoring and enforcement measures. Repeat offenders could face fines of up to 10 million Rands and/or 10 years in prison.

The plan provides for a 24-month transition period to phase out existing stock. Businesses affected will be required to notify the authorities and submit formal phase-out plans.

New Service Standards Announced for Cosmetic Notifications in Indonesia | 26 August 2025

Indonesia's National Agency of Drug and Food Control (BPOM) has issued updated service standards for cosmetic notification procedures, aiming to streamline regulatory processes and enhance industry compliance.

The revised standards cover the timeline, documentation, and procedural requirements for cosmetic product notifications—a mandatory step before cosmetics can be marketed in Indonesia. Key updates include clearer submission requirements, improved digital services, and stricter timelines for both applicants and regulators.

The changes are designed to increase transparency, efficiency, and accountability in cosmetic regulation, while also ensuring that products entering the market meet national safety and quality standards.

BPOM has urged cosmetic manufacturers, importers, and distributors to review the new guidelines carefully and adjust their internal compliance processes accordingly. The updated service standards are now in effect and apply to all new cosmetic notifications submitted in Indonesia.

ANMAT Requires Importers to Report Cosmetic Product Holders' CUITs | 14 August 2025

Argentina's National Administration of Drugs, Food and Medical Technology (ANMAT) has issued a new requirement under Provision No. 4033/25, mandating authorized importers of cosmetic products to report the CUITs of all product holders they service.

The information, which will be shared with ARCA for customs procedures, must include:

- Details of the authorized importing establishment.
- Its CUIT.
- Names or company names of the product holders.
- The corresponding CUITs of each holder.

Importers must submit this information via the ANMAT Entry Desk, using the official email address.

The declaration is treated as an affidavit and must be kept up to date whenever there are changes to the list of product holders, whether due to new registrations or cancellations.

List of ISO standards updated in August 2025

- ISO 5834-1:2025 - Implants for surgery - Ultra-high-molecular-weight polyethylene - Part 1: Powder form
- ISO 5834-2:2025 -Implants for surgery - Ultra-high-molecular-weight polyethylene - Part 2: Moulded forms
- ISO 5834-3:2025 - Implants for surgery - Ultra-high-molecular-weight polyethylene - Part 3: Accelerated ageing methods after gamma irradiation in air
- ISO 5834-4:2025 - Implants for surgery - Ultra-high-mo-lecular-weight polyethylene - Part 4: Oxidation index measurement method
- ISO 5834-5:2025 - Implants for surgery - Ultra-high-molecular-weight polyethylene - Part 5: Morphology assessment method
- ISO 18193:2021/Amd 1:2025 - Cardiovascular implants and artificial organs - Cannulae for extracorporeal circulation - Amendment 1