# Newsletter

## REGULATORY BRAINBOX


OMC MEDICAL
Regulatory Services

Medical Devices Regulatory Consultancy

## How we can help?

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

**AUGUST NEWSLETTER**

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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 KINGDOM (UK)

### MHRA Approves Lecanemab for Early Alzheimer's with Genetic and Safety Restrictions | 22 August 2024

The MHRA approved **lecanemab (Leqembi)** for early-stage Alzheimer's, marking the first licensed treatment in Great Britain that shows potential to slow disease progression. It is approved for adults with one or no copies of the **ApoE4 gene**, as those with two copies face higher risks of complications.

A clinical trial revealed increased risks of brain abnormalities, particularly in ApoE4 homozygous patients. As a result, lecanemab is recommended only for non-carriers or heterozygous patients, with gene testing advised before treatment. It is contraindicated for those on anticoagulants or with cerebral amyloid angiopathy.

Post-authorization studies will assess long-term safety.

### UK Launches AI Airlock to Tackle Challenges in Regulating AI Medical Devices | 21 August 2024

The UK's Medicines and Healthcare products Regulatory Agency (MHRA) has launched the **AI Airlock** project to tackle the regulatory issues surrounding Artificial Intelligence as a Medical Device (AIaMD). The initiative, involving the MHRA, UK Approved Bodies, the NHS, and other partners, will use real-world products to explore issues like product performance, clinical automation, and generative AI devices.

Applications will open in autumn, targeting various AIaMD products. The initiative aims to balance innovation with patient safety, demonstrating the UK's commitment to medical technology.

## UNITED STATES OF AMERICA (USA)

### FDA eMDR System Enhancements and Update Schedule | 26 August 2024

The FDA is planning improvements to its Electronic Medical Device Reporting (eMDR) system, which will be accompanied by updates to the FDA eSubmitter client. Manufacturers with AS2 accounts using the FDA Electronic Submissions Gateway should plan updates accordingly. The FDA is committed to providing advance notice of system changes, especially for HL7 ICSR XML reports.

The schedule for enhancements follows a regular schedule, with updates and detailed information communicated regularly through the CDRH Industry's email list.

### FDA Announces New Guidelines for Electronic Submission of De Novo Requests | 22 August 2024

The FDA has issued new guidance outlining the standards for submitting De Novo Requests electronically, including a timeline for implementation and criteria for waivers and exemptions. This initiative is part of the FDA's broader commitment to developing electronic submission templates designed to streamline the submission process and improve review efficiency. Starting October 1, 2025, all De Novo Request submissions must adhere to these electronic submission guidelines.

### FDA Enhances Safety of Pediatric and Perinatal Medical Devices | 15 August 2024

The FDA's Center for Devices and Radiological Health is enhancing patient care through its Pediatric and Perinatal Devices Program, a key initiative within the Office of Science and Engineering Laboratories. The program aims to ensure the safety and effectiveness of medical devices for children and during perinatal stages, including pregnancy and childbirth. The program aims to bridge gaps such as limited availability of pediatric-specific devices, inadequate test methods, and lack of comprehensive clinical data, while developing tools to reduce development and testing costs.

Ongoing research efforts are directed at creating advanced testing methods, datasets, phantoms, and computational models tailored to the needs of pediatric and perinatal patients.


## ANMAT and ARSA Sign Agreement to Boost Health Regulatory Collaboration | 22 August 2024

Argentina's ANMAT and Honduras' ARSA have signed a cooperation agreement to enhance scientific and technical collaboration in the health sector. The agreement aims to improve information exchange, training, and best practices in regulatory processes. It establishes a framework for joint activities to optimize procedures while adhering to national laws and competencies. The signing underscores the importance of international cooperation in tackling common health issues and driving impactful projects.

## ANMAT Revises Sales Conditions for Several Pharmaceuticals | 22 August 2024

ANMAT has updated the sales conditions for several Active Pharmaceutical Ingredients (APIs). The changes include:

- Free Sale: Retinol/Retinaldehyde (Vitamin A Palmitate) + Allantoin + Tocopherol (Vitamin E); Retinol/Retinaldehyde (Vitamin A Palmitate) + Boric Acid + Zinc Oxide; Amorolfine; Acyclovir.
- Prescription Required: Silver Sulfadiazine/Sulfadiazine Sodium (Sulfadiazine) + Lidocaine Hydrochloride (Lidocaine) + Retinol/Retinaldehyde (Vitamin A Palmitate); Betamethasone Acetate/Dipropionate/Sodium Phosphate/17-Valerate + Gentamicin + Miconazole.

New regulations will feature security overlabeling with QR codes to indicate updated sales conditions

## New Regulation on Medical Product Expiration Dates Open for Public Feedback | 15 August 2024

A new draft regulation, titled "Expiration Date Provision for Imported Products," has been released for public review. This document addresses the proposed reduction in the permitted expiration period for medical products. The draft is available for consultation and feedback from August 15 to September 19, 2024. Interested parties are encouraged to review and provide their comments during this period.

## ANMAT is not reviewing the importation of medicines from India | 10 August 2024

The National Administration of Drugs, Food and Medical Technology (ANMAT) has officially stated that it is not currently reviewing any submissions for the importation of drugs from the India.

Contrary to recent press reports suggesting that a presentation by the Mendoza government is under review, ANMAT has clarified that no such process is in progress.

The agency emphasizes that any evaluation for drug registration and authorization is conducted to ensure the product's quality, safety, and efficacy for public health.


## TGA Removes 12 Spinal Cord Stimulators from ARTG | 21 August 2024

The Therapeutic Goods Administration (TGA) has removed 12 spinal cord stimulator (SCS) devices from the Australian Register of Therapeutic Goods (ARTG) and imposed conditions of supply on 70 others.

The TGA makes regulatory decisions based on confidential commercial information and does not release standalone or interim reports. Consumers should consult their healthcare providers with any concerns about the safety or performance of their SCS devices.

Devices removed from the ARTG are not being recalled and do not need to be removed if already implanted. The Australian Commission on Safety and Quality in Health Care (ACSQHC) has released documents on clinical practices related to lower back pain and spinal cord stimulation. Ensuring appropriate patient selection and device suitability remains crucial.


## New Regulations Mandate Electronic Submissions for Medical Device Evaluations | 21 August 2024

The Federal Office for Safety in Health Care (BASG) has shifted its submission requirements for clinical evaluations and performance studies to electronic, following the revised Electronic Submission Ordinance (EEVO) 2011.

Postal submissions will no longer be accepted and deadlines will only be considered met once electronic documents are received. The BASG is revising its guidance to comply with this new requirement.

Applications for clinical investigations and performance studies will be blocked if they are missing, corrupted, lack a final positive ethics vote, or fail to meet required documentation standards.


## Anvisa Launches New Inspection Guidelines to Enhance Health Surveillance | 21 August 2024

Anvisa has released three new objective inspection guidelines (ROIs) to improve oversight in health services. The guidelines target therapeutic communities, services performing Type I clinical analysis tests without a supervision contract, and services conducting Type I EACs with a supervision contract.

Developed using the Potential Risk Assessment Model (Marp), the guidelines are part of a collaboration with the National Health Surveillance System (SNVS) and local health agencies across Brazil.

The guidelines aim to enhance transparency and predictability in health inspections, benefiting both the health surveillance system and the services inspected.


## Egyptian Drug Authority Warns Against Misleading Medical Product Advertisements | 25 August 2024

The Egyptian Drug Authority (EDA) has issued a warning to the public, cautioning against being influenced by advertisements promoting medical products and supplies on media outlets and satellite channels. The EDA stressed the importance of avoiding any unlicensed or unverified medical items of unknown origin that have not been approved for distribution by the Authority.

The EDA also encouraged citizens to report any misleading or inaccurate advertisements through its official website, either by using the provided link or scanning a code with their mobile devices. This initiative is part of the Authority's ongoing efforts to ensure the safety, quality, and efficacy of medical products in the Egyptian market, while empowering citizens to play a role in combating drug fraud and enhancing market oversight.


## European Commission Opens Applications for Civil Society Representatives on EMA Management Board | 22 August 2024

The European Commission is appointing four civil society representatives to the European Medicines Agency (EMA) Management Board. The positions include two for patient organizations, one for physician organizations, and one for veterinarian organizations.

Successful candidates will serve a three-year term starting June 15, 2025, with applications due October 20, 2024. The EMA Management Board convenes quarterly and requires in-person meetings for quorum. Applicants must submit applications via the EC website, and current and alternate board members can reapply.


## Swissmedic Aligns with EU Reforms to Secure In Vitro Diagnostic Device Supply | 14 Auugust 2024

Swissmedic has started enforcing EU updates to prevent supply shortages of in vitro diagnostic devices in Switzerland. The EU adopted Regulation 2024/1860, extending certificate validity until 2027-2029 to address bottlenecks at notified bodies. Switzerland's Federal Council announced these changes will be adopted in Switzerland to prevent supply disruptions.

Amendments to MedDO and IvDO are expected in autumn 2024, with product registration requirements taking effect in 2026. Swissmedic will follow updated EU conditions for certificate extensions.

## Swissmedic Launches First Module of swissdamed Medical Devices Database| 06 August 2024

The new Swissmedic database, swissdamed, for registering medical devices and economic operators in Switzerland went live on August 6, 2024. swissdamed is being rolled out in phases, with the initial launch of the "Actors" module enabling economic operators to register online. This platform aims to enhance transparency and information access for healthcare professionals and the public by centralizing data on medical devices and their associated companies, including manufacturers.

The system will eventually consist of two main modules—"Actors" and "Devices"—along with a public website. While the "Actors" module is now operational, the "Devices" module will be introduced gradually, starting in 2025. The platform's design aligns closely with the EU's EUDAMED database, ensuring consistency with European regulations. Device registration will become mandatory only after the swissdamed platform is fully developed and relevant legal adjustments are made.

Swissmedic has already informed previously registered economic operators about the necessary steps to transition to swissdamed. Further details and specifications will be published on the swissdamed website as the rollout progresses.

MEXICO

## Mesoamerican Health Authorities to Enhance Regional Cooperation on Laboratory Practices and Pharmacovigilance | 13 August 2024

The Mesoamerican Regulatory Roundtable, organized by Mexico's Federal Commission for the Protection against Sanitary Risks and the Mexican Agency for International Development Cooperation, aims to strengthen regulatory frameworks across the region. The event, organized by Mexico's Federal Commission for the Protection against Sanitary Risks, will focus on key regulations related to good laboratory practices, clinical trial safety assessments, and pharmacovigilance. The roundtable will discuss medicine authorization, medical device authorization, sanitary inspections, laboratory standards, and pharmacovigilance. The discussions will take place at the National Reference Laboratory in Mexico City.

## Mesoamerican Health Authorities to Enhance Regional Cooperation on Laboratory Practices and Pharmacovigilance | 13 August 2024

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## UNITED STATES OF AMERICA (USA)

### U.S. FDA Launches New Features in Cosmetics Direct for Improved Product Management | 02 August 2024

Cosmetics Direct, the electronic submission gateway for cosmetic facility registration and product listing under the Modernisation of Cosmetics Regulation Act of 2022 (MoCRA), has two additional capabilities, according to an announcement made by the U.S. FDA on July 29, 2024. The purpose of these revisions is to give accountable parties—manufacturers, packers, or distributors—whose names are on the product label—more control over how their registration and listing details are managed.

Cosmetics Direct now offers the following new features:

- **Cosmetic Product Listing Discontinuation**: Using this function, responsible individuals can designate as discontinued any cosmetic goods that are no longer sold. In contrast to deletion, discontinuation preserves the product data within the system, making it simple to relist the product in the event that it is later reintroduced.
- Relisting of Discontinued Products: This functionality makes it easier for responsible parties to reintroduce previously discontinued products to the market.

### U.S. FDA Delays Rulemaking on Fragrance Allergens and Asbestos Testing Methods Under MoCRA | 05 August 2024

The "Spring 2024 Unified Agenda of Regulatory and Deregulatory Actions" (the "Unified Agenda"), published on July 5, 2024 by the Office of Information and Regulatory Affairs (OIRA), contains updates on a number of proposed rules pertaining to cosmetics in the US.

Among these revisions is the postponement of the rulemaking process for two significant proposed rules under the Modernisation of Cosmetics Regulation Act of 2022 (MoCRA) relative to their initial schedules, with the possibility of more delays:

- Disclosure of Fragrance allergies in Cosmetic Labelling: By June 29, 2024, the FDA was required by MoCRA to publish a proposed rule that would create a list of fragrance allergies and require that information be disclosed on product labels. This proposed rule is now scheduled to be released in October 2024, according to the Unified Agenda.
- Testing Procedures for Finding and Identifying Asbestos in Cosmetic Products Containing Talc: In accordance with MoCRA, the FDA was obligated to submit a regulation by December 29, 2023, that would establish standardised testing procedures for finding and identifying asbestos in cosmetic products containing talc. The deadline for this proposed rule was extended to July 2024, but no pertinent proposal has been made public as of yet.

The Unified Agenda also revised the schedule for a proposed rule to prohibit the use of formaldehyde and formaldehyde-releasing chemicals in hair straightening and smoothing products, in addition to these delays caused by MoCRA. Originally unveiled by the FDA in October 2023, the proposed regulation is now slated for release in September 2024.

Since the law's adoption in December 2023, a number of MoCRA sections have already become operative, despite these delays. Among them are the specifications for facility registration, product listing, safety substantiation, professional-use cosmetics labelling, adverse event documentation, and reporting of significant adverse events. By the end of 2024, it will be mandatory to list the U.S. contact information on labels in order to receive complaints of adverse events.

## EUROPEAN UNION (EU)

### EU SCCS Issues Preliminary Opinions on Three Cosmetic Ingredients | 02 August 2024

The EU Scientific Committee on Consumer Safety (SCCS) published two preliminary opinions on August 1, 2024, in relation to three substances used in cosmetics. One viewpoint discusses sodium 2-biphenylolate and biphenyl-2-ol, while the other focusses on HC Yellow No. 16. The public may comment on these viewpoints through September 27, 2024.

SOUTH KOREA

## South Korea Consults on Cosmetic Safety Standard: Enhancing Management of UV filters, D4, D5, and Other Ingredients | 05 August 2024

The Ministry of Food and Drug Safety (MFDS) published a notice on August 2, 2024, asking for feedback on proposed changes to Cosmetic Safety Standard. The authority suggested increasing the consumption restrictions of six banned chemicals, designating one new UV filter, and removing one UV filter.

## South Korea Clarifies the Labeling Methods for Salicylic Acid-Contained Cosmetics | 07 August 2024

The Korean Cosmetic Association (KCA) published a notification on August 1, 2024, outlining the correct labelling procedures for cosmetic claims pertaining to salicylic acid1.

Salicylic acid is recognised as a useful ingredient in rinse-off acne and pimple solutions in South Korea which should only be used as a preservative in general cosmetics. However, the MFDS discovered instances in which salicylic acid-containing general cosmetics were promoted for their ability to exfoliate skin and regulate sebum production. Following collaborative research with the MFDS Cosmetics Policy Division, KCA released the review findings and future strategies for the enterprise's reference.

Salicylic acid labelling and promotion for uses other than preservation is often prohibited for general cosmetic products. On the other hand, if salicylic acid extracts were utilised in regular cosmetics, the goods may be marketed and labelled with exfoliation control efficacies. In this instance, it is not allowed to directly advertise or label the salicylic acid component.

The current advertising and labelling practices will be addressed by the MFDS through corrective measures. There are adjustment periods provided: six months until January 2025 for advertising, and one year until July 2025 for labelling. Administrative surveillance will thereafter take place.

## South Korea Functional Cosmetic Evaluation Situation in 2024 H1 | 08 August 2024

On July 30, 20241, the Ministry of Food and Drug Safety (MFDS) through the National Institute of Food and Drug Safety Evaluation (NIFDS) announced the "Functional Cosmetics Evaluation Status in 2024 H1". MFDS anticipates that these data will be a fundamental resource for functional cosmetic research and development after they are released.

The number of functional cosmetics examined by the Korean authority in the first half of 2024 was 572, an increase of 48 (9%) over the same period in the previous year (524). With 169, UV-filters held the highest percentage, followed by hair dyes, wrinkle-improvement, UV protection, and whitening cosmetics, as well as goods that assist reduce hair loss.

Remarkably, the number of hair colour cases (including bleaching and de-dying) rose dramatically from 29 in 2023 H1 to 143 in 2024 H1. This is perhaps because the business is actively creating a variety of coloured hair dye products in response to consumer demand.


## Thailand Reports a Non-Compliant Batch of Imported Cosmetics with Microbiological Violations | 16 August 2024

The Thai Food and Drug Administration (Thai FDA) is authorised to disclose the results of any inspection or analysis of cosmetics that are not in compliance, or are suspected of being in compliance, with the Cosmetic Act 2015, B.E. 2558 (2015), Thailand's governing cosmetic law.

Cosmetics containing pathogenic microorganisms like Pseudomonas aeruginosa, Staphylococcus aureus, Candida albicans, and Clostridium spp. (limited to cosmetics products containing herbal ingredients) are prohibited from production, import, and sale, according to the Ministry of Public Health's 2016 Announcement Regarding Determination of Characteristics of Cosmetics Prohibited for Production, Import, or Sale.

Cosmetics intended for children under three years old, mucous membranes, or the area around the eyes must have a total bacterial count greater than 500 CFU/g or CFU/ml. The restriction is set at 1,000 CFU/g or CFU/ml for all other cosmetics.

Manufacturers and importers of cosmetic items that violate these microbiological limitations may face up to two years in prison, a fine of up to 200,000 baht, or both under the Cosmetic Act of 2015. Retailers who sell these kinds of illegal cosmetics risk fines of up to 50,000 baht, six months in jail, or both.

Strict adherence to these microbiological criteria is required of companies exporting cosmetics to Thailand in order to prevent applicable legal and financial consequences.


**Australia Releases Interim Decisions to Amendments of Poisons Standard for Public Consultation | 06 August 2024**

A public consultation on proposed changes to eight drugs in the Poisons Standard was opened by Australia's Therapeutic Goods Administration (TGA) on January 5, 2024. These changes were considered at the Advisory Committee on Medicines Scheduling (ACMS) and the Advisory Committee on Chemicals Scheduling (ACCS) sessions in March 2024. The TGA published the interim findings pertaining to these proposals on July 26, 2024, and opened up public comment on the rulings. It is recommended that stakeholders take part in the consultation by August 23, 2024.

The suggested changes centre on eight different chemicals. Ethyl lactyl retinoate and tranexamic acid are two that are associated with cosmetic use.

The proposed amendments seek to add new exclusions to the current Schedule 4 Prescription Only Medicines and Prescription Animal Remedies listings for tranexamic acid and tretinoin.


## Canada Requires Companies to Provide PFAS Information | 12 August 2024

The notice was published in the Canada Gazette, Part I, Volume 158, Number 30 by the Government of Canada on July 27, 2024. By January 29, 2025, pertinent companies are required by this notice to provide information regarding the per- and polyfluoroalkyl substances (PFAS) listed in Schedule 1 of the notice. The Environment Minister shall receive the information through the Environment and Climate Change Canada Single Window, an online reporting mechanism.

The aim of this data collection is to evaluate the potential toxicity or non-toxicity of these PFAS. The government also seeks to assess whether controls are required in light of the risks these drugs bring.

The impacted parties' assigns or successors are also covered by this notice. Substances used for personal use, laboratory analysis or study, hazardous trash or recyclables, registered as pest control products, fertilisers, feeds, or mixes with registered seeds are not covered by this law, nor are substances that are simply in transit through Canada. In addition, microbusinesses are exempt from the notification.


## Malaysia NPRA Releases Cosmetics GMP Inspection Deficiency Report | 13 August 2024

A deficiency analysis report on routine on-site Good Manufacturing Practice (GMP) inspections of cosmetics manufacturers carried out in 2023 was made public by Malaysia's National Pharmaceutical Regulatory Agency (NPRA) on July 24, 2024. The report includes routine on-site inspections conducted between January and December 2023 of manufacturing facilities for a variety of items, including cosmetics.

Five out of the 130 domestic cosmetics manufacturers inspected had an inadequate GMP status, while 125 of the businesses were judged to have an acceptable GMP status.

Due to their unsatisfactory GMP status, two out of the five producers faced regulatory action. The detected GMP flaws were divided into three categories: minor, significant, and critical.


## Indonesia Revises Cosmetic Types Prohibited from Online Sales | 16 August 2024

On Aug. 21, 2023 and Jan 22, 2024, Indonesia released the initial draft and second draft amended Regulation Concerning the Control of Drug and Food Online Distribution. On August 5, 2024, the finalized version was released and implemented. This regulation primarily focuses on regulating the criteria for online sales of drugs (including cosmetics) and food. It is worth noting that cosmetics sold online must possess a notification number.


## India CDSCO Introduces New Restrictions on Cosmetics Applications | 21 August 2024

The Indian Cosmetics Regulatory Council (CDSCO) has introduced a new registration and import procedure for cosmetics, limiting the number of products per application to 50. The modification, effective since August 16, 2024, aims to increase efficiency, simplify the process, and ensure compliance with the Cosmetics Rules, 2020 deadlines. The Central Licensing Authority has six months to review, grant an import registration certificate, or reject the application.

**List of ISO standards updated in August 2024:**

- ISO 11040-4:2024 - Prefilled syringes — Part 4: Glass barrels for injectables and sterilized subassembled syringes ready for filling
- ISO 5362:2024 - Anaesthetic and respiratory equipment – Anaesthetic reservoir bags
- ISO 17256:2024 - Anaesthetic and respiratory equipment — Respiratory therapy tubing and connectors
- ISO 23138:2024 - Biological equipment for treating air and other gases — General requirements
- ISO 7197:2024 - Neurosurgical implants — Sterile, single-use hydrocephalus shunts
- ISO 5910:2024 en Cardiovascular implants and extracorporeal systems — Cardiac valve repair devices
- ISO 23500-2:2024 en fr Preparation and quality management of fluids for haemodialysis and related therapies — Part 2: Water treatment equipment for haemodialysis applications and related therapies
- ISO/IEEE 11073- 10206:2024 - Health informatics — Device interoperability — Part 10206: Personal health device communication — Abstract content information mode