Newsletter

REGULATORY BRAINBOX

OMC MEDICAL
Regulatory Services

Medical Devices Regulatory Consultancy

FEBRUARY NEWSLETTER 2025

How we can help?

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

SPECIAL OFFER
15% OFF

On EU Language Translation*

*Terms and conditions apply; we only use actual translators and not machine translations

Contact Us

www.omcmedical.com

info@omcmedical.co.uk

+44 7458300825

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

+44 7458300825 | info@omcmedical.co.uk

CONTENTS

MEDICAL DEVICES

COSMETICS

ISO STANDARDS

EUROPEAN UNION (EU)

MDCG Releases MDCG 2019-6 rev.5: Updated Guidance on Notified Bodies | 07 February 2025

On February 7, 2025, the Medical Device Coordination Group (MDCG) published the fifth revision of its guidance document, "MDCG 2019-6 rev.5 - Questions and Answers: Requirements Relating to Notified Bodies." This update provides enhanced clarity on the roles and expectations of notified bodies under EU medical device regulations.

Key Updates Include:

- **Organizational Requirements:** New questions (I.5.1 and I.5.2) offer clearer guidance on organizational obligations.
- **Scope of Activities:** Revised questions (I.6.1 to I.6.3) clarify the scope of activities that notified bodies can perform.

These updates aim to improve consistency and transparency in the conformity assessment process.

EU Launches Pilot Program for Coordinated Assessment | 06 February 2025

The European Commission is inviting sponsors of multinational clinical studies to participate in a new pilot program for coordinated assessments under Articles 78 MDR and 74 IVDR.

This initiative allows sponsors to submit a single application across multiple Member States, streamlining the approval process and ensuring more consistent evaluations. By harmonizing the assessment procedures, the pilot aims to reduce administrative burdens, enhance transparency, and enable faster decision-making.

Sponsors interested in participating should submit an expression of interest to SANTE-CA-CIPS@ec.europa.eu by June 30, 2025. This pilot is an opportunity to engage with a more efficient and coordinated regulatory system.

UNITED KINGDOM (UK)

MHRA Updates Guidance on Medicine Reclassifications | 20 February 2025

The Medicines and Healthcare products Regulatory Agency (MHRA) has updated its guidance on the reclassification of medicines, including the latest list of approved changes. This update provides important information for pharmaceutical companies and healthcare professionals looking to change a medicine's classification, such as from Prescription Only Medicine (POM) to Pharmacy (P) or General Sales List (GSL).

Reclassifying medicines improves patient access to treatments while maintaining safety standards. The updated guidance outlines the evidence required to demonstrate that medicines can be safely used without prescription oversight.

MHRA Updates DEKRA Certification UK Ltd Details in UK Approved Bodies List | 19 February 2025

The Medicines and Healthcare products Regulatory Agency (MHRA) has updated its list of UK approved bodies for medical devices, reflecting changes for **DEKRA Certification UK Ltd** (Approved Body number 8505).

This amendment includes updated contact information and details about DEKRA's role in issuing UK Conformity Assessed (UKCA) certifications for medical devices and in vitro diagnostic medical devices under the UK Medical Devices Regulations 2002 (SI 2002 No 618, as amended).

MHRA Updates Pharmacovigilance Guidance for UK Marketing Authorisation Holders | 19 February 2025

The Medicines and Healthcare products Regulatory Agency (MHRA) has issued updated guidance on the exceptions and modifications to the European Union's Good Pharmacovigilance Practices (GVP) that apply to UK Marketing Authorisation Holders (MAHs) and the MHRA. This update clarifies how certain EU GVP guidelines have been adapted or do not apply within the UK regulatory framework.

Key changes include adjustments to the roles and responsibilities of the Qualified Person responsible for Pharmacovigilance (QPPV), updates to the Periodic Safety Update Reports (PSURs) submission process, and revised procedures for post-authorisation safety studies.
UK MAHs are advised to review this updated guidance to ensure compliance with current pharmacovigilance obligations.

Swissmedic's Assessment of Post-Market Surveillance Documentation | 17 February 2025

Swissmedic has conducted a review of post-market surveillance (PMS) documentation for 30 high-risk legacy medical devices to ensure compliance with the Medical Devices Ordinance (MedDO). The review aimed to verify that manufacturers effectively monitor their devices once they reach the market, capturing safety trends that may only emerge after extended use. Manufacturers are required to establish PMS systems, create detailed plans, and periodically document safety analyses in reports.

Swissmedic identified non-conformities in 20 out of 30 cases, with 85 instances related to Articles 56, 58, 60, and 61 of MedDO. The issues were mainly related to inadequate systems for collecting and analyzing post-market data, absence of plans or plans that did not meet regulatory standards for 11 products, and inconsistencies between PMS plans and safety reports. Swissmedic has mandated corrective actions to resolve these non-conformities and encouraged Swiss authorized representatives to communicate the findings to foreign manufacturers they represent.

The review highlights gaps in compliance with PMS requirements and underscores the importance of vigilant post-market surveillance in safeguarding public health.

Algeria Chosen as North Africa's Pharmaceutical Registration Hub | 20 February 2025

Algeria has been designated as the contact point for pharmaceutical registration in North Africa, represented by the National Agency for Pharmaceutical Products (ANPP). This move underscores Algeria's growing influence in the regional pharmaceutical industry and its commitment to regulatory advancement.

As the regional contact point, the ANPP will streamline pharmaceutical registration processes, facilitate faster access to essential medicines, and harmonize regulatory standards across North Africa. This step also supports Algeria's ambition to expand pharmaceutical exports within Africa, solidifying its position as a key player in the continent's healthcare landscape.

ARGENTINA

PAHO Launches Technical Sessions to Strengthen Health Regulation in the Americas | 18 February 2025

The Pan American Health Organization (PAHO) initiated a series of technical sessions in Buenos Aires from February 18 to 20, aimed at strengthening the National Regulatory Reference Authorities (NRAs) in health across the Americas. The event brings together representatives from regulatory agencies in Argentina, Brazil, Colombia, Cuba, Mexico, and Chile.

The sessions focus on enhancing regional collaboration to improve access to quality and safe health technologies. Working groups are addressing key areas such as interagency communication, public information transparency, performance indicators, and interlaboratory testing. These discussions build on decisions made at the last NRAs meeting in Washington, D.C.

The initiative is part of an ongoing effort to bolster regulatory capacities as the region advances toward the designation of reference authorities for medicines. This development aligns with the evolving technological landscape and regulatory challenges in the health sector.

BRAZIL

Anvisa Streamlines Access to Good Manufacturing Practice Certificates | 25 February 2025

The Brazilian Health Regulatory Agency (Anvisa) has improved access to Good Manufacturing Practice (GMP) certificates through its official platforms. These certificates are crucial for manufacturers of pharmaceuticals, medical devices, and other health-related products.

GMP certificates are valid for two years, but for medical device manufacturers in the Medical Device Single Audit Program (MDSAP), the validity extends to four years under Resolution RDC 850/2024. Anvisa also provides dashboards for tracking inspections and compliance.

Anvisa Trains Teams on VigiMed and MedDRA for Better Drug Safety | 21 February 2025

Anvisa held a training session in Brasília to enhance pharmacovigilance using VigiMed and MedDRA tools. The event aimed to improve drug safety monitoring and regulatory communication.

VigiMed allows reporting of adverse drug and vaccine events, helping monitor safety in Brazil. MedDRA standardizes medical terminology for international regulatory use, supporting system interoperability.

Participants practiced using the tools, boosting their understanding of digital pharmacovigilance. The training reinforces Anvisa's commitment to effective drug safety strategies.

Anvisa Seeks Input to Improve Borderline Product Classification | 14 February 2025

Anvisa aims to enhance the classification process for borderline products, which are difficult to categorize as medicines, medical devices, cosmetics, or food due to their composition or use. The initiative is part of its 2024-2025 Regulatory Agenda.

To gather industry insights, Anvisa launched Directed Consultation 01/2025 on February 14. The feedback will help design new, more transparent and efficient procedures, supporting innovation and public access to new products.

The review follows growing demand and builds on the work of the Committee for Classification of Products Subject to Health Surveillance (COMEP), established in 2016 to advise on borderline product classifications.

HALMED Publishes PSUSA Procedure Outcomes for Medicinal Products| 19 February 2025

The Agency for Medicinal Products and Medical Devices of Croatia (HALMED) has announced the outcomes of the PSUSA procedures related to medicinal products authorized in Croatia. Detailed information can be found on the HALMED website under the Medicinal products/ Variation applications section.

According to the Medicinal Products Act and EU Regulation, marketing authorization holders must ensure that product information is aligned with the latest scientific knowledge. If the PSUSA outcomes require regulatory changes, such as updates to the Summary of Product Characteristics (SmPC) and the Package Leaflet (PL), authorization holders are required to submit a variation application, including the relevant PSUSA procedure number.

This update aims to maintain the safety and efficacy of medicinal products in line with current scientific standards.

Egypt Leads North Africa's Drug Regulatory Harmonization | 20 February 2025

Egypt hosted the inaugural meeting of the North Africa Medicines Regulatory Harmonization (NA-MRH) initiative, collaborating with the African Union Agency for Development (AUDA-NEPAD) and the World Health Organization (WHO). Egypt was elected as President of the initiative for three years, with Morocco as Vice President and Tunisia as the Technical Secretariat.

The meeting aimed to enhance regional cooperation in drug regulation, streamline registration procedures, and ensure the safety and quality of medicines. It also focused on developing unified legal and technical frameworks to support pharmaceutical integration among member states.

Egypt's leadership in the initiative underscores its role in advancing regulatory systems in North Africa and strengthening regional drug security.

Finnish Notified Body Expands Services for Medical Device Approval | 24 February 2025

The Finnish Medicines Agency (Fimea) has extended the scope of SGS Fimko Oy's designation as a notified body under the Medical Devices Regulation (MDR 2017/745). This expansion enables SGS Fimko Oy to offer a broader range of services to medical device manufacturers. The update was published on the European Commission's Nando database on February 22, 2025.

This extension is expected to enhance the capacity of notified bodies, supporting the introduction of new, innovative medical devices to the market. In Finland, Fimea is responsible for designating and supervising notified bodies for medical devices and actively collaborates with European authorities in their evaluation and oversight.

Manufacturers are free to choose any European notified body that meets their needs, allowing Finnish-designated bodies like SGS Fimko Oy to serve both domestic and international clients.

PAKISTAN

Pakistan Amends Drugs (Research) Rules Under S.R.O 168(I)/2025 | 18 February 2025

On February 18, 2025, the Drug Regulatory Authority of Pakistan (DRAP) issued S.R.O 168(I)/2025, announcing amendments to the Drugs (Research) Rules, 1978. These revisions aim to enhance the regulatory framework governing drug research within the country. While the specific details of the amendments have not been publicly disclosed, stakeholders are encouraged to review the official notification available on DRAP's website.

These changes are part of DRAP's ongoing efforts to align Pakistan's pharmaceutical research standards with international best practices, ensuring the safety and efficacy of drugs developed and tested domestically.

SAUDI ARABIA

Saudi Arabia Introduces Traveler's Permit for Controlled Drugs | 12 February 2025

Saudi Arabia has introduced a new permit system to streamline the process for travelers carrying controlled medications. Launched at the LEAP 2025 conference, the "Traveler's Permit for Controlled Drugs" service allows travelers to declare their medications in advance through the Electronic Controlled Drugs System (CDS) at https://cds.sfda.gov.sa.

Travelers must provide details about the type and quantity of medication and the duration of their stay. Once approved, the permit can be presented at entry points, ensuring compliance with local and international regulations. The system enhances oversight and prevents misuse while simplifying the declaration process.

This initiative not only strengthens drug monitoring but also contributes to a smoother travel experience, supporting Saudi Arabia's vision of becoming a leading global tourist destination as part of Vision 2030.

Saudi Arabia Charts New Regulatory Pathways for Healthspan Innovation | 04 February 2025

Riyadh hosted the Global Healthspan Summit 2025, where experts discussed the role of regulatory frameworks in advancing health innovations while ensuring public safety. The panel focused on how regulations can promote longer, healthier lifespans by influencing the entire healthspan lifecycle, from disease prevention to the adoption of new health technologies.

Saudi Arabia is actively developing its regulatory capabilities and collaborating with innovators and biotech companies. The country has introduced dedicated pathways for medicines, AI, medical devices, and smart health solutions to streamline product approvals and enhance accessibility.

A key focus of the discussion was redefining food's role in health. Building on initiatives like calorie labeling and salt reduction, Saudi Arabia aims to address chronic diseases linked to aging by examining food components more closely. This approach seeks to influence industry practices, improve community health, and reduce hospitalizations.

The summit highlighted Saudi Arabia’s commitment to pioneering healthspan innovation while maintaining a balance between safety and progress.

EUROPEAN UNION (EU)

EU Updates Borderline Manual with Classification Guidance for Products in Vials and Ampoules | 24 February 2025

On January 24, 2025, the European Commission released an updated version of the ***Manual of the Working Group on Cosmetic Products (Sub-group on Borderline Products)***, which provides guidance on the application of the Cosmetics Regulation (EC) No 1223/2009 (Art. 2(1)(A)). This revision introduces a dedicated section addressing the classification of products in vials or ampoules.

The ***Cosmetics Regulation*** defines cosmetic products based on their nature, application site, and intended purpose. However, some products—known as "borderline products"—pose classification challenges, as it may be unclear whether they fall under the Cosmetics Regulation or other regulatory frameworks. To clarify such cases, the Commission maintains the ***Borderline Manual.***

Compared to the February 2024 edition, the updated manual adds Section 3.3.34. Products in a ***Vial or Ampoule***, which provides specific criteria for determining whether these products qualify as cosmetics. It states that substances or mixtures in vials or ampoules intended for injection do not fall within the definition of cosmetics. For a product to be classified as a cosmetic, it must:

- Serve a cosmetic function (e.g., cleansing, perfuming, or addressing body odours of external body parts).
- Be intended exclusively for external use, with clear labelling and instructions specifying external application.
- Be presented in a way that avoids ambiguity and prevents confusion with medicinal products or medical devices.
- Not be marketed with a device that enables injection or delivery below the epidermis.

Additionally, the updated manual underscores that national competent authorities are responsible for product classification on a case-by-case basis. Their assessment should consider factors such as product presentation, usage instructions, intended function, ingredients, mode of action, and marketing approach.

EU Commission Launches Call for Evidence on the EU CPR | 24 February 2025

On February 21, 2025, the EU Commission initiated a call for evidence as part of its evaluation of the *EU Cosmetic Products Regulation (EU CPR)*—marking the first step in this review process.

The evaluation aims to assess how the regulation is implemented, whether it has achieved its objectives, and if it remains suitable in light of the green and digital transitions, as well as the competitiveness of EU businesses both internally and globally. The review covers all aspects of the regulation, including the *Cosmetic Products Notification Portal (CPNP)*.

Following this call for evidence, the EU Commission plans to launch a 12-week public consultation in the second quarter of 2025. A final report on the consultation findings will likely be published before any regulatory changes, which are expected to be adopted in the second quarter of 2026.

CFS Requirement Lifted for UK Cosmetics in Most CPTPP Member States | 11 February 2025

On 5 February 2025, the UK Department for Business and Trade (DBT) announced changes to Certificates of Free Sale (CFS) for cosmetic products due to the UK's accession to the Comprehensive and Progressive Agreement for Trans-Pacific Partnership (CPTPP).

Under Article 19 of the Cosmetics Annex 8-D of CPTPP, CFS are no longer required to market, distribute, or sell cosmetic products in the following CPTPP member countries:

- Brunei
- Chile
- Japan
- Malaysia
- New Zealand
- Peru
- Singapore
- Vietnam
- Australia.

However, CFS are still required for exports to Canada and Mexico, as these countries have not yet ratified the UK's accession. DBT will provide further updates once ratification is completed in Canada and Mexico.

SOUTH KOREA

South Korea Proposes New Guidelines for Lifting Bans on Prohibited Ingredients | 24 February 2025

On February 21, 2025, South Korea's Ministry of Food and Drug Safety (MFDS) opened a public consultation on proposed amendments to the Regulations on the ***Designation and Change of Cosmetic Ingredient Standards***. Stakeholders interested in submitting feedback on the draft revisions must do so by March 13, 2025.

South Korea Amends Labelling Requirements for Cosmetic Packaging | 18 February 2025

On February 7, 2025, South Korea's Ministry of Food and Drug Safety (MFDS) implemented amendments to the Enforcement Rule of the Cosmetics Act, which took effect immediately upon publication.

A key revision exempts the submission of certain documents if they are issued in electronic format. These include cosmetic manufacturing registration licenses, functional cosmetics evaluation result notifications, and cosmetic responsible sales business registration certificates.

Additionally, the amendments introduce significant updates to cosmetic packaging labeling requirements, with notable revisions to Annex 4 – Standards and Methods for Labeling on Cosmetic Packaging.

Canada Implements Phased Compliance for Fragrance Allergen Labelling in Cosmetics | 26 February 2025

On April 24, 2024, Health Canada published amendments to the Cosmetic Regulations in Canada Gazette, Part II, Volume 158, Number 9, introducing mandatory labelling of fragrance allergens in cosmetics with a phased implementation:

- **By April 12, 2026:** Both new and existing cosmetics must list 24 fragrance allergens (Appendix 1, List 1, Industry Guide for the Labelling of Cosmetics) in the ingredient list if present above 0.01% in rinse-off products or 0.001% in leave-on products.

- **By August 1, 2026:** New cosmetics must disclose 81 fragrance allergens from Lists 1 and 2 (Appendix 1, Industry Guide for the Labelling of Cosmetics) if they exceed 0.01% in rinse-off products or 0.001% in leave-on products.

- **By August 1, 2028:** Existing cosmetics must also comply with the requirement to disclose 81 fragrance allergens under the same concentration thresholds.

To address industry concerns about meeting compliance deadlines, Health Canada's Consumer and Hazardous Products Safety Directorate issued a notice on February 21, 2025, outlining the phased compliance approach.

- **Phase 1 (April 12, 2026 – April 11, 2027):** Health Canada will prioritize compliance promotion through education, guidance, and stakeholder collaboration. Efforts will focus on providing information, consulting with industry, and supporting policy and regulatory development. However, if health or safety-related complaints arise after the 24-allergen labelling requirement takes effect on April 12, 2026, the agency will assess them using its standard risk-based process.

- **Phase 2 (From April 12, 2027 onward):** Full compliance and enforcement will begin, following a risk-based approach aligned with departmental and program guidelines.

The transition periods for other amendments under Canada Gazette, Part II, Volume 158, Number 9, remain unchanged.

INDONESIA

Indonesia's New Cosmetic Notification System – Notifkos 3.0 Officially Launched | 25 February 2025

On July 12, 2024, the Indonesian Food and Drug Authority (BPOM) officially launched the updated Notifkos cosmetic notification system. The Notifkos 3.0 system became fully operational on January 2, 2025, introducing several enhancements and new functionalities.

Key Updates in Notifkos 3.0

- **Streamlined A-Window (Enterprise Verification) and B-Window (Enterprise Data Update) Processes:** Businesses can now update their data independently without appointment emails or queue numbers. Once the completed template is submitted, reviewers verify the information directly within the system.
- **Full Integration with OSS:** The system now supports all cosmetic notification services, including new applications, updates, and modification notifications.
- **Simplified Enterprise/Factory Modification Process:** In-person queuing is no longer required. Fees are based solely on the modification application, and changes are automatically applied to all related products.
- **Direct Product Deregistration Requests**: Businesses can now submit deregistration requests directly within the system.
- New Packaging Update Feature for Export-Only Products.
- Enhanced Notification and Supplementary Information Functions for Packaging Changes.

ARGENTINA

ANMAT Prohibits Unauthorized Hair Straighteners Due to Health Risks | 12 February 2025

ANMAT has issued a prohibition on the use, commercialization, distribution, advertising, and online sale of unauthorized hair straighteners. This decision comes after detecting products on the market that lack proper registration, posing significant health risks to users and applicators.

The most commonly reported adverse effects include irritation, redness, and itching of the scalp or skin. Additionally, some products were found to contain dangerous concentrations of harmful substances or were contaminated with bacteria, fungi, or mold due to inadequate hygiene controls during manufacturing.

A particular concern is the presence of formaldehyde in some hair straighteners. When used for hair straightening, formaldehyde can release toxic fumes that may cause serious health issues, including an increased risk of carcinomas, especially nasopharyngeal carcinomas.

To safeguard public health, ANMAT urges consumers to verify the list of registered hair straighteners to ensure they are using authorized and safe products.

TGA Literature Review Confirms Sunscreen Benefits Outweigh Minimal Risks | 04 February 2025

The Therapeutic Goods Administration (TGA) has released a literature review on active ingredients used in sunscreens to identify any new evidence regarding their safety. The review reinforces that the benefits of sunscreen in preventing skin cancer far outweigh any minimal theoretical risks associated with frequent use. In Australia, approximately 2,000 people die each year from skin cancer, highlighting the importance of sun protection, including sunscreen.

The TGA's ongoing monitoring ensures the highest standards of quality, safety, and efficacy for therapeutic goods in the Australian market. The review is also informed by the Australian Sunscreen Exposure Model (ASEM), which evaluates sunscreen usage rates among children and adults in Australia.

Anvisa Cancels 47 Hair Styling Ointments for Non-Compliance | 24 February 2025

Anvisa Cancels 47 Hair Styling Ointments for Non-Compliance
Anvisa has canceled 47 hair styling ointments, effective immediately, as part of ongoing efforts to ensure product safety. The cancellation, announced on Monday (24/2) through Resolution-RE 681/2025, follows reports of adverse events linked to these products.

The affected ointments were regularized through the notification method but failed to comply with RDC 814/2023 requirements.

Most did not meet Article 5, which mandates that products notified before September 15, 2023, must update their registration in the SGAS system by December 31, 2024. Required updates include a valid health license, detailed usage instructions, and a safety declaration digitally signed by the manufacturer. Non-compliance resulted in the immediate cancellation of product registration.

Since the introduction of RDC 814 in September 2023, all new hair ointments must be registered with Anvisa to ensure they meet safety and technical standards. Notified products with irregularities are now being systematically canceled. Manufacturing or selling unauthorized products is a health violation subject to penalties under Law 6,437/1977.

Anvisa publishes a list of authorized ointments, and only those listed are permitted for sale.

VIETNAM

Vietnam Amends Circular 06/2011/TT-BYT Providing Cosmetic Management | 24 February 2025

On February 10, 2025, the Drug Administration of Vietnam (DAV) issued a draft Circular proposing amendments to certain articles and appendices of Circular 06/2011/TT-BYT. The key revisions include:

- **Electronic Cosmetic Notification:** Enhancing the administrative process for electronic submission of cosmetic notifications to better align with practical requirements.

- **Decentralization of Administrative Procedures:** Transferring the responsibility for approving import orders of cosmetics intended for research and testing from the Ministry of Health to local Departments of Health based on the location of the importing organization's headquarters.

List of ISO standards updated in February 2025:

- ISO 16900- 6:2021/Amd 1:2025 - Respiratory protective devices — Methods of test and test equipment — Part 6: Mechanical resistance/strength of components and connections — Amendment 1

- ISO 16900-11:2025 - Respiratory protective devices — Methods of test and test equipment — Part 11: Determination of field of vision

- ISO 10993- 4:2017/Amd 1:2025 - Biological evaluation of medical devices — Part 4: Selection of tests for interactions with blood — Amendment 1

- ISO/TS 81001-2-1:2025 - Health software and health IT systems safety, effectiveness and security — Part 2-1: Coordination — Guidance and requirements for the use of assurance cases for safety and security