Newsletter

REGULATORY BRAINBOX

OMC MEDICAL
Regulatory Services

Medical Devices Regulatory Consultancy

SEPTEMBER NEWSLETTER

How we can help?

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

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On EU Language Translation*

Contact Us

www.omcmedical.com

info@omcmedical.co.uk

+44 7458300825

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

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

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EUROPEAN UNION (EU)

EU Releases New MDCG Guideline for Class D IVDs under IVDR | 25 September 2024

The European Commission has released a new MDCG guideline titled "Application of transitional provisions for certification of Class D in vitro diagnostic medical devices according to Regulation (EU) 2017/746." This guideline provides clarity on the transitional provisions for high-risk Class D IVDs under the In Vitro Diagnostic Regulation (IVDR).

It covers certification timelines, conformity assessment expectations, and management of legacy devices, helping manufacturers ensure a smooth transition to the updated regulatory framework.

New EU Guidance on Validity of Clinical Studies for Health Technology Assessment | 23 September 2024

The Commission has released guidance on the validity of clinical studies for joint clinical assessments under the EU Health Technology Assessment Regulation. The guidance aims to define, classify, and assess the certainty of clinical study results objectively, reproducibly, and transparently.

It covers data analysis from various types of single clinical studies. The guidance complements previous documents on outcomes, quantitative evidence synthesis, reporting requirements, and multiplicity issues in joint clinical assessments.

EU Extends Imvanex Vaccine Use to Adolescents for Mpox Protection | 20 September 2024

The European Medicines Agency (EMA) has extended the authorization of the Imvanex vaccine for adolescents aged 12-17 years, making it the only vaccine against Mpox in the EU. The approval follows a recommendation from the EMA, which assessed the vaccine as effective and safe for this age group.

The vaccine was first authorized in 2013 to protect adults from smallpox and extended in 2022 to protect adults from Mpox and vaccinia virus-related diseases. The EMA prioritized the extension of the vaccine's authorization to adolescents, and the Commission authorized it using an accelerated decision-making process.

The EMA is working with African regulators to advance vaccine authorizations in the African region.

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It covers data analysis from various types of single clinical studies. The guidance complements previous documents on outcomes, quantitative evidence synthesis, reporting requirements, and multiplicity issues in joint clinical assessments.

MHRA Seeks Applicants for AI Airlock Regulatory Sandbox | 23 September 2024

On September 23, the MHRA,announced a call for applications from manufacturers and developers of Artificial Intelligence (AI) medical devices to join the AI Airlock regulatory sandbox.

This initiative aims to tackle regulatory challenges and expedite the safe integration of innovative AI devices into healthcare. Candidates will receive tailored testing plans and expert collaboration, enhancing their understanding of regulatory requirements. Applications are open until October 7, targeting a diverse range of healthcare disciplines.

The insights gained will shape future guidelines and support the UK's MedTech framework, prioritizing patient safety and innovation.

First IVDR Application Approved in Northern Ireland | 19 September 2024

The recent establishment of a submission route for manufacturers conducting performance studies has led to the approval of the first application for In Vitro Diagnostic (IVD) devices under the EU IVDR in Northern Ireland. This process, developed over the last eighteen months in collaboration with HSCNI and HRA, signifies a crucial advancement in the regulatory management of in vitro diagnostics in the region.

This achievement demonstrates a robust and efficient framework for processing future applications. We anticipate further progress as we continue to support the implementation of this initiative, aiming to enhance public and NHS access to safe and effective medical technologies.

It is important to note that, under the Windsor Framework, the regulations for placing medical devices on the Northern Ireland market differ from those in Great Britain (England, Wales, and Scotland).

MHRA Releases New Guidelines on Labelling and Packaging of Medicinal Products | 13 September 2024

The MHRA has released new guidelines on the labeling and packaging of medicinal products for human use, aligning with the recent agreement of the Windsor Framework.

These guidelines aim to enhance clarity, compliance, and safety in product information, ensuring that consumers and healthcare professionals receive accurate and effective guidance on medicinal products.

For more information, please visit our website: <Click Here>

New Windsor Framework Rules for UK Product Licensing and Labelling Effective January 2025 | 12 September 2024

Starting 1 January 2025, the Windsor Framework will implement new regulations in the UK concerning product licensing, labelling, and the Falsified Medicines Directive (FMD). These changes will enable the Medicines and Healthcare products Regulatory Agency (MHRA) to approve and license medicines on a UK-wide basis, allowing for consistent packaging of medicines throughout the UK.

Additionally, the framework will exempt medicines marketed and supplied in Northern Ireland from the EU's FMD safety features.

Guidance for Manufacturers and Wholesale Dealers Under the Windsor Framework | 12 September 2024

The MHRA has released guidance that aims to assist manufacturers and wholesale dealers authorized by the Medicines and Healthcare Products Regulatory Agency (MHRA), along with Qualified Persons (QPs), Responsible Persons (RPs), and Responsible Persons for Import (RPIs), in effectively implementing the provisions of the Windsor Framework concerning human medicines.

For more information, please visit our website <Click here>

Early Access to Medicines Scheme: Facilitating Patient Access to Innovative Treatments| 10 September 2024

The Early Access to Medicines Scheme (EAMS) is designed to provide patients suffering from life-threatening or severely debilitating conditions with access to medicines that have not yet received marketing authorisation, particularly when there is a significant unmet medical need. This includes both new medicines and new indications for existing treatments.

Under EAMS, the Medicines and Healthcare products Regulatory Agency (MHRA) assesses the benefit-risk balance of the medicine based on the available data at the time of the EAMS submission. Patient access involves a two-step evaluation process:

1. Promising Innovative Medicine (PIM) designation
2. Early Access to Medicines Scheme Scientific Opinion

The scientific opinion facilitates the prescribing of EAMS medicines by healthcare professionals, and these medicines are made available through the EAMS Scientific Opinion holder, typically a pharmaceutical company.

The scientific opinion is valid for up to one year and can be renewed. It’s important to note that participation in the scheme is voluntary, and the scientific opinion from the MHRA does not replace standard licensing procedures for medicines.

UNITED STATES OF AMERICA (USA)

Enhancing Medical Device Submissions with the ASCA Program | 20 September 2024

The FDA's Center for Devices and Radiological Health (CDRH) is encouraging medical device sponsors to use FDA-recognized voluntary consensus standards in their submissions to reduce regulatory burdens and enhance product quality. The Voluntary Accreditation Scheme for Conformity Assessment (ASCA) Program aims to streamline conformity assessment, boost the FDA's confidence in test methods, reduce additional information requests, and promote consistency and efficiency in device reviews.

By aligning with recent legislative changes, such as the Food and Drug Omnibus Reform Act of 2022 and the Medical Device User Fee Amendments of 2022, the ASCA Program is designed to ensure timely access to safe, effective, and high-quality medical devices for patients. Overall, it represents a significant step forward in integrating standards into the regulatory process, supporting innovation while maintaining public health.

FDA Classifies New Medical Devices into Class II to Ensure Safety and Effectiveness | September 2024

The FDA has classified three medical devices into Class II (special controls) to ensure safety and effectiveness while enhancing patient access to innovative treatments. Below is a summary of each device and its classification:

Device	Purpose
Pediatric Continuous Renal Replacement Therapy System	Provides renal support for pediatric patients, ensuring safety and effectiveness.
Radiofrequency Toothbrush	Enhances dental care through innovative technology, ensuring safety and effectiveness.

Device	Purpose
Adjunctive Open Loop Fluid Therapy Recommender	Improves fluid management in clinical settings, ensuring safety and effectiveness.

These classifications demonstrate the FDA's commitment to promoting patient safety while supporting the introduction of beneficial medical innovations.

ARMENIA

New Medicine Registration Regulations in Armenia | 12 September 2024

The Minister of Health of the Republic of Armenia has issued Order No. 4896-A, allowing applications for the registration of medicines for human use to be submitted under the national procedure until December 31, 2024.

Additionally, all medicines registered nationally must have their dossiers updated to comply with EAEU requirements by December 31, 2025. Further details on the new regulations will be provided soon.

BRAZIL

Anvisa Updates Guidelines on the Safe Use and Production of Platelet-Rich Plasma (PRP)| 12 September 2024

Anvisa has revised its 2015 guidelines on the production and therapeutic use of platelet-rich plasma (PRP) to ensure safety and quality through good manufacturing practices. PRP can be used in clinical research or recognized treatments, but patients should only seek licensed healthcare providers due to potential health risks.

Anvisa has received complaints about unapproved uses of PRP, which may transmit serious infections like HIV and hepatitis. The agency urges reporting of any adverse events and choosing regulated procedures to protect public health.

Egyptian Drug Authority Launches Initiative to Safely Dispose of Expired Medicines | 25 September 2024

The Egyptian Drug Authority (EDA) has launched an initiative to safely withdraw expired medicines from the market to protect public health. The initiative, carried out in partnership with manufacturers, distributors, and pharmacies, aims to ensure proper disposal and raise public awareness about the dangers of using expired medicines.

The EDA emphasizes compliance with regulations and warns against purchasing drugs from unreliable sources, highlighting the risk of poisoning and harmful drug interactions.

Strict penalties will be imposed for non-compliance, and companies are encouraged to strengthen internal monitoring to ensure a safer pharmaceutical market.

New Service Launched by Drug Authority to Ensure Medicine Availability for Public Pharmacies | 19 September 2024

The Drug Authority has launched a new service to help public pharmacies track the availability of medicines from distribution companies and warehouses. Pharmacy officials can register their medicine requests through a dedicated link, and the authority will verify availability.

If a distributor refuses to supply available stock, legal action will be taken.

If the medicine is unavailable, the authority will coordinate with manufacturers to ensure adequate production and distribution based on consumption needs. The goal is to maintain a steady supply of medicines in pharmacies across all regions.

SWITZERLAND

Swissmedic Urges Economic Operators to Validate Their Data in swissdamed by November 2024 | 27 September 2024

In August 2024, Swissmedic reached out to all economic operators registered with a CHRN, requesting them to validate their migrated data in swissdamed within a three-month period. The final deadline for validation is 13 November 2024.

The validation involves two main steps: first, reviewing your company data, and second, verifying the information of each registered actor. Make sure to follow the detailed instructions provided to complete all five steps.

This validation is a mandatory requirement for all registered economic operators and is crucial for ensuring the data integrity and reliability of swissdamed's Actors module. It also lays the groundwork for the successful implementation of the upcoming Devices module and supports an accurate overview of the Swiss medical devices market.

Swissmedic Releases New Guidance Documents for Medical Device Regulations | September 2024

Swissmedic has published two new guidance documents for stakeholders in the medical device industry.

Title	Overview
Guidance document Export Certificates	This guidance outlines the procedures, requirements, and documentation for manufacturers to successfully navigate the export process, emphasizing the importance of export certificates in ensuring medical devices meet safety and efficacy standards in foreign markets.

Title	Overview
Information sheet Clinical investigations with medical devices	The guidance document outlines Swiss regulations for clinical investigations involving medical devices, outlining the application process, ethical considerations, and stakeholder roles. It is crucial for ensuring compliance and promoting innovation in the medical device sector.

Important Updates on Medical Device Regulations in the EU | 23 September 2024

Regulation (EU) 2023/607 of the European Parliament and Council modifies the transitional provisions for certain medical devices and in vitro diagnostic medical devices outlined in Regulations (EU) 2017/745 and (EU) 2017/746. These amendments were published in the Official Gazette on April 2, 2023, and have been implemented in our country to align with EU member states.

Under these regulations, manufacturers or importers of medical devices covered by the MDD and AIMDD that do not qualify for the transitional provisions are permitted to market these devices until May 26, 2024. It has been communicated to all stakeholders that medical devices legally available before this date can remain on the market for their shelf life, if applicable.

In light of discussions with the Ministry of Trade regarding feedback from manufacturers, importers, and end users, it has been determined that products with a shelf life that have been individually notified, as well as those currently stored in the manufacturer's warehouse or imported from non-EU countries, can be sold throughout their shelf life. However, products without a specified shelf life will not be notified after December 31, 2025.

This announcement is made with the utmost importance to all concerned parties.

SOUTH KOREA

Updates on Cosmetic Labeling Regulations by MFDS | 27 September 2024

On September 24, 2024, the Ministry of Food and Drug Safety (MFDS) released the latest version of the regulations concerning cosmetic labeling, including precautions for use and fragrance allergens. The updates primarily address safety measures for small-packaged cosmetics and eyelash permanent wave products.

The new regulations took effect immediately upon issuance. However, the specific provisions pertaining to small-packaged cosmetics will come into effect on July 10, 2025.

INDONESIA

Indonesia Strengthens Halal Certification with Italy through Mutual Recognition Agreement | 26 September 2024

Indonesia has strengthened its halal certification process by signing a Mutual Recognition Agreement (MRA) with Halal Italia on September 19, 2024. Under Law Number 33 of 2014, all products traded in Indonesia must be halal certified, with phased implementation starting with food and beverages from October 17, 2019, until October 17, 2024, and cosmetics from October 17, 2021, until October 17, 2026.

The MRA allows products certified by Halal Italia to enter the Indonesian market without needing additional halal certification from Indonesia's Halal Product Assurance Agency (BPJPH). This agreement is expected to enhance cooperation in halal product assurance, improve regional market integration, and boost consumer trust in halal products.

Updates to Indonesia's Cosmetic Contamination Regulation | 24 September 2024

The revised Regulation on Limitations for Contamination in Cosmetics provides greater clarity regarding its scope, broadens the range of institutions permitted to conduct tests for cosmetic contaminants, and revises standards related to chemical contamination.

On November 9, 2023, Indonesia introduced an amended draft of this regulation for public feedback. The finalized version was then published on September 18, 2024, with an effective date set for September 18, 2025.

This regulation seeks to define and clarify the categories of microbial, heavy metal, and chemical contamination in cosmetics, as well as to establish administrative penalties for non-compliance.

Indonesia Proposes Draft Amendment to Cosmetic Labeling and Advertising Regulations | 04 September 2024

On August 29, 2024, Indonesia unveiled a draft amendment to its Regulation on Cosmetic Labeling, Promotion, and Advertising for public consultation. This proposed amendment introduces corporate responsibilities and oversight obligations concerning labeling, promotion, and advertising, as specified in the Technical Requirements for Cosmetic Labeling, the Technical Guidelines for Cosmetics Advertising, and the Regulation for Supervision of Cosmetic Manufacture and Circulation.

The amendments primarily emphasize the following essential aspects of cosmetic labeling, promotion, and advertising.

JAPAN

New JCIA Guidelines on Advertising Quasi-Drugs with Wrinkle Improvement Claims | 20 September 2024

On August 30, 2024, the Japan Cosmetic Industry Association (JCIA) released new guidelines concerning the marketing of quasi-drugs that make claims about improving wrinkles. The guidelines stress the necessity of accurately conveying approved effects and outline five essential compliance points.

While claims about age-related wrinkle improvements for quasi-drugs are permissible, those that associate these improvements with youthfulness are not allowed.

New Japan Proposes Updates to Quasi-Drug Ingredient Standards| 19 September 2024

On September 13, 2024, the Ministry of Health, Labour and Welfare (MHLW) of Japan announced a proposal to update the Japanese Standards of Quasi-drug Ingredients 2021. This proposal includes modifications to testing methods, standard solutions, and reference samples. The revisions will impact the specifications for 222 quasi-drug ingredients. Stakeholders are invited to submit their feedback by October 14, 2024, through the e-GOV platform.

CHINA

China Introduces New Draft Measures for Cosmetic Safety Risk Monitoring | 18 September 2024

On September 14, 2024, the China National Medical Products Administration (NMPA) published a draft of the Administrative Measures on Cosmetic Safety Risk Monitoring (referred to as "Measures"), which is open for public feedback until October 8.

These Measures govern the safety risk monitoring of cosmetics and toothpaste, with the exception of special monitoring prompted by emergencies.

The document includes 30 articles divided into six chapters: general provisions, plan formulation, sampling and inspection, investigation and handling, application of monitoring results, and supplementary provisions.

The new Measures are intended to replace the Working Rules for Cosmetic Risk Monitoring that have been in effect since January 2018. In comparison to the current Rules, the draft Measures offer more detailed and comprehensive guidance.

New Guidelines for Good Cosmetovigilance Practices in Brazil: Anvisa's RDC 894/2024 | 03 September 2024

Anvisa issued Collegiate Board Resolution (RDC) 894 on August 27, 2024, establishing guidelines for Good Cosmetovigilance Practices in Brazil. This regulation focuses on the post-marketing surveillance of cosmetic products to monitor and manage adverse reactions, enhancing safety and effective risk management.

Key points of RDC 894/2024 include:

1. Defined responsibilities for companies in post-marketing monitoring.
2. Requirement for a robust cosmetovigilance system to collect and report adverse events.
3. Mandate for each company to appoint a responsible professional for cosmetovigilance.
4. Specific deadlines for reporting serious adverse events to Anvisa.
5. Definitions of important terms like "cosmetovigilance" and "serious adverse event."
6. Risk minimization measures when safety issues are identified.

The regulation will take effect in 12 months, replacing the previous RDC 332 from 2005, aiming to modernize the regulatory framework in line with international standards. An inspection manual is also anticipated to be released to assist health surveillance agencies in monitoring cosmetics.

HSA Alerts Public on Overseas Products Containing Potent Ingredients | 17 September 2024

The Health Sciences Authority (HSA) has issued an update regarding products identified by international regulators in August 2024 that contain potent, prohibited ingredients. These ingredients pose potential side effects and safety risks.

The HSA aims to raise awareness about these safety concerns for products found overseas that could affect the local population.

List of ISO standards updated in September 2024:

- ISO 15378:2017/ Amd 1:2024 - Primary packaging materials for medicinal products — Particular requirements for the application of ISO 9001:2015, with reference to good manufacturing practice (GMP) — Amendment 1: Climate action changes
- ISO 6872:2024 - Dentistry — Ceramic materials
- ISO 19211:2024 - Anaesthetic and respiratory equipment — Fire-activated oxygen shut-off devices for use during oxygen therapy
- ISO 80601-2-79:2024 - Medical electrical equipment — Part 2-79: Particular requirements for basic safety and essential performance of ventilatory support equipment for ventilatory impairment
- ISO 80601-2-80:2024 - Medical electrical equipment — Part 2-80: Particular requirements for basic safety and essential performance of ventilatory support equipment for ventilatory insufficiency
- ISO 23500-1:2024 - Preparation and quality management of fluids for haemodialysis and related therapies — Part 1: General requirements