Newsletter

REGULATORY BRAINBOX

OMC MEDICAL
Regulatory Services

Medical Devices Regulatory Consultancy

NOVEMBER 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

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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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EUROPEAN UNION (EU)

EU Releases New MDCG Documents | November 2024

The European Commission has recently released two important guidance documents aimed at clarifying regulatory requirements under the Medical Device Regulation (MDR, Regulation (EU) 2017/745) and In Vitro Diagnostic Regulation (IVDR, Regulation (EU) 2017/746). These publications address critical aspects of vigilance and the gradual implementation of Eudamed, the European Database on Medical Devices.

Title	Overview
MDCG 2023-3 Rev. 1: Questions and Answers on Vigilance Terms and Concepts ***MDCG 2023-3 Rev. 1***	The updated guidance document clarifies vigilance-related terms and concepts in the MDR and IVDR, ensuring consistent interpretation across member states and stakeholders. Key topics include definitions of reportable incidents and field safety corrective actions, reporting timelines, and vigilance obligations thresholds. The document aims to support manufacturers, notified bodies, and competent authorities in navigating the complex requirements of the vigilance system under the EU regulatory framework.
Q&A on practical aspects related to the implementation of the gradual roll-out of Eudamed pursuant to the MDR and IVDR, as amended by Regulation (EU) 2024/1860 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards a gradual roll-out of Eudamed, the obligation to inform in case of interruption or discontinuation of supply, and transitional provisions for certain in vitro diagnostic medical devices ***Gradual roll out of EUDAMED***	The document, following the EU 2024/1860 amendment to the MDR and IVDR, outlines the practical aspects of the phased roll-out of Eudamed. It outlines manufacturers' obligations to inform authorities, transitional provisions for specific in vitro diagnostic medical devices, and timelines for gradual implementation of Eudamed's functionalities. The aim is to ensure a smooth transition to full Eudamed functionality while maintaining transparency and continuity in EU market supply.

UNITED KINGDOM (UK)

Innovative Licensing and Access Pathway Speeds Up Medicine Access in the UK | 20 November 2024

The UK's Innovative Licensing and Access Pathway (ILAP) accelerates patient access to innovative medicines, including new drugs, repurposed treatments, and novel indications. Open to global developers, it streamlines regulatory approval through collaboration and tailored support.

Key features include the Innovation Passport, the gateway designation for products addressing significant health needs, and the Target Development Profile (TDP), a roadmap guiding regulatory and development strategies. ILAP also offers a flexible toolkit to enhance medicine development.

Governed by partners like MHRA, NICE, and the Scottish Medicines Consortium, ILAP ensures collaboration and patient-centered outcomes. To date, 115 Innovation Passports have been awarded, with applications spanning oncology, neurology, and respiratory conditions.

ILAP complements other initiatives, such as the Early Access to Medicines Scheme (EAMS), by catering to a broader range of products and fostering early-stage engagement. Developers are encouraged to apply early to maximize pathway benefits.
Further updates, including enhancements to the ILAP, are expected later in 2024.

MHRA Launches Consultation on Pre-Market Medical Device Regulations | 14 November 2024

The MHRA has launched a consultation on reforms to pre-market regulations for medical devices in Great Britain, aiming to enhance patient safety and access to innovative technologies. Open until January 5, 2025, the consultation will shape the forthcoming Pre-market Statutory Instrument, set for Parliament in 2025.

Key areas include replacing physical UKCA markings with Unique Device Identification, expediting approvals for internationally certified devices, updating requirements for Class B in vitro diagnostic devices, and retaining select EU-derived regulations to ensure a smooth transition. These changes support NHS recovery and health innovation.

New Rules for Advertising Medicines in the UK Post-Windsor Framework | 07 November 2024

From 1 January 2025, updated regulations for the advertising and promotion of human medicines will come into effect, following the implementation of the Windsor Framework. These changes align with new UK-wide licensing arrangements agreed as part of the framework.

The Medicines and Healthcare products Regulatory Agency (MHRA) has released guidance to support businesses in navigating these changes. The document complements the MHRA's existing Blue Guide on the Advertising and Promotion of Medicines in the UK and should be read alongside the agency's broader guidance on the Windsor Framework.

This step marks a significant update to ensure consistency in the regulation of human medicines across the UK under the framework's provisions.

UNITED STATES OF AMERICA (USA)

FDA Outlines Processes for Medical Device Reclassification Under FD&C Act | 08 November 2024

The U.S. Food and Drug Administration (FDA) has three key reclassification processes for medical devices under the Food, Drug, and Cosmetic Act (FD&C Act). These processes allow for reclassification based on new information or regulatory needs, ensuring device classifications reflect current safety and effectiveness standards.

Section 513(e) allows the FDA to reclassify an already-classified device based on new information, which can be initiated by the FDA or through a petition by an interested party. The process transitioned from rulemaking to an administrative order system after the 2012 enactment of the Food and Drug Administration Safety and Innovation Act (FDASIA).

Section 513(f)(3) addresses post-1976 devices automatically classified as Class III, which can be FDA-initiated or petition-based. Approved reclassifications include a detailed order outlining reasons and health risks associated with the device type.

The De Novo Classification Under Section 513(f)(2) allows novel devices to be classified without first undergoing a premarket notification (510(k)) process, facilitating innovation while ensuring safety.

ANMAT Updates National Drug Vademecum to Reflect Marketed Medicines | 21 November 2024

The National Administration of Drugs, Food, and Medical Technology (ANMAT) has revised the National Vademecum of Drugs (VNM) to include only medicines currently available on the market. This comprehensive review, conducted by ANMAT's Technical Information Management Directorate, led to the removal of 60 products, some with multiple concentrations, such as 1, 3, and 5 milligrams.

The update, which will now occur quarterly, aims to ensure that the VNM remains a reliable and up-to-date resource. The streamlined list will enhance access to accurate information for laboratories, healthcare professionals, and the general public, providing clarity on medicines that can be effectively purchased.

Established in 2014, the VNM previously adhered to varying criteria for its composition. Moving forward, it will solely feature medications readily available to the public, with periodic updates to maintain relevance and accuracy.

Mandatory Transition to EU Clinical Trials Regulation by January 2025 | 14 November 2024

The FAMHP has issued a final call for sponsors to transition clinical trials to comply with the Clinical Trials Regulation (EU) 536/2014 (CTR) by 31 January 2025. Trials not approved in the Clinical Trials Information System (CTIS) by this date will lose authorisation, violating the CTR and Belgium's Act of 7 May 2017, with potential penalties, including fines or imprisonment.

Sponsors are urged to submit transition applications immediately, as processing may take up to 37 days. Substantial modifications under the older directive remain acceptable but should follow CTR rules after approval.

Anvisa Tightens Regulations on Hormonal Implants with Anabolic Steroids or Androgenic | 26 November 2024

Anvisa has approved stricter measures for the handling of hormonal implants containing anabolic steroids or androgenic hormones, following Resolution 4,353/2024. The resolution prohibits the manipulation, sale, and use of these implants for aesthetic enhancement, muscle mass gain, or improved sports performance. It also reinforces the ban on advertising compounded hormonal implants to the public. These implants are designed for personalized treatment when no suitable industrialized medication is available.

The new measures aim to strengthen oversight, requiring prescriptions to include the ICD code for the clinical condition being treated and a signed Term of Responsibility to inform patients about potential risks.

Adverse events must be reported through the VigiMed system. Anvisa emphasizes that compounded medicines should be used only when necessary under medical supervision.

Anvisa Issues Guidance on Medical Device Notification and Registration Procedures | 22 November 2024

Anvisa released Circular Letter 01/2024 to medical device registrants, providing procedural guidelines for submitting notification and registration petitions. The document clarifies requirements for sworn translations, legally valid signatures, and the minimum level of electronic signatures needed for interactions with public entities. These guidelines were also distributed to relevant associations, societies, and chambers involved in medical device regulation.

Anvisa Implements AI to Optimize Drug Impurity Analysis | 11 November 2024

Anvisa has introduced an AI-based tool to enhance the efficiency of its impurity and degradation product qualification analyses for synthetic drugs. This process, crucial for ensuring medicine safety during registration and post-registration, involves evaluating impurity levels that exceed established regulatory limits.

The AI tool leverages prior knowledge to quickly identify previously analyzed impurities, systematize data, and improve decision-making.

The initiative aims to accelerate petition reviews, with all pending impurity qualification requests to be processed using the new tool. Companies do not need to take additional actions for already submitted petitions.

This strategy complements existing measures like the List of Qualified Impurities under Normative Instruction IN 258/2023, aiming to streamline regulatory updates and protect public health.

China Strengthens Drug Regulatory Cooperation with Vietnam and Thailand | 22 November 2024

From November 11 to 15, a delegation from China's National Medical Products Administration (NMPA) visited Vietnam and Thailand to enhance cooperation in drug, medical device, and cosmetic regulation.

In Vietnam, discussions with the Ministry of Health focused on regulatory information exchange, quality control, and Good Manufacturing Practices, culminating in the signing of a memorandum of understanding (MoU).

Similarly, in Thailand, the delegation engaged with the Thai Food and Drug Administration, signing an MoU to deepen collaboration in regulatory practices. Both agreements aim to foster high-quality pharmaceutical development and safeguard public health. The delegation also toured drug testing and clinical trial facilities in both countries.

China and Saudi Arabia Sign MoU to Enhance Drug Regulation Cooperation | 12 November 2024

China's National Medical Products Administration (NMPA) and the Saudi Food and Drug Authority (SFDA) signed a memorandum of understanding (MoU) on November 1 in Beijing to enhance collaboration in the regulation of drugs, medical devices, and cosmetics.

The agreement follows discussions where the NMPA shared insights on China's drug regulatory framework and pharmaceutical industry development, emphasizing its strict and efficient practices. SFDA representatives outlined their regulatory strategy, laboratory capabilities, and testing processes. Both parties committed to implementing the MoU to facilitate the availability of high-quality pharmaceutical products for their populations.

China and Denmark Sign Agreement to Deepen Drug and Medical Device Regulatory Cooperation | 04 November 2024

On October 24 in Beijing, the Chinese National Medical Products Administration (NMPA) and the Danish Medicines Agency signed a letter of intent to enhance bilateral cooperation in the regulation of drugs and medical devices.

This followed a working meeting where China outlined its regulatory framework and pharmaceutical industry development, highlighting previous exchanges in drug evaluation and medical device regulation.

Both parties expressed a commitment to advancing collaboration, particularly through the phase-2 project of their strategic cooperation in these fields. Officials from relevant NMPA organizations also participated in the meeting.

Egyptian Drug Authority Ensures Adequate Supply of Diabetes and Effervescent Medications | 01 November 2024

The Egyptian Drug Authority announced the distribution of approximately 9.5 million packages of diabetes treatments, including various insulin types and metformin preparations, and increased stocks of raw materials to sustain production.

Effervescent medications, such as Urivin-N Eff, Urosolvin, and Epimag Eff, have also been supplied in significant quantities, with over 11 million packages of these products ready for future manufacturing.

Authorities confirmed the availability of these medications in pharmacies nationwide and are closely monitoring production to prevent shortages. These efforts aim to ensure patient access to critical treatments and maintain market stability.

Transition to European Regulation No. 536/2014: Deadline for Clinical Trial Sponsors Approaching | 15 November 2024

European Regulation No. 536/2014 (CER), governing clinical trials for medicinal products, replaced Directive 2001/20/EC on 31 January 2022. Clinical trial authorizations under the previous directive remain valid only until 30 January 2025. After this date, trials must comply with the new CER framework, or they risk losing authorization and data usability.

Sponsors of clinical trials active in France as of January 31, 2025, must transition their studies to CER by submitting an application via the Clinical Trials Information System (CTIS). While this process does not involve a new assessment, applications must be submitted promptly, considering the review time required. Sponsors are urged to confirm their intent to transition by 16 December 2024 to avoid corrective measures.

The CER aims to harmonize processes across Europe, improving patient access to treatments, enhancing Europe's competitiveness in clinical research, and increasing data transparency.

SAHPRA Urges Public to Report Side Effects During #MedSafetyWeek 2024 | 07 November 2024

The South African Health Products Regulatory Authority (SAHPRA) is participating in the global #MedSafetyWeek initiative from 4 to 10 November 2024, aimed at promoting the safe use of medicines and encouraging the reporting of side effects. SAHPRA emphasizes that proper medication use, guided by healthcare professionals, can significantly reduce adverse effects, with research indicating that half of all side effects are preventable.

In collaboration with international organizations under the WHO Programme for International Drug Monitoring, SAHPRA urges patients, caregivers, and healthcare professionals to report suspected side effects or adverse reactions via its MedSafety App or eReporting portal. These tools help identify, assess, and address risks associated with medicines, vaccines, and other health products. Improved reporting contributes to patient safety by uncovering unknown side effects and informing changes in medication use.

New Format for Veterinary Drug Distribution Authorisations Implemented in Spain | 26 November 2024

The Spanish Agency for Medicines and Health Products (AEMPS) has adopted the EU-harmonized format for Wholesale Distribution Authorisations (WDA) of veterinary medicinal products, effective from November 1, 2024. As mandated by Regulation (EU) 2019/6, these authorisations are now published in the European database Eudra GMDP, aligning veterinary distributors with the same standards previously applied to human medicinal distributors.

From November 12, updates reflecting this change are incorporated into the AEMPS Catalogue and Eudra GMDP. Regional authorities must adjust existing veterinary drug distributor authorisations to the new format for inclusion in these databases. Until March 2025, the existing Ministry of Health database (MAPA) will coexist with the updated Catalogue. Over time, authorisations for human and veterinary medicinal distributors will also transition to the new format during subsequent updates.

Spain Introduces New Application for In-House Medical Device Manufacturing in Hospitals | 08 November 2024

The Spanish Agency for Medicines and Medical Devices (AEMPS) has launched a digital platform for hospitals to electronically submit notifications about the start of in-house manufacturing of medical devices for exclusive use within their premises. This process aims to address specific patient needs that cannot be met by CE-marked devices available on the market.

The activity is governed by Regulation (EU) 2017/745 and Royal Decree 192/2023, which restrict such manufacturing to hospitals and exclude class IIb, III, or implantable devices. Hospitals are required to notify AEMPS before commencing or modifying activities, and this does not apply to custom-made devices, which require separate licensing. Hospitals can access the application using credentials, and detailed instructions are available on the AEMPS website.

EUROPEAN UNION (EU)

ECHA Pilot Project Reveals Non-Compliance in Cosmetic Products Containing Hazardous Substances | 08 November 2024

A recent pilot project conducted by the European Chemicals Agency (ECHA) from November 2023 to April 2024 found that 285 cosmetic products violated substance restrictions under EU regulations. The project, which inspected 4,686 products across 13 European Economic Area (EEA) countries, revealed a 6.4% non-compliance rate for cosmetics. The inspections, which primarily focused on product labels and websites, identified six restricted substances, with perfluorononyl dimethicone and cyclopentasiloxane (D5) being the most commonly detected. The findings highlight ongoing concerns over hazardous chemicals in cosmetic products.

Substance	Non-compliant Products Count	Risks	Restrictions for Cosmetic Use
Perfluorononyl dimethicone	151	The substances in question are toxic to reproduction, persistent in the environment, and may be carcinogenic.	The REACH Regulation, effective February 25, 2023, limits the sum of C9-C14 perfluorocarboxylic acids (PFCAs) and their salts in mixtures to 25 ppb and 260 ppb, respectively. The POPs Regulation, effective July 4, 2020, limits perfluorooctanoic acid (PFOA) or its salts in mixtures to 0.025 mg/kg and 1 mg/kg for individual compounds or combinations.
Perfluorooctylethyl triethoxysilane	5		
Perfluorononyleth yl carboxydecyl PEG-10 dimethicone	4		

Substance	Non-compliant Products Count	Risks	Restrictions for Cosmetic Use
Cyclopentasiloxane (D5)	111	These substances are known to be persistent, bioaccumulative, and potentially toxic, endangering aquatic life in particular and perhaps disrupting human hormones.	The REACH Regulation mandates that the concentration of D4 and D5 in rinse-off cosmetics and cyclohexasiloxane (D6) in leave-on cosmetics, effective from January 31, 2020, and June 6, 2027, must not exceed 0.1%, respectively.
Cyclomethicone*	12		
Cyclotetrasiloxane (D4)	11		
** Cyclomethicone: a blend of D4, D5 and D6*			

The project report provides recommendations for stakeholders involved in implementing legislation related to the cosmetics industry, emphasizing compliance with EC No 1223/2009, POPs and REACH Regulations, and advising close monitoring of regulatory changes regarding per- and polyfluoroalkyl substances (PFAS) and D4/D5/D6.

INDONESIA

Indonesia Releases Draft Regulation on Risk Assessment for Ingredients in Natural Medicines and Cosmetics | 25 November 2024

On November 21, 2024, the Indonesian Food and Drug Supervisory Agency (BPOM) released a draft Regulation for public consultation concerning the risk assessment of ingredients used in natural medicines, health supplements, quasi-drugs, and certain cosmetic products, including dental and oral care items.

The regulation mandates that ingredients in these products must meet pharmaceutical standards and quality requirements. Ingredients listed in a provided table are subject to risk assessment when used in dental and oral care preparations, while other unlisted ingredients will require supporting data and risk assessments.

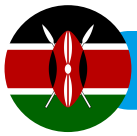
BPOM Proposes Changes to Cosmetic GMP Certification Requirements |11 November 2024

On November 5, 2024, Indonesia's Food and Drug Supervisory Agency (BPOM) released a draft of updated Technical Requirements for Cosmetic Good Manufacturing Practices (GMP) Certification, open for public consultation until November 18, 2024.

The key proposed changes include the cancellation of certain required documents and updates to the verification period for GMP applications. Additionally, revisions to the GMP certificate renewal process are outlined to improve ongoing compliance.

GMP certification ensures that cosmetic products meet quality standards, with Class A certificates for companies producing all types of cosmetics and Class B for those producing specific products.

Industry feedback is encouraged via email or online form during the consultation period.

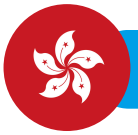


KENYA

Cosmetics Industry Delegation Meets Kenya's Pharmacy and Poisons Board to Discuss Regulatory Collaboration | 13 November 2024

A delegation from the Personal Care Products Council (PCPC) and Cosmetics Europe (CE) visited Kenya's Pharmacy and Poisons Board (PPB) on November 13, 2024, to explore opportunities for enhancing collaboration on cosmetics and personal care product regulations.

Representing the U.S. and European industries, the delegation advocated for the adoption of global regulatory standards, a stance they have supported in Sub-Saharan Africa and through U.S. trade agreements. During the visit, PPB CEO emphasized Kenya's dedication to ensuring the safety and quality of consumer products.



HONG KONG

Hong Kong's Mercury Control Ordinance Implements Minamata Convention | 25 November 2024

Hong Kong's Mercury Control Ordinance, effective from December 1, 2021, fully enforces the Minamata Convention on Mercury. The ordinance regulates the import, export, storage, and use of mercury, along with mercury compounds and products. It also covers manufacturing processes involving mercury. Starting December 1, 2021, the ordinance prohibits the import, export, and manufacture of certain mercury-added products, with a planned extension of this prohibition to their supply, effective December 1, 2024.

JAPAN

Effective Marketing of Whitening Products in Japan through Regulatory Compliance | 08 November 2024

Whitening products are a major segment of Japan's cosmetics market, and clear, accurate promotional messaging is crucial for building trust and a strong brand image. However, the use of terms like "whitening" is strictly regulated under the Pharmaceutical and Medical Device Act (PMDA).

This law prohibits misleading claims that suggest a cosmetic product has medicinal effects. To avoid legal issues and foster consumer confidence, businesses must ensure their marketing aligns with these regulations while providing truthful product information.

List of ISO standards updated in November 2024:

- ISO 14356:2024 - Dentistry — Duplicating material
- ISO 25539-3:2024 - Cardiovascular implants — Endovascular devices — Part 3: Vena cava filters
- ISO 11979-2:2024 - Ophthalmic implants — Intraocular lenses — Part 2: Optical properties and test methods
- ISO 11334-4:2024 - Assistive products for walking, manipulated by one arm — Requirements and test methods — Part 4: Walking sticks with three or more leg
- ISO 15883-1:2024 - Washer-disinfectors — Part 1: General requirements, terms and definitions and tests
- ISO 80369-2:2024 - Small-bore connectors for liquids and gases in healthcare applications — Part 2: Connectors for respiratory applications
- ISO 24442:2022 - Cosmetics — Sun protection test methods — In vivo determination of sunscreen UVA protection