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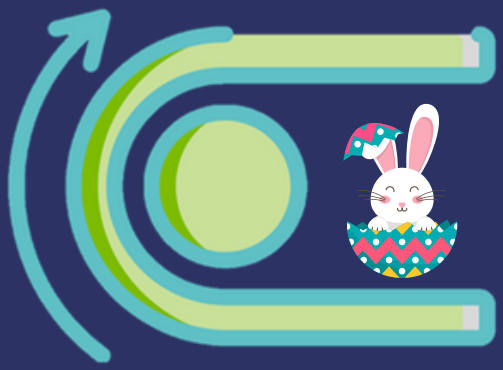


SMT@ESPL-REGULATORY.COM

CONTENTS

Welcome to our regular newsletter, which provides a digest of some of the latest EU/UK and some of the worldwide regulatory news. As ever, Q1 2025 has been another very busy time for new emerging guidelines from the regulatory agencies of the world.

Feel free to contact us on: smt@espl-regulatory.com if you have any questions on the information provided.

EUROPEAN-WIDE NEWS

EUROPEAN MEDICINES AGENCY (EMA)

NEW EMA Introduce New Fee Regulation from 1 January 2025

https://www.ema.europa.eu/en/about-us/fees-payable-european-medicines-agency/new-fee-regulation-1-january-2025

Updated scientific guidelines with summary-of-product-characteristics recommendations

The comprehensive list of scientific guidelines that provide specific recommendations for preparing and reviewing the Summary of Product Characteristics (SmPC) for human medicines has been updated.
https://www.ema.europa.eu/en/documents/other/scientific-guidelines-summary-product-characteristics-recommendations_en.pdf

EMA publishes revised rules on handling of competing interests

The EMA has updated its policy on managing competing interests following two court cases questioning advisory group impartiality. Key changes include stricter, more consistent restrictions for experts with current conflicts and clearer guidance on the use of 'expert witnesses'—specialists with limited availability but some competing interests. The new policy takes effect in May 2025.
https://www.ema.europa.eu/en/news/revised-rules-handling-competing-interests-published

Updated version of EU variations form, valid from 1 January 2025

https://esubmission.ema.europa.eu/eaf/index.html

NEW **New EU rules for health technology assessments become effective**

New EU rules on health technology assessments (HTAs) are effective from January 12, 2025, aiming to improve patient access to innovative treatments. The regulation introduces joint clinical assessments (JCAs) for new medicines and high-risk medical devices, comparing their effectiveness and safety to existing options to support national pricing and reimbursement decisions. The EMA will support this by sharing regulatory data to aid JCAs, co-leading joint scientific consultations with developers and exchanging information on upcoming health technologies.
https://www.ema.europa.eu/en/news/new-eu-rules-health-technology-assessments-become-effective

EU eSubmission Validation Criteria Updated

From 1 March 2025 only eCTDs compliant with EU M1 v3.1 and validation criteria v8.1 are accepted. Notably, “uk” has changed to “xi” for Northern Ireland in the Module 1 envelope.
https://esubmission.ema.europa.eu/ectd/index.html

European Shortages Monitoring Platform (ESMP) live 29 January 2025

The ESMP is a new EU-wide system launching in 2025 to improve reporting and coordination around medicine shortages. Developed by the EMA, it will centralise data from pharmaceutical companies and national authorities, enabling faster, more consistent responses across member states. The delivery of the ESMP is a key requirement of EMA’s extended mandate, fulfilling the legal requirements under Regulation (EU) 2022/123, to enhance shortages monitoring and preparedness across the EU/EEA.
https://www.ema.europa.eu/en/human-regulatory-overview/post-authorisation/medicine-shortages-availability-issues/european-shortages-monitoring-platform-esmp

NEW **New clinical trial map launched in the EU**

The EMA has launched a new clinical trial map in the Clinical Trials Information System (CTIS), helping users find ongoing trials in the EU by location and condition. Part of the ACT EU initiative, the tool includes lay language search and investigator contact details. It launched in English in March 2025, with more languages to follow.
https://www.ema.europa.eu/en/news/new-clinical-trial-map-launched-eu

EMA NEWSLETTERS

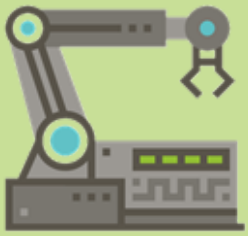
The EMA publishes monthly newsletters to provide updates on various topics to patients, healthcare professionals and the pharmaceutical industry. The latest newsletters are:

Human Medicines Highlights
Key information on human medicines and changes to regulatory processes each month:

- January: https://ec.europa.eu/newsroom/ema/newsletter-archives/59179
- February: https://ec.europa.eu/newsroom/ema/newsletter-archives/60285
- March: https://ec.europa.eu/newsroom/ema/newsletter-archives/61382

Veterinary Medicines Highlights
Q1 2025 highlights from the EMA Veterinary Medicines Division:
https://ec.europa.eu/newsroom/ema/newsletter-archives/61100

Scientific Advice, Strategy & Specialist Applications



Medical Device Submissions

Publishing

www.espl-regulatory.com

https://www.linkedin.com/company/espl-regulatory-consulting/

+44 1806 242 852

smt@espl-regulatory.com

EUROPEAN COMMISSION (EC)

European Council Progress Report on General Pharmaceutical Legislation

The European Council published a progress report on proposed pharmaceutical legislation. Under Hungary's 2024 presidency, the Council pushed back on key proposals from the Commission and Parliament—particularly around incentives and definitions for Orphan medicines. Poland now holds the presidency, and the Council has yet to adopt a first reading position, with discussions between EU institutions still ongoing.
https://data.consilium.europa.eu/doc/document/ST-14955-2024-INIT/en/pdf

European Commission Targeted Consultation on MDR and IVDR

The European Commission launched a public consultation to evaluate the Medical Devices Regulation (MDR) and In Vitro Diagnostic Regulation (IVDR) ahead of the revised 2025 guidance review timeline. The consultation was open until 21st March 2025 and sought stakeholder feedback on implementation challenges, regulatory burden, innovation impact, and international alignment. The feedback from the consultation is now being reviewed by the Commission with the aim to guide future improvements to ensure the regulations balance patient safety with innovation and global competitiveness.
https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/14155-EU-rules-on-medical-devices-and-in-vitro-diagnostics-targeted-evaluation_en

INTERNATIONAL COUNCIL FOR HARMONISATION (ICH)

ICH Q13 IWG Video Training Material Modules 1-12 are available on the ICH Website

https://www.ich.org/news/ich-q13-iwg-video-training-material-modules-1-12-are-now-available-ich-website

EUROPEAN DIRECTORATE FOR THE QUALITY OF MEDICINES & HEALTHCARE (EDQM)

General chapter Elemental Impurities (G-07) harmonised by the Pharmacopoeial Discussion Group

The Pharmacopoeial Discussion Group (PDG) approved a new harmonised chapter, "Elemental Impurities (G-07)," which was developed over a decade with input from the Ph. Eur., IPC, JP, and USP. The chapter aligns with ICH Q3D guidelines on limits, assessment, and control of elemental impurities. It aims to standardise requirements and analytical approaches across regions.
https://www.edqm.eu/en/-/general-chapter-elemental-impurities-g-07-harmonised-by-the-pharmacopoeial-discussion-group

HEADS OF MEDICINES AGENCY (HMA)

Update to the examples for acceptable and not acceptable groupings for MRP/DCP products

https://www.hma.eu/fileadmin/dateien/Human_Medicines/CMD_h_/procedural_guidance/Variations/CMDh_173_2010_Rev.23_2025_02_clean_-_Examples_for_groupings_for_MRP_DCP_MPs.pdf

EUROPEAN FOOD SAFETY AUTHORITY (EFSA)

Saccharin: safety threshold increased - Re-evaluation of saccharin and its sodium, potassium and calcium salts (E 954) as food additives

https://www.efsa.europa.eu/en/news/saccharin-safety-threshold-increased

MEDRA

English MedDRA Version 28.0 is now available

https://www.meddra.org/news-and-events/news/english-meddra-version-280-now-available

INDIVIDUAL AGENCY NEWS

MHRA - UK

How Marketing Authorisation Applications referred under Article 29 are handled

The MHRA explains how it handles marketing authorisation applications referred under Article 29 when EU countries disagree during MRP or DCP procedures. For Northern Ireland, the MHRA follows the final EU decision. From January 2025, NI will continue participating in these referrals, with the MHRA bound by EU outcomes unless UK-specific changes are needed.
https://www.gov.uk/guidance/how-marketing-authorisation-applications-referred-under-article-29-are-handled

Update to Innovative Licensing and Access Pathway (ILAP)

The updated ILAP process—open from March 2025—now requires initial clinical data for eligibility. This change may limit access for some innovative products that need early regulatory input on non-clinical plans or novel trial designs. The revised focus appears to be on products with demonstrated human benefit and greater potential for market approval, supporting early engagement with HTAs and the NHS. Despite the shift, ILAP still offers value for shaping QSE development plans for novel therapies.
https://www.gov.uk/guidance/innovative-licensing-and-access-pathway

NEW Guidance on the new Medical Devices Post-Market Surveillance requirements

The MHRA has published guidance to help medical device manufacturers prepare for new post-market surveillance (PMS) rules in Great Britain, effective from 16 June 2025. Key changes include improved data collection, faster serious incident reporting, and clearer risk management duties. Businesses are encouraged to review the guidance now to ensure compliance.
https://www.legislation.gov.uk/uksi/2024/1368/contents/made

Windsor Framework Now in Effect

As of 1 January 2025, the Windsor Framework introducing UK-wide licensing for medicines came into effect. Most companies – 95% – met the 31 December 2024 deadline for updating registered artwork. The option to use 'UK Only' stickers ends on 30 June 2025. Updated guidance, including revised Category 1 and new Category 2 medicine lists, is available on the WF Hub. Companies needing support should contact MHRA at partnerships@mhra.gov.uk
https://www.gov.uk/government/collections/mhra-windsor-framework

Scientific Advice Requests Update

From 21 January 2025, the MHRA will assess all new scientific advice requests to determine if they can be addressed via existing guidance, written advice, or a meeting. More requests may be handled as written-only advice. From 1 February 2025, payment for advice must be made at least 3 weeks before the meeting, via the issued personalised Gov Pay links.
https://www.gov.uk/guidance/medicines-get-scientific-advice-from-mhra#ask-for-scientific-advice

NEW New point of care and modular manufacturer regulations

The MHRA has announced a new, world-first regulation for Point of Care and Modular Manufacture of innovative medicines, coming into force on 23 July 2025. It enables safe, local production of breakthrough therapies and aims to boost the UK's appeal for launching new medicines. Guidance will be shared during the transition period.
https://www.legislation.gov.uk/uksi/2025/87/introduction/made

MHRA Update on Assimilated EU Law (26 Feb 2025)

The UK government has confirmed it will retain four key pieces of assimilated EU law related to medical devices beyond the 26 May 2025 sunset date, to prevent regulatory gaps and protect patient safety. This includes rules on IVD specifications, electronic instructions for use, animal tissue devices, and approved body oversight. These changes follow a public consultation and will feed into upcoming MHRA 'Pre-Market' legislation, which will also modernise device regulations and remove outdated COVID-19 test requirements.
https://www.gov.uk/government/consultations/consultation-on-medical-devices-regulations-routes-to-market-and-in-vitro-diagnostic-devices/outcome/response-to-assimilated-eu-law-consultation-proposal

MHRA Fees Update

MHRA updated their fees at the start of April-2025. Notably, the MHRA has changed how it charges for scientific advice. Fees will now be based on the number of MHRA specialists needed to respond, rather than the type of questions asked. This may make it harder to predict costs in advance, as the required expertise isn't always clear upfront.
https://www.gov.uk/government/publications/mhra-fees/current-mhra-fees

FDA - USA

FDA Issues Draft Guidance on AI-Enabled Device Software Functions

The FDA has issued draft guidance on AI-enabled medical devices, offering recommendations for marketing submissions and lifecycle management. It supports a Total Product Life Cycle (TPLC) approach and helps developers apply relevant existing FDA guidances. This draft is not yet for implementation.
https://www.fda.gov/regulatory-information/search-fda-guidance-documents/artificial-intelligence-enabled-device-software-functions-lifecycle-management-and-marketing

HEALTH CANADA

Consultation on draft guidance on applications for medical device licences

Health Canada's draft guidance updates the process for medical device licence applications. Key changes include revised reconsideration steps, guidance on withdrawing applications, types of info requests, and standardized response times. Applies to Class II–IV devices. Open for feedback until 21 April 2025.
https://www.canada.ca/en/health-canada/programs/consultation-draft-guidance-managing-applications-medical-device-licences.html