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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, Q4 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

EUR-LEX

DON'T FORGET

NEW EU Variations Guideline Published (Final Version)

The European Commission has published the final EU Variations Guideline, introducing significant structural and procedural changes compared with the January 2025 draft. The guideline applies immediately to centralised procedures and will apply to national, MRP and DCP procedures from 15 January 2026. Key changes include:

- Substantial reclassification of changes, with several variations moving between Type IA, IB and Type II, altering submission strategy and timelines.
- Expanded scope of changes eligible for Type IA notifications, increasing post-implementation flexibility for certain quality and manufacturing changes.
- Clearer differentiation between implementation date and submission date, particularly impacting Type IA and grouped variations.
- Revised expectations for grouping and worksharing, including tighter rules on which variations may be submitted together.
- More explicit treatment of manufacturing and control strategy changes, especially for API and finished product sites.
- Alignment updates across CTD modules, clarifying documentation expectations and reducing ambiguity seen in the draft guideline.
- Removal, consolidation or rewording of several draft provisions, meaning assumptions based on the January 2025 draft may no longer be valid.

MAHs will need to re-review their variation strategies and internal SOPs, as changes previously planned under the January 2025 draft may now fall under different variation types, with direct impact on timelines, sequencing and implementation risk. Greater use of Type IA notifications may speed up low-risk changes, but this also increases the importance of accurate classification at implementation, as errors will be less forgiving post-implementation. Teams should reassess grouping and worksharing approaches, as tighter eligibility rules may reduce flexibility and require more standalone submissions. Manufacturing and control-strategy changes, particularly for APIs and site-related updates, will need earlier regulatory input to avoid misclassification. Finally, with immediate applicability to centralised procedures and a fixed 15 January 2026 date for national/MRP/DCP products, companies should prioritise portfolio impact assessments in 2025 to prevent last-minute rework and compliance risk.
https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=OJ:C_202505045

NEW Publication of Harmonised Standards Under the Medical Devices Regulations – October 2025

The EU has published a set of new harmonised standards under the Medical Devices Regulation (MDR) and In Vitro Diagnostic Medical Devices Regulation (IVDR) in October 2025, providing presumption of conformity tools to support compliance with essential requirements.
https://eur-lex.europa.eu/eli/dec_impl/2025/2078/oj

Commission Decision (EU) 2025/2371 on EUDAMED Electronic Systems Functionality

Commission Decision (EU) 2025/2371 of 26 November 2025 addresses the functionality and fulfilment of the functional specifications of certain electronic systems included in EUDAMED under Article 34(1) of the Medical Devices Regulation (MDR), providing formal confirmation and notice regarding the operational status of these systems.
https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=OJ:L_202502371

EUROPEAN MEDICINES AGENCY (EMA)

NEW Questions and Answers about the SEND Proof-of-Concept for Industry

EMA published a Q&A on the Standard for Exchange of Non-clinical Data (SEND) proof-of-concept, explaining the scope, voluntary participation terms, and how to submit non-clinical SEND datasets as part of initial centralised marketing-authorisation applications to support regulatory review.
https://www.ema.europa.eu/en/documents/other/questions-answers-about-send-proof-concept-industry-scope-terms-participation-data-submission-process_en.pdf

Updated Pre-Authorisation Guidance – Selected Q&A Revisions

EMA has updated several Pre-Authorisation Guidance Q&A sections, clarifying expectations for risk-management planning and procedural steps ahead of centralised marketing-authorisation submissions.

The update confirms the current RMP template and approach to RMP publication, clarifies how educational risk-minimisation measures are assessed, restricts substantive RMP changes after CHMP opinion without a formal variation, and sets clearer conditions for sharing EMA assessment and inspection documents with non-EU regulators.
https://www.ema.europa.eu/en/human-regulatory-overview/marketing-authorisation/pre-authorisation-guidance

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:

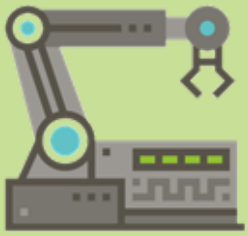
- July: https://ec.europa.eu/newsroom/ema/newsletter-archives/65546
- August: https://ec.europa.eu/newsroom/ema/newsletter-archives/66078
- September: https://ec.europa.eu/newsroom/ema/newsletter-archives/67267
- October: https://ec.europa.eu/newsroom/ema/newsletter-archives/68274
- November: https://ec.europa.eu/newsroom/ema/newsletter-archives/69378
- December: https://ec.europa.eu/newsroom/ema/newsletter-archives/70471

Veterinary Medicines Highlights

Highlights from the EMA Veterinary Medicines Division:

- Q3 2025: https://ec.europa.eu/newsroom/ema/newsletter-archives/67593
- Q4 2025: https://ec.europa.eu/newsroom/ema/newsletter-archives/70047

Scientific Advice, Strategy & Specialist Applications



Medical Device Submissions

Publishing

INTERNATIONAL COUNCIL FOR HARMONISATION (ICH)

ICH E20 Draft Guideline Available on ICH Website
The draft ICH E20 guideline on Adaptive Designs for Clinical Trials is now published on the ICH website, providing global guidance on planning, conduct, analysis and interpretation of confirmatory clinical trials using adaptive design, and is open for public consultation.
https://www.ich.org/news/ich-e20-draft-guideline-available-now-ich-website

ICH Q3E – Extractables and Leachables (Draft Update)
ICH has endorsed a draft update to Q3E setting out principles for extractables and leachables safety assessments, mainly focusing on organic leachables, with consultation ongoing until the end of 2025.
https://www.ich.org/page/safety-guidelines

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

All-Digital 12th Edition of the European Pharmacopoeia
EDQM has announced that the 12th Edition of the European Pharmacopoeia will be fully digital, marking a shift away from printed volumes and enabling more dynamic access, updates and use of pharmacopoeial standards.
https://www.edqm.eu/en/-/all-digital-12th-edition-marks-a-new-era-for-the-european-pharmacopoeia

Changes to e-Submission Requirements for CEP Applications
EDQM has updated the e-submission requirements for CEP (Certificate of Suitability) applications, introducing revised formats and technical expectations to align electronic submissions with current standards and improve dossier handling.
https://www.edqm.eu/en/-/changes-to-e-submission-requirements-for-cep-applications

Draft Revised Guideline on Revision/Renewal of CEPs – Public Consultation
EDQM has released a draft revised guideline on requirements for revision and renewal of Certificates of Suitability (CEPs) to the European Pharmacopoeia monographs for public consultation, with stakeholders invited to comment by 16 January 2026.
https://www.edqm.eu/en/-/edqm-releases-draft-revised-guideline-on-requirements-for-revision-renewal-of-certificates-of-suitability-to-the-european-pharmacopoeia-monographs

Pharmeuropa 37.4 Just Released
EDQM has published Pharmeuropa 37.4, containing the latest adopted texts of monographs, general chapters, and revisions for the European Pharmacopoeia, now available for reference and implementation planning.
https://www.edqm.eu/en/-/pharmeuropa-37.4-just-released

CEP Holders Invited to Comment on Draft Monographs in Pharmeuropa 37.4
EDQM has invited CEP holders and stakeholders to submit comments on draft monographs published in Pharmeuropa 37.4, offering an opportunity to influence final Ph. Eur. texts before they are adopted.
https://www.edqm.eu/en/-/cep-holders-invited-to-comment-on-draft-monographs-published-in-pharmeuropa-37.4

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European Pharmacopoeia Publishes First Individual Monoclonal Antibody Medicinal Product Monograph
The European Pharmacopoeia has published its first individual monograph for a monoclonal antibody medicinal product, marking a significant step in establishing harmonised quality standards for specific biological medicines.
https://www.edqm.eu/en/-/european-pharmacopoeia-publishes-first-individual-monoclonal-antibody-medicinal-product-monograph

Ph Eur Monograph on Particulate Contamination
The European Pharmacopoeia has updated general chapters on particulate contamination, including harmonised testing procedures and PDG-aligned standards for visible and sub-visible particles to improve quality control of injectable products.
https://info.edqm-info.eu/t.htm?u=/e/3/54654/2510/120285/r16jhhpeuezhhpbooogpyfhooabjespefim/r.aspx

Ph Eur Water Standards Update
EDQM adopted revisions to monographs on pharmaceutical waters (Water for Injections, Purified Water and Total Organic Carbon method) to enhance impurity detection and harmonise quality requirements, with texts slated for Ph Eur Issue 12.3 and entry into force in July 2026.
https://info.edqm-info.eu/t.htm?u=/e/3/54654/2510/120291/r16jhhpeuezhhpbooogpyfhooabjespefim/r.aspx

Ph Eur Glass Containers for Pharmaceutical Use
Ph Eur has published a revised general chapter 3.2.1 on glass containers for pharmaceutical use, clarifying test purposes (A, B, C) and modernising spectral transmission testing for coloured glass based on wall thickness instead of volume/closure.
https://info.edqm-info.eu/t.htm?u=/e/3/54654/2510/120297/r16jhhpeuezhhpbooogpyfhooabjespefim/r.aspx

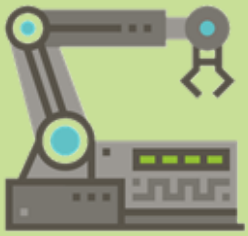
EUROPEAN COMMISION (EC)

Health Technology Assessment – Commission Adopts Rules for Joint Clinical Assessments of Medical Devices and IVDs
The European Commission has adopted joint clinical assessment rules for medical devices and in vitro diagnostics under the EU Health Technology Assessment framework, aiming to harmonise and streamline clinical evaluation across member states.
https://ec.europa.eu/newsroom/sante/newsletter-archives/68113

First Four EUDAMED Modules Declared Functional and Mandatory from 28 May 2026
The European Commission has confirmed that the first four EUDAMED modules (Actor Registration, UDI/Device Registration, Notified Bodies & Certificates, and Market Surveillance) have been declared functional, triggering mandatory use from 28 May 2026 following a six-month transition period under the MDR and IVDR, with manufacturers, economic operators and Notified Bodies required to be fully registered and compliant by that date.
https://health.ec.europa.eu/latest-updates/eudamed-four-first-modules-will-be-mandatory-use-28-may-2026-2025-11-27_en

EU GMP Annex Updates – Documentation, Computerised Systems & AI
EU authorities have opened consultation on GMP annex updates covering hybrid documentation systems, strengthened oversight of computerised systems, and new requirements for the use of artificial intelligence in manufacturing.
https://health.ec.europa.eu/medicinal-products/eudralex/eudralex-volume-4_en

Scientific Advice, Strategy & Specialist Applications



Medical Device Submissions

Publishing

Provisional Agreement Reached on Comprehensive Reform of EU Pharmaceutical Legislation

The European Parliament and Council have reached a provisional agreement on the revised EU human medicines legislation, including a new framework for regulatory data and market protection with an eight-year data protection period, one year of market protection, capped extensions up to eleven years, and strengthened obligations on companies to prevent and manage medicine shortages; the final legal texts will now be formalised and published in the Official Journal.
https://www.europarl.europa.eu/news/en/press-room/20251209IPR32110/deal-on-comprehensive-reform-of-eu-pharmaceutical-legislation

HEADS OF MEDICINES AGENCIES (HMA)

NEW Post-Brexit Q&A Document

CMDh has published a new Post-Brexit Q&A clarifying regulatory procedures and requirements for human medicines in the post-EU/UK transition environment, with the aim of providing greater consistency and certainty for MAHs operating across both regimes.
https://www.hma.eu/fileadmin/dateien/Human_Medicines/CMD_h_/Questions_Answers/CMDh_457_2025_Rev0_2025_10_-_Q_A_Post-Brexit.pdf

MEDRA

All Languages for MedDRA Version 28.1 Are Now Available for Download

The MedDRA Maintenance and Support Services Organization (MSSO) has released all language versions of MedDRA 28.1, making the updated terminology downloadable worldwide to support consistent reporting and coding of medical information.
https://www.meddra.org/news-and-events/news/all-languages-meddra-version-281-are-now-available-download

INDIVIDUAL AGENCY NEWS

FDA - USA

FDA Publishes New Product-Specific Guidances (PSGs) to Facilitate Generic Drug Development

FDA has published a new batch of 81 product-specific guidances (17 new, 64 revised) to support generic drug development and ANDA approvals, including guidance for complex products and treatments across multiple therapeutic areas, with the aim of streamlining development and improving access to generics.
https://www.fda.gov/drugs/guidances-drugs/product-specific-guidances-generic-drug-development

FDA Publishes Filing Checklists to Prevent Submission Delays

FDA has published filing checklists for various regulatory submission types to help applicants avoid common deficiencies and prevent delays at the start of the review process.
https://www.fda.gov/news-events/press-announcements/fda-publishes-filing-checklists-prevent-submission-delays

FDA Accepting Requests for CMC Development and Readiness Pilot (CDRP) Program

FDA is accepting requests to participate in Year 4 of the CMC Development and Readiness Pilot Program, offering selected drug and biological product sponsors enhanced, product-specific CMC advice and additional CMC-focused meetings to support readiness for marketing applications under accelerated development timelines.
https://www.fda.gov/drugs/development-approval-process-drugs/cmc-development-and-readiness-pilot-program

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BsUFA III Regulatory Science Program – Interim Public Meeting and Progress Report
FDA held the BsUFA III interim public meeting on 18 September 2025 and published an interim progress report reviewing advances in biosimilar interchangeability and development efficiency. FDA signalled a clear shift toward greater reliance on advanced analytical evidence, reduced dependence on clinical studies, and prioritisation of regulatory science projects that accelerate interchangeable biosimilar approvals.
https://www.fda.gov/news-events/fda-meetings-conferences-and-workshops/fda-public-meeting-bsufa-iii-regulatory-science-program-interim-public-meeting-09182025

MHRA - UK

MHRA Confirms UK Adoption of New EU Variations Guideline
MHRA has confirmed that the UK will implement the new EU Variations Guideline, with the new requirements applying from 15 January 2026; until then, existing UK variation guidance remains in force, and a new electronic application form aligned to the guideline is still pending.
https://www.gov.uk/government/collections/variations-to-marketing-authorisations-medicines

NEW Decentralised / Point-of-Care & Modular Manufacturing Framework
MHRA has introduced a legal framework for medicines manufactured without a fixed site, covering point-of-care and modular manufacturing where manufacture must occur close to use or for deployment reasons rather than convenience.
https://www.gov.uk/government/collections/point-of-care-manufacturing

MHRA–NICE Joint Information Sharing Agreement
MHRA and NICE have agreed to share information earlier in development to reduce delays between marketing authorisation and NHS access, allowing voluntary parallel engagement up to three years before approval.
https://www.gov.uk/government/news/mhra-and-nice-agree-to-share-information-to-speed-up-patient-access

MHRA Approves UK's First New Type of Antibiotic for Urinary Tract Infections in Nearly 30 Years
MHRA has approved gepotidacin (Blujepa) — the first new oral antibiotic for uncomplicated UTIs in the UK in nearly three decades, providing a new treatment option effective against many drug-resistant infections.
https://www.gov.uk/government/news/mhra-approves-uks-first-new-type-of-antibiotic-for-urinary-tract-infections-in-nearly-30-years G

AIFA - ITALY

AIFA Clarifications on Safety Features and Serialisation (Post-Brexit / National Implementation)
AIFA has issued clarifications on the application of Italian safety-feature and serialisation requirements, including practical expectations for data matrix layout, use of GTIN, labelling conventions, and future changes to national requirements, with further updates anticipated following industry feedback.
https://www.aifa.gov.it/en/farmaci-uso-umano

MDA - MALAYSIA

Malaysia Issues New Guidance to Expedite Medical Device Registration
Malaysia's MDA has issued new guidance for Class B, C and D medical devices to streamline conformity assessment and accelerate product registration.
https://portal.mda.gov.my/index.php/documents/ukk/3766-final-medical-device-registration-submission-guide-for-conformity-assessment-by-way-of-verification-process-and-submission-of-application-in-medc-st-second-edition

NMPA - CHINA

China Introduces 30-Day IND Pathway for Innovative Drugs
China has launched a 30-day IND review pathway for innovative drugs to accelerate clinical trial initiation, supplementing the existing 60-day default pathway.
https://english.nmpa.gov.cn/2025-10/14/c_1132769.htm

China Revises Good Manufacturing Practice for Medical Devices
China's NMPA has published a revised Medical Device GMP, the first major update since 2014, strengthening quality system requirements and supporting higher-quality device manufacturing, with implementation from 1 November 2026.
https://english.nmpa.gov.cn/2025-11/07/c_1138713.htm

HSA - SINGAPORE

HSA Opens eCTD Portal for Test Submissions
Singapore's HSA has opened a new eCTD portal for test submissions, supporting the digitalisation of regulatory submissions for therapeutic products, with eCTD Specification Package v1.0 available for testing from 30 September 2025 to 27 March 2026.
https://www.hsa.gov.sg/therapeutic-products/submit-application/electronic-submissions

CDSCO - INDIA

India Releases Draft Guidance on Medical Device Software
CDSCO has issued its first draft guidance on Medical Device Software, setting out regulatory expectations for classification, licensing, validation and post-market surveillance of SiMD and SaMD, including AI-based devices.
https://cdsco.gov.in/opencms/opencms/en/Medical-Device-Diagnostics/Guidelines/

We wish you all a Merry Christmas & Happy New Year!