28. November -
12. Dezember 2025

# MEGRA NEWSLETTER

# Humanarzneimittel - EMA

## Allgemeines – General

***National competent authorities (human)***
***Published on:*** *28 - November - 2025*
***For more information, please refer to:***
*https://www.ema.europa.eu/en/partners-networks/eu-partners/eu-member-states/national-competent-authorities-human*

***Abbreviations used in EMA scientific committees and Coordination Group for Mutual Recognition and Decentralised Procedures (CMD) documents, and in relation to EMA's regulatory activities***
***Published on:*** *03 - December - 2025*
***For more information, please refer to:***
*https://www.ema.europa.eu/en/documents/other/abbreviations-used-ema-scientific-committees-coordination-group-mutual-recognition-decentralised-procedures-cmd-documents-relation-emas-regulatory-activities_en.pdf*

***Medicines for human use under evaluation***
***Published on:*** *05 - December - 2025*
***For more information, please refer to:***
*https://www.ema.europa.eu/en/medicines/medicines-human-use-under-evaluation*

***EMA welcomes political agreement on new EU pharmaceutical legislation***
***Published on:*** *11 - December - 2025*
***For more information, please refer to:***
*https://www.ema.europa.eu/en/news/ema-welcomes-political-agreement-new-eu-pharmaceutical-legislation*

***Consolidated 3-year work plan for the Emergency Task Force (ETF)***
***Published on:*** *11 - December - 2025*
***For more information, please refer to:***
*https://www.ema.europa.eu/en/documents/work-programme/consolidated-3-year-work-plan-emergency-task-force-etf_en.pdf*

***Supporting innovation***
***Published on:*** *12 - December - 2025*
***For more information, please refer to:***
*https://www.ema.europa.eu/en/human-regulatory-overview/research-development/supporting-innovation*

## Pharmakovigilanz – PRAC

***Referral: Levamisole-containing medicinal products***
***Published on:*** *28 - November - 2025*
***For more information, please refer to:***
*https://www.ema.europa.eu/en/medicines/human/referrals/levamisole-containing-medicinal-products*

# Humanarzneimittel - EMA

***Referral: Melatomed and associated names***
***Published on:*** *12 - December - 2025*
***For more information, please refer to:***
*https://www.ema.europa.eu/en/medicines/human/referrals/melatomed-associated-names*

***Compliance notifications explanation and Q&A***
***Published on:*** *02 - December - 2025*
***For more information, please refer to:***
*https://www.ema.europa.eu/en/documents/other/compliance-notifications-explanation-qa_en.pdf*

***Outcomes of imposed non-interventional post-authorisation safety studies***
***Published on:*** *02 - December - 2025*
***For more information, please refer to:***
*https://www.ema.europa.eu/en/human-regulatory-overview/post-authorisation/pharmacovigilance-post-authorisation/post-authorisation-safety-studies-pass/outcomes-imposed-non-interventional-post-authorisation-safety-studies*

***Q&A clinic on eXtended EudraVigilance Medicinal Product Dictionary (XEVMPD) service***
***Video recording available***
***Published on:*** *02 - December - 2025*
***For more information, please refer to:***
*https://www.ema.europa.eu/en/events/qa-clinic-extended-eudravigilance-medicinal-product-dictionary-xevmpd-service-0*

***Safety of medicines***
***Published on:*** *03 - December - 2025*
***For more information, please refer to:***
*https://www.ema.europa.eu/en/about-us/what-we-do/safety-medicines*

***EudraVigilance: electronic reporting***
***Published on:*** *03 - December - 2025*
***For more information, please refer to:***
*https://www.ema.europa.eu/en/human-regulatory-overview/research-development/pharmacovigilance-research-development/eudravigilance/eudravigilance-electronic-reporting*

***List of substances and products subject to worksharing for signal management***
***Published on:*** *09 - December - 2025*
***For more information, please refer to:***
*https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/list-substances-products-subject-worksharing-signal-management_en.xlsx*

***List of medicines under additional monitoring***
***Published on:*** *10 - December - 2025*
***For more information, please refer to:***
*https://www.ema.europa.eu/en/human-regulatory-overview/post-authorisation/pharmacovigilance-post-authorisation/medicines-under-additional-monitoring/list-medicines-under-additional-monitoring*

# Humanarzneimittel - EMA

***Article 57 product data***
***Published on:*** *10 - December - 2025*
***For more information, please refer to:***
*https://www.ema.europa.eu/en/documents/other/article-57-product-data_en.xlsx*

***20th industry stakeholder platform - operation of European Union (EU) pharmacovigilance Presentations available***
***Published on:*** *10 - December - 2025*
***For more information, please refer to:***
*https://www.ema.europa.eu/en/events/20th-industry-stakeholder-platform-operation-european-union-eu-pharmacovigilance*

***First EMA/HMA multi-stakeholder forum on EudraVigilance and signal detection Video recording available***
***Published on:*** *11 - December - 2025*
***For more information, please refer to:***
*https://www.ema.europa.eu/en/events/first-ema-hma-multi-stakeholder-forum-eudravigilance-signal-detection*

## Zulassung – Regulatory Affairs

***Fifteenth meeting of the industry stakeholder platform on the operation of the centralised procedure for human medicines Presentations available***
***Published on:*** *28 - November - 2025*
***For more information, please refer to:***
*https://www.ema.europa.eu/en/events/fifteenth-meeting-industry-stakeholder-platform-operation-centralised-procedure-human-medicines*

***IRIS guide for applicants - How to create, submit and manage IRIS applications, for industry and individual applicants***
***Published on:*** *02 - December - 2025*
***For more information, please refer to:***
*https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/iris-guide-applicants-how-create-submit-scientific-applications-industry-individual-applicants_en.pdf*

***Questions and answers clinic on Product Management Service (PMS) Product User Interface (PUI) and Application Programming Interface (API) - November 2025 Video recording available***
***Published on:*** *03 - December - 2025*
***For more information, please refer to:***
*https://www.ema.europa.eu/en/events/questions-answers-clinic-product-management-service-pms-product-user-interface-pui-application-programming-interface-api-november-2025*

# Humanarzneimittel - EMA

***European Medicines Agency post-authorisation procedural advice for users of the centralised procedure***
***Published on:*** *03 - December - 2025*
***For more information, please refer to:***
*https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/european-medicines-agency-post-authorisation-procedural-advice-users-centralised-procedure_en.pdf*

***CHMP opinions on consultation procedures***
***Published on:*** *04 - December - 2025*
***For more information, please refer to:***
*https://www.ema.europa.eu/en/human-regulatory-overview/medical-devices/consultation-procedure-ancillary-medicinal-substances-medical-devices/chmp-opinions-consultation-procedures*

***Substance and product data management services***
***Published on:*** *08 - December - 2025*
***For more information, please refer to:***
*https://www.ema.europa.eu/en/human-regulatory-overview/research-development/data-medicines-iso-idmp-standards-overview/substance-product-organisation-referential-spor-master-data/substance-product-data-management-services*

***Classification of changes***
***Published on:*** *08 - December - 2025*
***For more information, please refer to:***
*https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/classification-changes_en.pdf*

***How to submit information on authorised and investigational medicines***
***Published on:*** *10 - December - 2025*
***For more information, please refer to:***
*https://www.ema.europa.eu/en/human-regulatory-overview/post-authorisation/data-medicines-iso-idmp-standards-post-authorisation/reporting-requirements-marketing-authorisation-holders/how-submit-information-authorised-investigational-medicines*

***Union list of critical medicines***
***Published on:*** *12 - December - 2025*
***For more information, please refer to:***
*https://www.ema.europa.eu/en/human-regulatory-overview/post-authorisation/medicine-shortages-availability-issues/availability-medicines-during-crises/union-list-critical-medicines*

***Meeting highlights from the Committee for Medicinal Products for Human Use (CHMP) 8-11 December 2025***
***Published on:*** *12 - December - 2025*
***For more information, please refer to:***
*https://www.ema.europa.eu/en/news/meeting-highlights-committee-medicinal-products-human-use-chmp-8-11-december-2025*

# Humanarzneimittel - EMA

## Orphan Drugs und neuartige Therapierichtungen (ATMP)

***CAT quarterly highlights and approved ATMPs - December 2025***
***Published on:*** *02 - December - 2025*
***For more information, please refer to:***
*https://www.ema.europa.eu/en/documents/committee-report/cat-quarterly-highlights-approved-atmps-december-2025_en.pdf*

## Qualität – Quality

***Guidance on good manufacturing practice and good distribution practice: Questions and answers***
***Published on:*** *10 - December - 2025*
***For more information, please refer to:***
*https://www.ema.europa.eu/en/human-regulatory-overview/research-development/compliance-research-development/good-manufacturing-practice/guidance-good-manufacturing-practice-good-distribution-practice-questions-answers*

## (Prä-) Klinische Forschung – Research and Development

***Good pharmacogenomic practice - Scientific guideline***
***Published on:*** *08 - December - 2025*
***For more information, please refer to:***
*https://www.ema.europa.eu/en/good-pharmacogenomic-practice-scientific-guideline*

***Questions and answers for biological medicinal products***
***Published on:*** *09 - December - 2025*
***For more information, please refer to:***
*https://www.ema.europa.eu/en/human-regulatory-overview/research-and-development/scientific-guidelines/biological-guidelines/questions-answers-biological-medicinal-products*

## Kinderarzneimittel – Paediatrics

***No news published***

## Pflanzliche Arzneimittel – Herbal medicines

***HMPC: overview of assessment work - priority list***
***Published on:*** *03 - December - 2025*
***For more information, please refer to:***
*https://www.ema.europa.eu/en/documents/other/hmpc-overview-assessment-work-priority-list_en.pdf*

# Humanarzneimittel - EMA

***Herbal medicinal product: Althaeae radix, F: Assessment finalized***
***Published on:*** *08 - December - 2025*
***For more information, please refer to:***
*https://www.ema.europa.eu/en/medicines/herbal/althaeae-radix*

***Herbal medicinal product: Carvi aetheroleum, F: Assessment finalized***
***Published on:*** *08 - December - 2025*
***For more information, please refer to:***
*https://www.ema.europa.eu/en/medicines/herbal/carvi-aetheroleum*

***Herbal medicinal product: Carvi fructus, F: Assessment finalized***
***Published on:*** *08 - December - 2025*
***For more information, please refer to:***
*https://www.ema.europa.eu/en/medicines/herbal/carvi-fructus*

***HMPC meeting report on European Union herbal monographs, guidelines and other activities - 17-19 November 2025***
***Published on:*** *12 - December - 2025*
***For more information, please refer to:***
*https://www.ema.europa.eu/en/documents/committee-report/hmpc-meeting-report-european-union-herbal-monographs-guidelines-other-activities-17-19-november-2025_en.pdf*

# European Commission

***EU launches plan to strengthen preparedness for cross-border health crises***
***Published on:*** *28 - November - 2025*
***For more information, please refer to:***
*https://ec.europa.eu/commission/presscorner/detail/en/ip_25_2836*

***Health Technology Assessment – 2026 Work Programme adopted***
***Published on:*** *02 - December - 2025*
***For more information, please refer to:***
*https://ec.europa.eu/newsroom/sante/newsletter-archives/69817*

***Questions and Answers on general methodological and procedural issues for joint clinical assessments***
***Published on:*** *05 - December - 2025*
***For more information, please refer to:***
*https://health.ec.europa.eu/latest-updates/questions-and-answers-general-methodological-and-procedural-issues-joint-clinical-assessments-2025-12-05_en*

***Updated rolling plan - Implementation of the Regulation on health technology assessment (December 2025)***
***Published on:*** *08 - December - 2025*
***For more information, please refer to:***
*https://health.ec.europa.eu/latest-updates/updated-rolling-plan-implementation-regulation-health-technology-assessment-december-2025-2025-12-08_en*

# EDQM

***EDQM releases draft revised "Guideline on requirements for revision/renewal of certificates of suitability to the European Pharmacopoeia monographs" – for public consultation***
***Published on:*** *01 - December - 2025*
***For more information, please refer to:***
*https://www.edqm.eu/en/-/edqm-releases-draft-revised-guideline-on-requirements-for-revision/renewal-of-certificates-of-suitability-to-the-european-pharmacopoeia-monographs-for-public-consultation*

***EDQM reference standards monthly newsletter – November 2025***
***Published on:*** *01 - December - 2025*
***For more information, please refer to:***
*https://www.edqm.eu/en/-/edqm-reference-standards-monthly-newsletter-november-2025*

***Two new EDQM publications on herbal food supplements for healthcare professionals and consumers***
***Published on:*** *04 - December - 2025*
***For more information, please refer to:***
*https://www.edqm.eu/en/-/edqm-publications-herbal-food-supplements*

***Pharmacopoeial discussion group achievements***
***Published on:*** *05 - December - 2025*
***For more information, please refer to:***
*https://www.edqm.eu/en/-/pharmacopoeial-discussion-group-achievements-15*

***Outcome of the 183rd session of the European Pharmacopoeia Commission***
***Published on:*** *08 - December - 2025*
***For more information, please refer to:***
*https://www.edqm.eu/en/-/outcome-183-session-european-ph-commission*

***Certification monthly report of activities: End of November 2025***
***Published on:*** *08 - December - 2025*
***For more information, please refer to:***
*https://www.edqm.eu/en/-/certification-monthly-report-of-activities-end-of-november-2025*

# Medizinprodukte

***Monitoring of availability of medical devices on the EU Market - Study overview and 2nd survey results***
***Published on:*** *01 - December - 2025*
***For more information, please refer to:***
*https://health.ec.europa.eu/latest-updates/monitoring-availability-medical-devices-eu-market-study-overview-and-2nd-survey-results-2025-12-01_en*

***Questions and answers on implementation of the medical devices and in vitro diagnostic medical devices Regulations ((EU) 2017/745 and (EU) 2017/746)***
***Published on:*** *02 - December - 2025*
***For more information, please refer to:***
*https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/questions-answers-implementation-medical-devices-vitro-diagnostic-medical-devices-regulations-eu-2017-745-eu-2017-746_en.pdf*

***Medical devices***
***Published on:*** *10 - December - 2025*
***For more information, please refer to:***
*https://www.ema.europa.eu/en/human-regulatory-overview/medical-devices*

# CMDh

***CTCG Introduction/Overview/Mandate***
***Published on:*** *08 - December - 2025*
***For more information, please refer to:***
*https://www.hma.eu/about-hma/working-groups/clinical-trials-coordination-group/clinical-trials-coordination-group.html#c7040*

# Humanarzneimittel - Deutschland

***Pharmacovigilance Risk Assessment Committee (PRAC)***
***Veröffentlicht am:*** *28 - November - 2025*
***Weitere Informationen finden Sie unter:***
*https://www.bfarm.de/DE/Arzneimittel/Pharmakovigilanz/Ausschuesse-und-Gremien/PRAC/_artikel.html?nn=986770*

***Offene ordnungsgemäß eingegangene Anträge auf Zulassung und Registrierung für Arzneimittel im Zuständigkeitsbereich des BfArM***
***Veröffentlicht am:*** *01 - Dezember - 2025*
***Weitere Informationen finden Sie unter:***
*https://www.bfarm.de/DE/Aktuelles/Statistiken/Arzneimittelzulassung/offene-Zulassungsantraege/_artikel.html?nn=986770*

***Für die Genehmigung multinationaler klinischer Prüfungen in der EU/EWR wird testweise ein Schnellverfahren gestartet***
***Veröffentlicht am:*** *03 - Dezember - 2025*
***Weitere Informationen finden Sie unter:***
*https://www.bfarm.de/DE/Arzneimittel/Klinische-Pruefung/News/FAST-EU-pilot.html?nn=986770*

***Wirkstoffe und Arzneimittel, für die die Erstellung von Schulungsmaterialien beauflagt worden ist***
***Veröffentlicht am:*** *03 - Dezember - 2025*
***Weitere Informationen finden Sie unter:***
*https://www.bfarm.de/SharedDocs/Downloads/DE/Arzneimittel/Pharmakovigilanz/Risikoinformationen/EducationMaterial/weitere-informationen/tabelle-educatmaterial.html?nn=986770*

***ATC Downloads***
***Veröffentlicht am:*** *04 - Dezember - 2025*
***Weitere Informationen finden Sie unter:***
*https://www.bfarm.de/DE/Kodiersysteme/Klassifikationen/ATC/Downloads/_artikel.html?nn=986770*

***Paul-Ehrlich-Institut veröffentlicht Jahresbericht 2023/2024 des Deutschen Hämophilieregisters (DHR)***
***Veröffentlicht am:*** *04 - Dezember - 2025*
***Weitere Informationen finden Sie unter:***
*https://www.pei.de/DE/newsroom/hp-meldungen/2025/251204-paul-ehrlich-institut-dhr-jahresbericht-2023-2024.html?nn=170852*

***Paul-Ehrlich-Institut veröffentlicht Bericht zur Blut- und Blutprodukteversorgung 2024***
***Veröffentlicht am:*** *08 - Dezember - 2025*
***Weitere Informationen finden Sie unter:***
*https://www.pei.de/DE/newsroom/hp-meldungen/2025/251208-paul-ehrlich-institut-veroeffentlicht-bericht-blutprodukteversorgung-2024.html?nn=170852*

***Anzeigen von Medizinprodukten und In-vitro-Diagnostika***
***Veröffentlicht am:*** *11 - Dezember - 2025*
***Weitere Informationen finden Sie unter:***
*https://www.bfarm.de/DE/Medizinprodukte/Aufgaben/DMIDS/Anzeigen/_artikel.html?nn=986770*

# Humanarzneimittel - Deutschland

***Maßnahmen des BfArM und ergänzende Informationen zu Lieferengpässen***
***Veröffentlicht am:*** *12 - Dezember - 2025*
***Weitere Informationen finden Sie unter:***
*https://www.bfarm.de/DE/Arzneimittel/Arzneimittelinformationen/Lieferengpaesse/Massnahmen-des-BfArM/_artikel.html?nn=986770*

***FAST-EU: Paul-Ehrlich-Institut beteiligt sich am Pilotprojekt zu multinationalen klinischen Prüfungen***
***Veröffentlicht am:*** *12 - Dezember - 2025*
***Weitere Informationen finden Sie unter:***
*https://www.pei.de/DE/newsroom/hp-meldungen/2025/251212-fast-eu-paul-ehrlich-institut-pilotprojekt-multinationale-klinische-pruefungen.html?nn=170852*

# Humanarzneimittel - Österreich

***Geschäftsordnung***
***Veröffentlicht am:*** *01 - Dezember - 2025*
***Weitere Informationen finden Sie unter:***
*https://www.basg.gv.at/ueber-uns/basg-veroeffentlichungen/geschaeftsordnung*

***Sicherheitsmerkmale***
***Veröffentlicht am:*** *01 - Dezember - 2025*
***Weitere Informationen finden Sie unter:***
*https://www.basg.gv.at/fuer-unternehmen/zulassung-life-cycle/zulassungsverfahren/sicherheitsmerkmale*

***Verpflichtende Nutzung der ersten vier Module von EUDAMED***
***Veröffentlicht am:*** *02 - Dezember - 2025*
***Weitere Informationen finden Sie unter:***
*https://www.basg.gv.at/marktbeobachtung/amtliche-nachrichten/detail/verpflichtende-nutzung-der-ersten-vier-module-von-eudamed*

***1225_Register Arzneimittelvermittler***
***Veröffentlicht am:*** *10 - Dezember - 2025*
***Weitere Informationen finden Sie unter:***
*https://www.basg.gv.at/fileadmin/redakteure/04_Marktbeobachtung/%C3%96ffentliche_Register/1225_Register_Arzneimittelvermittler.pdf*

***1225_Bearbeitungsstand***
***Veröffentlicht am:*** *10 - Dezember - 2025*
***Weitere Informationen finden Sie unter:***
*https://www.basg.gv.at/fuer-unternehmen/bewilligung-und-zertifizierung/gute-herstellungs-/-vertriebspraxis-gmp/gdp#c23173*

***1225_Register bewilligter AM Betriebe Österreich***
***Veröffentlicht am:*** *10 - Dezember - 2025*
***Weitere Informationen finden Sie unter:***
*https://www.basg.gv.at/marktbeobachtung/oeffentliche-register/arzneimittelbetriebe#c12499*

***PSUR outcome: Vancomycin***
***Veröffentlicht am:*** *02 - Dezember - 2025*
***Weitere Informationen finden Sie unter:***
*Mustertext Vancomycin*
*Link zur Webseite der EMA*

***PSUR outcome: Propylthiouracil***
***Veröffentlicht am:*** *03 - Dezember - 2025*
***Weitere Informationen finden Sie unter:***
*Mustertext Propylthiouracil*
*Link zur Webseite der EMA*

# Humanarzneimittel - Schweiz

***Tagung des ICH (International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use)***
***Veröffentlicht am:*** *01 - Dezember - 2025*
***Weitere Informationen finden Sie unter:***
*https://www.swissmedic.ch/swissmedic/de/home/news/mitteilungen/tagung-ich-singapur.html*

***Swissmedic Journal***
***Veröffentlicht am:*** *05 - Dezember - 2025*
***Weitere Informationen finden Sie unter:***
*https://www.swissmedic.ch/swissmedic/de/home/ueber-uns/publikationen/swissmedic-journal.html*

***Aufsichtsabgabe 2025 – Selbstdeklaration***
***Veröffentlicht am:*** *05 - Dezember - 2025*
***Weitere Informationen finden Sie unter:***
*https://www.swissmedic.ch/swissmedic/de/home/news/mitteilungen/aufsichtsabgabe-2025.html*

***Aktualisierte Vorgabedokumente***
***Veröffentlicht am:*** *12 - Dezember - 2025*
***Weitere Informationen finden Sie unter:***
*https://www.swissmedic.ch/swissmedic/de/home/news/updates/updated_documents.html*

# Fragen an das Netzwerk

**Falls Sie eine Frage haben, die Sie gerne in unserem Netzwerk diskutieren würden, senden Sie uns einfach eine E-Mail an info-as@megra.org zur anonymen Publikation im nächsten Newsletter.***

*Bei der Beantwortung der Fragen handelt es sich um eine Zusammenfassung von persönlichen Meinungen und Erfahrungswerten der MEGRA Mitglieder mit keinem Anspruch auf Rechtssicherheit. Wir empfehlen zur Absicherung die Konsultation entsprechender zugrunde liegender Regularien.

# Veranstaltungen / Events – Behörden und andere Veranstalter

## Deutschland

***Gemeinsame Ringvorlesung Wintersemester 2025/2026***
***Ort:*** *online*
***Termin:*** *verschiedene 2025 - 2026*
***Weitere Informationen finden Sie unter:***
*https://www.bfarm.de/DE/Aktuelles/Veranstaltungen/Ringvorlesung/Termine/Ringvorlesung_2025-26.html?nn=986770*

## Österreich

***Keine Veranstaltungen veröffentlicht***

## Schweiz

***Keine Veranstaltungen veröffentlicht***

## Europa

***Questions and answers clinic on Product Management Service (PMS) Product User Interface (PUI) and Application Programming Interface (API) - December 2025 to May 2026***
***Where:*** *online and European Medicines Agency, Amsterdam, the Netherlands*
***Date:*** *18 - December - 2025, 13 - January - 2026, 10 - February, 10 - March, 14 -April, 12 - May - 2026*
***For more information, please refer to:***
*https://www.ema.europa.eu/en/events/questions-answers-clinic-product-management-service-pms-product-user-interface-pui-application-programming-interface-api-december-2025*
*https://www.ema.europa.eu/en/events/qa-clinic-product-management-service-pms-product-user-interface-pui-application-programming-interface-api-january-2026*
*https://www.ema.europa.eu/en/events/qa-clinic-product-management-service-pms-product-user-interface-pui-application-programming-interface-api-february-2026*
*https://www.ema.europa.eu/en/events/qa-clinic-product-management-service-pms-product-user-interface-pui-application-programming-interface-api-march-2026*
*https://www.ema.europa.eu/en/events/qa-clinic-product-management-service-pms-product-user-interface-pui-application-programming-interface-api-april-2026*
*https://www.ema.europa.eu/en/events/qa-clinic-product-management-service-pms-product-user-interface-pui-application-programming-interface-api-may-2026*

# Veranstaltungen / Events – Behörden und andere Veranstalter

***Q&A clinic on eXtended EudraVigilance Medicinal Product Dictionary (XEVMPD) service***
***Where:*** *online and European Medicines Agency, Amsterdam, the Netherlands*
***Date:*** *18 - December - 2025, 15 - January - 2026, 12 - February, 12 - March, 16 -April, 13 - May - 2026*
***For more information, please refer to:***
*https://www.ema.europa.eu/en/events/qa-clinic-extended-eudravigilance-medicinal-product-dictionary-xevmpd-service*
*https://www.ema.europa.eu/en/events/qa-clinic-extended-eudravigilance-medicinal-product-dictionary-xevmpd-service-january-2026*
*https://www.ema.europa.eu/en/events/qa-clinic-extended-eudravigilance-medicinal-product-dictionary-xevmpd-service-february-2026*
*https://www.ema.europa.eu/en/events/qa-clinic-extended-eudravigilance-medicinal-product-dictionary-xevmpd-service-march-2026*
*https://www.ema.europa.eu/en/events/qa-clinic-extended-eudravigilance-medicinal-product-dictionary-xevmpd-service-april-2026*
*https://www.ema.europa.eu/en/events/qa-clinic-extended-eudravigilance-medicinal-product-dictionary-xevmpd-service-may-2026*

***New variations guidelines: webinar for marketing authorisation holders (human)***
***Where:*** *online and European Medicines Agency, Amsterdam, the Netherlands*
***Date:*** *13 - January - 2026*
***For more information, please refer to:***
*https://www.ema.europa.eu/en/events/new-variations-guidelines-webinar-marketing-authorisation-holders-human*

***Q&A clinic on Substance, Organisation, Referentials Management Services - January to May 2026***
***Where:*** *online and European Medicines Agency, Amsterdam, the Netherlands*
***Date:*** *13 - January, 10 - February, 10 - March, 14 -April, 12 – May - 2026*
***For more information, please refer to:***
*https://www.ema.europa.eu/en/events/qa-clinic-substance-organisation-referentials-management-services-january-2026*
*https://www.ema.europa.eu/en/events/qa-clinic-substance-organisation-referentials-management-services-february-2026*
*https://www.ema.europa.eu/en/events/qa-clinic-substance-organisation-referentials-management-services-march-2026*
*https://www.ema.europa.eu/en/events/qa-clinic-substance-organisation-referentials-management-services-april-2026*
*https://www.ema.europa.eu/en/events/qa-clinic-substance-organisation-referentials-management-services-may-2026*

# Veranstaltungen / Events – Behörden und andere Veranstalter

***Seventh European Medicines Agency - EuropaBio bilateral meeting***
***Where:*** *European Medicines Agency, Amsterdam, the Netherlands*
***Date:*** *20 - January - 2026*
***For more information, please refer to:***
*https://www.ema.europa.eu/en/events/seventh-european-medicines-agency-europabio-bilateral-meeting*

***Joint EDQM-EPAA Symposium: Pyrogen testing 2.0: Ethical, Evolving and Eco-friendly Implementing safe, rapid, state-of-the-art and sustainable non-animal approaches worldwide***
***Where:*** *online and Albert Borschette Conference Centre (CCAB), rue Froissart 36, Brussels, Belgium*
***Date:*** *25 to 26 - February - 2026*
***For more information, please refer to:***
*https://www.edqm.eu/en/joint-edqm-epaa-symposium-pyrogen-testing-2.0-ethical-evolving-and-eco-friendly-implementing-safe-rapid-state-of-the-art-and-sustainable-non-animal-approaches-worldwide*

***SPOR and XEVMPD status update webinar - Q2 2026***
***Where:*** *online and European Medicines Agency, Amsterdam, the Netherlands*
***Date:*** *13 - April - 2026*
***For more information, please refer to:***
*https://www.ema.europa.eu/en/events/spor-xevmpd-status-update-webinar-q2-2026*