17. - 31. Oktober 2025

MEGRA

NEWSLETTER

Humanarzneimittel - EMA

Allgemeines – General

Medicinal products for human use: monthly figures - September 2025
Published on: *21 - October - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/documents/report/medicinal-products-human-use-monthly-figures-september-2025_en.pdf

Medicines for human use under evaluation
Published on: *22 - October - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/medicines/medicines-human-use-under-evaluation

International Coalition of Medicines Regulatory Authorities (ICMRA)
Published on: *24 - October - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/partners-networks/international-activities/multilateral-coalitions-initiatives/international-coalition-medicines-regulatory-authorities-icmra

HMA/EMA multi-stakeholder workshop on reporting and qualification of mechanistic models for regulatory assessment, Event - 08 - 09 October - 2025
Presentations and Video recording available
Published on: *27 - October - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/events/hma-ema-multi-stakeholder-workshop-reporting-qualification-mechanistic-models-regulatory-assessment

Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG)
Published on: *28 - October - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/about-us/who-we-are/executive-steering-group-shortages-medicinal-products

Pharmakovigilanz – PRAC

Referral: Ipidacrine-containing medicinal products
Published on: *20 - October - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/medicines/human/referrals/ipidacrine-containing-medicinal-products

Referral: Azithromycin-containing medicinal products for systemic use
Published on: *21 - October - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/medicines/human/referrals/azithromycin-containing-medicinal-products-systemic-use

Humanarzneimittel - EMA

Referral: Sodium oxybate-containing syrup and oral solution for alcohol dependence
Published on: *28 - October - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/medicines/human/referrals/sodium-oxybate-containing-syrup-oral-solution-alcohol-dependence

List of European Union reference dates (EURD) and frequency of submission of periodic safety update reports (PSURs)
Published on: *21 - October - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/documents/other/list-european-union-reference-dates-eurd-frequency-submission-periodic-safety-update-reports-psurs_en.xlsx

PRAC recommendations on signals adopted at the 29 September - 2 October 2025 PRAC meeting
Published on: *27 - October - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/documents/prac-recommendation/prac-recommendations-signals-adopted-29-september-2-october-2025-prac-meeting_en.pdf

Article 57 product data
Published on: *28 - October - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/documents/other/article-57-product-data_en.xlsx

List of medicines under additional monitoring
Published on: *29 - October - 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

List of centrally authorised products with safety-related changes to the product information
Published on: *31 - October - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/list-centrally-authorised-products-safety-related-changes-product-information_en.xlsx

Zulassung – Regulatory Affairs

Substance, product, organisation and referential (SPOR) master data
Published on: *27 - October - 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

Humanarzneimittel - EMA

Pre-authorisation guidance
Published on: *28 - October - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/human-regulatory-overview/marketing-authorisation/pre-authorisation-guidance

Plasma master file certificates
Published on: *28 - October - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/human-regulatory-overview/plasma-master-file-pmf-certification/plasma-master-file-certificates

Questions and answers clinic on Product Management Service (PMS) Product User Interface (PUI) and Application Programming Interface (API), Event - 14 - October - 2025
Video recording available
Published on: *29 - October - 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-october-2025

Unlocking PMS API potential: Edit functionality training for MAHs, Event - 16 - October – 2025
Video recording available
Published on: *29 - October - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/events/unlocking-pms-api-potential-edit-functionality-training-mahs

PRIME: priority medicines
Published on: *29 - October - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/human-regulatory-overview/research-development/prime-priority-medicines

Orphan Drugs und neuartige Therapierichtungen (ATMP)

Scientific recommendations on classification of advanced therapy medicinal products
Published on: *21 - October - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/documents/other/scientific-recommendations-classification-advanced-therapy-medicinal-products_en.xlsx

Advanced therapy classification
Published on: *28 - October - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/human-regulatory-overview/marketing-authorisation/advanced-therapies-marketing-authorisation/advanced-therapy-classification

Humanarzneimittel - EMA

Qualität – Quality

Quality aspects of phage therapy medicinal products
Published on: *22 - October - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/quality-aspects-phage-therapy-medicinal-products

(Prä-) Klinische Forschung – Research and Development

European Platform for Regulatory Science Research meeting September 2025
Presentations available
Published on: *21 - October - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/events/european-platform-regulatory-science-research-meeting-september-2025

Clinical Trial Information System (CTIS) structured data form - Notifications, Annual Safety Report (ASR) and results
Published on: *23 - October - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/documents/template-form/clinical-trial-information-system-ctis-structured-data-form-notifications-results_en.xlsx

Opinions and letters of support on the qualification of novel methodologies for medicine development
Published on: *24 - October - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/human-regulatory-overview/research-development/scientific-advice-protocol-assistance/opinions-letters-support-qualification-novel-methodologies-medicine-development

Clinical Trials Information System
Published on: *29 - October - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/human-regulatory-overview/research-development/clinical-trials-human-medicines/clinical-trials-information-system

Kinderarzneimittel – Paediatrics

No news published

Humanarzneimittel - EMA

Pflanzliche Arzneimittel – Herbal medicines

Herbal medicinal product: Plantaginis lanceolatae folium, F: Assessment finalized
Published on: *20 - October - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/medicines/herbal/plantaginis-lanceolatae-folium

Herbal medicinal product: Primulae radix, F: Assessment finalized
Published on: *20 - October - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/medicines/herbal/primulae-radix

Herbal medicinal product: Primulae flos , F: Assessment finalized
Published on: *20 - October - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/medicines/herbal/primulae-flos

European Commission

New publication of Harmonised standards under the medical devices Regulations – October 2025
Published on: *20 - October - 2025*
For more information, please refer to:
https://eur-lex.europa.eu/eli/dec_impl/2025/2078/oj

Video recording - The EU HTA Regulation: Webinar for health technology developers of medicinal products (17 October 2025)
Published on: *22 - October - 2025*
For more information, please refer to:
https://health.ec.europa.eu/events/eu-hta-regulation-webinar-health-technology-developers-medicinal-products-2025-10-17_en

New and updated documents - EudraLex Volume 10: Clinical trials guidelines
Published on: *30 - October - 2025*
For more information, please refer to:
https://health.ec.europa.eu/latest-updates/new-and-updated-documents-eudralex-volume-10-clinical-trials-guidelines-2025-10-30_en

EDQM

Changes to e-submission requirements for CEP applications
Published on: *17 - October - 2025*
For more information, please refer to:
https://www.edqm.eu/en/-/changes-to-e-submission-requirements-for-cep-applications

European Pharmacopoeia Issue 12.2 now available
Published on: *20 - October - 2025*
For more information, please refer to:
https://www.edqm.eu/en/-/european-pharmacopoeia-issue-12.2-now-available

Implementation of the European Pharmacopoeia Issue 12.2 – Notification for CEP holders
Published on: *23 - October - 2025*
For more information, please refer to:
https://www.edqm.eu/en/-/implementation-of-the-european-pharmacopoeia-issue-12.2-notification-for-cep-holders

Council of Europe Health Protection Conference 2025 – Recording and spotlight on Session 3
Published on: *24 - October - 2025*
For more information, please refer to:
https://www.edqm.eu/en/-/council-of-europe-health-protection-conference-2025-recording-and-spotlight-on-session-3

Medizinprodukte

No news published

CMDh

UPDATE - List of active substances for which data has been submitted in accordance with Article 45 of the Paediatric Regulation
Published on: *21 - October - 2025*
For more information, please refer to:
https://www.hma.eu/human-medicines/cmdh/paediatric-regulation/article-45-and-previous-worksharing.html

UPDATE - Guidance on eSubmissions
Published on: *22 - October - 2025*
For more information, please refer to:
https://www.hma.eu/human-medicines/cmdh/procedural-guidance/esubmissions.html

NEW - D70 Overview AR Template (incl. instructions)
Published on: *23 - October - 2025*
For more information, please refer to:
https://www.hma.eu/human-medicines/cmdh/templates/assessment-reports/dcp-ar/comments.html

NEW - Q&A Post-Brexit
Published on: *23 - October - 2025*
For more information, please refer to:
https://www.hma.eu/fileadmin/dateien/Human_Medicines/CMD_h_/Questions_Answers/CMDh_457_2025_Rev0_2025_10_-_Q_A_Post-Brexit.pdf

CTCG Introduction/Overview/Mandate
Published on: *31 - October - 2025*
For more information, please refer to:
https://view.officeapps.live.com/op/view.aspx?src=https%3A%2F%2Fwww.hma.eu%2Ffileadmin%2Fdateien%2FHMA_joint%2F00-_About_HMA%2F03-Working_Groups%2FCTCG%2F2025_08_CTCG_Simplified_template_ASR_final.docx&wdOrigin=BROWSELINK

Humanarzneimittel - Deutschland

Erklärung zur Bereitstellung von harmonisiertem Schulungsmaterial (Educational Material)
Veröffentlicht am: *21 - Oktober - 2025*
Weitere Informationen finden Sie unter:
https://www.bfarm.de/SharedDocs/Downloads/DE/Arzneimittel/Pharmakovigilanz/Risikoinformationen/EducationMaterial/weitere-informationen/erklaerung-bereitstellung.html?nn=986770

Aktuell laufende und bestätigte Arzneimittel-Härtefallprogramme
Veröffentlicht am: *21 - Oktober - 2025*
Weitere Informationen finden Sie unter:
https://www.bfarm.de/DE/Arzneimittel/Klinische-Pruefung/Compassionate-Use/compUse-tabelle.html?nn=986770

Informationen zu SNOMED CT
Veröffentlicht am: *24 - Oktober - 2025*
Weitere Informationen finden Sie unter:
https://www.bfarm.de/DE/Kodiersysteme/Terminologien/SNOMED-CT/Informationen/_artikel.html?nn=986770

PSUR Single Assessment (PSUSA)
Veröffentlicht am: *28 - Oktober - 2025*
Weitere Informationen finden Sie unter:
https://www.bfarm.de/DE/Arzneimittel/Pharmakovigilanz/Periodic-Safety-Update-Reports_PSURs/PSUR-Single-Assessment/_artikel.html?nn=986770

10 Jahre #MedSafetyWeek – Wir alle haben es in der Hand, Arzneimittel sicherer zu Machen
Veröffentlicht am: *30 - Oktober - 2025*
Weitere Informationen finden Sie unter:
https://www.bfarm.de/SharedDocs/Pressemitteilungen/DE/2025/pm14-2025.html?nn=986770

Paul-Ehrlich-Institut veröffentlicht Gewebevigilanzbericht für 2023
Veröffentlicht am: *31 - Oktober - 2025*
Weitere Informationen finden Sie unter:
https://www.pei.de/DE/newsroom/hp-meldungen/2025/251031-paul-ehrlich-institut-gewebevigilanzbericht-2023.html?nn=170852

Humanarzneimittel - Österreich

Qualitätsmanagement
Veröffentlicht am: *22 - Oktober - 2025*
Weitere Informationen finden Sie unter:
https://www.basg.gv.at/ueber-uns/qualitaetsmanagement

Zulassung/Registrierung - Einreichungen
Veröffentlicht am: *22 - Oktober - 2025*
Weitere Informationen finden Sie unter:
https://www.basg.gv.at/fuer-unternehmen/zulassung-life-cycle/faq-zulassung-life-cycle/zulassung/registrierung-einreichungen

FAQ – Informationsbeauftragte
Veröffentlicht am: *29 - Oktober - 2025*
Weitere Informationen finden Sie unter:
https://www.basg.gv.at/fuer-unternehmen/arzneimittel-informationen/informationsbeauftragte/faq-informationsbeauftragte
https://www.basg.gv.at/fuer-unternehmen/arzneimittel-informationen/informationsbeauftragte

PHAROS Nutzergruppe
Veröffentlicht am: *29 - Oktober - 2025*
Weitere Informationen finden Sie unter:
https://www.basg.gv.at/fuer-unternehmen/online-service/pharos-nutzergruppe

Leitfaden Pharmakovigilanz
Veröffentlicht am: *30 - Oktober - 2025*
Weitere Informationen finden Sie unter:
https://www.basg.gv.at/fuer-unternehmen/pharmakovigilanz/leitfaeden

PSUR outcome: Bisoprolol/Hydrochlorothiazid
Veröffentlicht am: *30 - Oktober - 2025*
Weitere Informationen finden Sie unter:
Mustertexte Bisoprolol_HCT
Link zur Webseite der EMA

PSUR outcome: Ciclosporin (systemische Anwendung)
Veröffentlicht am: *30 - Oktober - 2025*
Weitere Informationen finden Sie unter:
Mustertexte Ciclosporin (systemisch)
Link zur Webseite der EMA

PSUR outcome: Dexketoprofen / Tramadol
Veröffentlicht am: *30 - Oktober - 2025*
Weitere Informationen finden Sie unter:
Link zur Webseite der EMA

PSUR outcome: Botulinum-Toxin Typ A zur Injektion (Ph.Eur.) (150 kDa), frei von Komplexproteinen
Veröffentlicht am: *30 - Oktober - 2025*
Weitere Informationen finden Sie unter:
Link zur Webseite der EMA

Humanarzneimittel - Schweiz

Anwendbare EU-Rechtsakte
Veröffentlicht am: *21 - Oktober - 2025*
Weitere Informationen finden Sie unter:
https://www.swissmedic.ch/swissmedic/de/home/medizinprodukte/regulierung-medizinprodukte/anwendbare-rechtsakte-gemaess-eu-mdr.html

Vigilance der Tierarzneimittel Jahresbericht 2024
Veröffentlicht am: *27 - Oktober - 2025*
Weitere Informationen finden Sie unter:
https://www.swissmedic.ch/swissmedic/de/home/tierarzneimittel/market-surveillance/meldung-unerwuenschter-tierarzneimittelwirkungen/publikationen/tamvigilance-news-2024.html

Aktualisierung des Positionspapiers von Swissmedic und swissethics zu dezentralisierten klinischen Versuchen (DCTs) mit Arzneimitteln
Veröffentlicht am: *30 - Oktober - 2025*
Weitere Informationen finden Sie unter:
https://www.swissmedic.ch/swissmedic/de/home/humanarzneimittel/clinical-trials/klinische-versuche-mit-arzneimitteln/publikationen.html

Aktualisierte Vorgabedokumente
Veröffentlicht am: *31 - Oktober - 2025*
Weitere Informationen finden Sie unter:
https://www.swissmedic.ch/swissmedic/de/home/news/updates/updated_documents/okt-2025.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

Klinische Prüfung: BfArM trifft...!
Ort: *online*
Termin: *18 - November - 2025*
Weitere Informationen finden Sie unter:
https://www.bfarm.de/DE/Aktuelles/Veranstaltungen/Termine/2025-11-18-klinische-pruefung-austausch.html?nn=986770

"The Product is the Process – Is it?" Manufacturing and Translation of ATMPs and Tissue- & Cell-based products
Ort: *Investitionsbank des Landes Brandenburg, Babelsberger Straße 21, 14473 Potsdam, Germany*
Termin: *20 - November - 2025*
Weitere Informationen finden Sie unter:
https://www.pei.de/SharedDocs/veranstaltungen-events/DE/2025/2025-11-20-workshop-manufacturing-translation-atmp.html?nn=170994

BfArM meets Europe: Shaping the EHDS
Ort: *BfArm, Kurt-Georg-Kiesinger-Allee 3, 53175 Bonn, Germany*
Termin: *24 bis 25 - November*
Weitere Informationen finden Sie unter:
https://www.bfarm.de/EN/News/events/2025-Health-Data/_node.html

Österreich

Keine Veranstaltungen veröffentlicht

Schweiz

Keine Veranstaltungen veröffentlicht

Veranstaltungen / Events – Behörden und andere Veranstalter

Europa

Q&A clinic on Substance, Organisation, Referentials Management Services
Where: *online and European Medicines Agency, Amsterdam, the Netherlands*
Date: *10 - November - 2025, 15 - December - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/events/qa-clinic-substance-organisation-referentials-management-services-2
https://www.ema.europa.eu/en/events/qa-clinic-substance-organisation-referentials-management-services

Mandatory use of ISO/ICH E2B(R3) individual case safety reporting in the EU: hands-on training course using the EudraVigilance system
Where: *online*
Date: *10 to 14 - November - 2025, 01 to 05 - December - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/events/mandatory-use-iso-ich-e2br3-individual-case-safety-reporting-eu-hands-training-course-using-eudravigilance-system-53
https://www.ema.europa.eu/en/events/mandatory-use-iso-ich-e2br3-individual-case-safety-reporting-eu-hands-training-course-using-eudravigilance-system-54

Questions and answers clinic on Product Management Service (PMS) Product User Interface (PUI) and Application Programming Interface (API)
Where: *online and European Medicines Agency, Amsterdam, the Netherlands*
Date: *18 - November - 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

Q&A clinic on eXtended EudraVigilance Medicinal Product Dictionary (XEVMPD) service
Where: *online and European Medicines Agency, Amsterdam, the Netherlands*
Date: *18 - November - 2025, 18 - 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
https://www.ema.europa.eu/en/events/qa-clinic-extended-eudravigilance-medicinal-product-dictionary-xevmpd-service

CombiStats Online – Training
Where: *online*
Date: *17 to 21 - November - 2025*
For more information, please refer to:
https://www.edqm.eu/en/combistats-online-training

Veranstaltungen / Events – Behörden und andere Veranstalter

EMA workshop: Non-clinical data for regulatory decision-making on the efficacy of medical countermeasures
Where: *online and European Medicines Agency, Amsterdam, the Netherlands*
Date: *24 to 25 - November - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/events/ema-workshop-non-clinical-data-regulatory-decision-making-efficacy-medical-countermeasures

Clinical Trials Information System (CTIS) sponsor end user training programme - November 2025
Where: *online and European Medicines Agency, Amsterdam, the Netherlands*
Date: *25 to 28 - November - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/events/clinical-trials-information-system-ctis-sponsor-end-user-training-programme-november-2025

How to read a CEP webinar
Where: *online*
Date: *25 - November - 2025*
For more information, please refer to:
https://www.edqm.eu/en/how-to-read-a-cep-webinar

2025 EDQM virtual training programme: independent modules on the Ph. Eur., reference standards and the CEP Procedure
Where: *online*
Date: *01 to 12 - December - 2025*
For more information, please refer to:
https://www.edqm.eu/en/virtual-training-ph-eur-rs-and-cep-procedure

EMA Information Day on submission predictability of initial marketing authorisation December 2025
Where: *online and European Medicines Agency, Amsterdam, the Netherlands*
Date: *03 - December - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/events/ema-information-day-submission-predictability-initial-marketing-authorisation-december-2025

EMA/HMA annual data forum
Where: *online and European Medicines Agency, Amsterdam, the Netherlands*
Date: *09 - December - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/events/ema-hma-annual-data-forum