21. Februar 2025
- 07. März 2025

MEGRA NEWSLETTER

Humanarzneimittel - EMA

Allgemeines – General

World Health Organization (WHO)
Published on: *21 - February - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/partners-networks/international-activities/multilateral-coalitions-initiatives/world-health-organization-who

Medicinal products for human use: monthly figures - January 2025
Published on: *25 - February - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/documents/report/medicinal-products-human-use-monthly-figures-january-2025_en.pdf

Pharmakovigilanz – PRAC

List of medicines under additional monitoring
Published on: *24 - February - 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 European Union reference dates (EURD) and frequency of submission of periodic safety update reports (PSURs)
Published on: *05 - March - 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

Referral: Azithromycin-containing medicinal products for systemic use – updated
Published on: *05 - March - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/medicines/human/referrals/azithromycin-containing-medicinal-products-systemic-use

Zulassung – Regulatory Affairs

Biosimilar medicines: marketing authorization
Published on: *24 - February - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/human-regulatory-overview/marketing-authorisation/biosimilar-medicines-marketing-authorisation

Humanarzneimittel - EMA

Meeting highlights from the Committee for Medicinal Products for Human Use (CHMP) 24-27 February 2025
Published on: *28 - February - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/news/meeting-highlights-committee-medicinal-products-human-use-chmp-24-27-february-2025

Nitrosamine impurities in specific medicines
Published on: *28 - February - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/human-regulatory-overview/post-authorisation/pharmacovigilance-post-authorisation/referral-procedures-human-medicines/nitrosamine-impurities/nitrosamine-impurities-specific-medicines

Regulatory Procedure Management (RPM) for the Product Lifecycle Management (PLM) - Frequently asked questions
Published on: *03 - March - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/documents/other/regulatory-procedure-management-rpm-product-lifecycle-management-plm-frequently-asked-questions_en.pdf

Medicines for human use under evaluation
Published on: *04 - March - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/medicines/medicines-human-use-under-evaluation

CHMP opinions on consultation procedures
Published on: *05 - March - 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

Orphan Drugs und neuartige Therapierichtungen (ATMP)

Infographic - Orphan Medicines in the EU
Published on: *27 - February - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/documents/leaflet/infographic-orphan-medicines-eu_en.pdf

Minutes of the CAT meeting 22-24 January 2025
Published on: *27 - February - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/documents/minutes/minutes-cat-meeting-22-24-january-2025_en.pdf

Humanarzneimittel - EMA

Qualität – Quality

Good manufacturing practice
Published on: *24 - February - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/human-regulatory-overview/research-development/compliance-research-development/good-manufacturing-practice

Good distribution practice
Published on: *24 - February - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/human-regulatory-overview/post-authorisation/compliance-post-authorisation/good-distribution-practice

Questions and answers for biological medicinal products
Published on: *24 - February - 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

(Prä-) Klinische Forschung – Research and Development

Clinical Trials Information System (CTIS): training and support
Published on: *24 - February - 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-ctis-training-support

Development of the Clinical Trials Information System
Published on: *24 - February - 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/development-clinical-trials-information-system

Pre-authorisation guidance
Published on: *25 - February - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/human-regulatory-overview/marketing-authorisation/pre-authorisation-guidance

ACT EU workshop on ICH E6 R3 (principles and Annex 1), Event – 19 to 20 - February – 2025
Presentations and Video recording available
Published on: *25 - February - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/events/act-eu-workshop-ich-e6-r3-principles-annex-1

Humanarzneimittel - EMA

CTIS newsflash - 25 February 2025
Published on: *25 - February - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/documents/newsletter/ctis-newsflash-25-february-2025_en.pdf

Clinical evaluation of new vaccines - Scientific guideline
Published on: *26 - February - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/clinical-evaluation-new-vaccines-scientific-guideline

Investigation of bioequivalence - Scientific guideline
Published on: *26 - February - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/investigation-bioequivalence-scientific-guideline

Clinical Trial Information System (CTIS) evaluation timelines (updated)
Published on: *27 - February - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/documents/other/clinical-trial-information-system-ctis-evaluation-timelines_en.pdf

News: New clinical trial map launched in the EU
Published on: *03 - March - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/news/new-clinical-trial-map-launched-eu

Frequently asked questions (FAQs): How to create, submit and withdraw a Clinical Trial Application - CTIS Training Programme - Module 10
Published on: *05 - March - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/documents/other/faqs-how-create-submit-withdraw-clinical-trial-application-ctis-training-programme-module-10_en.pdf

Frequently asked questions (FAQs) : How to create and submit an annual safety report and respond to related requests for information - CTIS Training Programme - Module 18
Published on: *05 - March - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/documents/other/frequently-asked-questions-faqs-how-create-and-submit-annual-safety-report-and-respond-related-requests-information-ctis-training-programme-module-18_en.pdf

Clinical Trials Information System (CTIS) bitesize talk: Change of sponsor in CTIS), Event – 05 - March – 2025
Presentations and Video recording available
Published on: *07 - March - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/events/clinical-trials-information-system-ctis-bitesize-talk-change-sponsor-ctis

Humanarzneimittel - EMA

Kinderarzneimittel – Paediatrics

No news published

Pflanzliche Arzneimittel – Herbal medicines

Herbal medicinal product: Prunus avium peduncle, D: Draft under discussion (updated)
Published on: *25 - February - 2025*
For more information, please refer to
https://www.ema.europa.eu/en/medicines/herbal/prunus-avium-peduncle

Herbal medicinal product: Tribuli terrestris herba, D: Draft under discussion (updated)
Published on: *25 - February - 2025*
For more information, please refer to
https://www.ema.europa.eu/en/medicines/herbal/tribuli-terrestris-herba

Herbal medicinal product: Pilosellae herba cum radice, F: Assessment finalised (updated)
Published on: *26 - February - 2025*
For more information, please refer to
https://www.ema.europa.eu/en/medicines/herbal/pilosellae-herba-cum-radice

Herbal medicinal product: Hederae helicis folium, F: Assessment finalised (updated)
Published on: *28 - February - 2025*
For more information, please refer to
https://www.ema.europa.eu/en/medicines/herbal/hederae-helicis-folium

Herbal medicinal product: Passiflorae herba, F: Assessment finalised (updated)
Published on: *28 - February - 2025*
For more information, please refer to
https://www.ema.europa.eu/en/medicines/herbal/passiflorae-herba

Herbal medicinal product: Eleutherococci radix, F: Assessment finalised (updated)
Published on: *28 - February - 2025*
For more information, please refer to
https://www.ema.europa.eu/en/medicines/herbal/eleutherococci-radix

Herbal medicinal product: Betulae folium, F: Assessment finalised (updated)
Published on: *28 - February - 2025*
For more information, please refer to
https://www.ema.europa.eu/en/medicines/herbal/betulae-folium

Herbal medicinal product: Eucalypti aetheroleum, F: Assessment finalised (updated)
Published on: *28 - February - 2025*
For more information, please refer to
https://www.ema.europa.eu/en/medicines/herbal/eucalypti-aetheroleum

Humanarzneimittel - EMA

Procedures for monograph and list entry establishment
Published on: *28 - February - 2025*
For more information, please refer to
https://www.ema.europa.eu/en/human-regulatory-overview/herbal-medicinal-products/procedures-monograph-list-entry-establishment

European Commission

Critical Medicines Alliance Report recommends priority actions to strengthen the supply of medicines in the EU and prevent shortages
Published on: *28 - February - 2025*
For more information, please refer to:
https://health.ec.europa.eu/latest-updates/critical-medicines-alliance-report-recommends-priority-actions-strengthen-supply-medicines-eu-and-2025-02-28_en

Regulation on the European Health Data Space published
Published on: *05 - March - 2025*
For more information, please refer to:
https://ec.europa.eu/newsroom/sante/newsletter-archives/60931

EDQM

EDQM reference standards monthly newsletter – February 2025
Published on: *04 - March - 2025*
For more information, please refer to:
https://www.edqm.eu/en/-/edqm-reference-standards-monthly-newsletter-february-2025

Medizinprodukte

EU reference laboratories (EURLs) - The Commission has launched a second call for EURLs for high-risk IVDs
Published on: *06 - March - 2025*
For more information, please refer to:
https://health.ec.europa.eu/medical-devices-vitro-diagnostics/eu-reference-laboratories-eurls_en

CMDh

NEW - 28-29 January CMDh minutes
Published on: *03 - March - 2025*
For more information, please refer to:
https://www.hma.eu/human-medicines/cmdh/agendas-and-minutes.html

Summary of CMDh activities 2024
Published on: *05 - March - 2025*
For more information, please refer to:
https://www.hma.eu/human-medicines/cmdh/about-cmdh/cmdh-reports.html

BPG Article 45 and 46 EU Worksharing Procedure - Paediatric Regulation
Published on: *05 - March - 2025*
For more information, please refer to:
https://www.hma.eu/human-medicines/cmdh/paediatric-regulation/guidance-documents.html

Examples for acceptable and not acceptable groupings for MRP/DCP products
Published on: *05 - March - 2025*
For more information, please refer to:
https://www.hma.eu/human-medicines/cmdh/procedural-guidance/variation.html

Template CMS comments in MRP (January 2011)
Published on: *06 - March - 2025*
For more information, please refer to:
https://www.hma.eu/human-medicines/cmdh/templates/assessment-reports/mrp.html#c1207

Humanarzneimittel - Deutschland

Meldeverpflichtungen
Veröffentlicht am: *26 - Februar - 2025*
Weitere Informationen finden Sie unter:
https://www.bfarm.de/DE/Arzneimittel/Arzneimittelinformationen/Lieferengpaesse/Meldeverpflichtungen/_artikel.html?nn=986770

Maßnahmen des BfArM und ergänzende Informationen zu Lieferengpässen
Veröffentlicht am: *26 - Februar - 2025*
Weitere Informationen finden Sie unter:
https://www.bfarm.de/DE/Arzneimittel/Arzneimittelinformationen/Lieferengpaesse/Massnahmen-des-BfArM/_artikel.html?nn=986770

Fachausschüsse der Homöopathischen Arzneibuch-Kommission
Veröffentlicht am: *26 - Februar - 2025*
Weitere Informationen finden Sie unter:
https://www.bfarm.de/DE/Arzneimittel/Zulassung/Zulassungsrelevante-Themen/Arzneibuch/Arzneibuchkommissionen/Homoeopathische-Arzneibuch-Kommission/fachausschuss_HAB-Kom-inhalt.html?nn=986770

Offene ordnungsgemäß eingegangene Anträge auf Zulassung und Registrierung für Arzneimittel im Zuständigkeitsbereich des BfArM
Veröffentlicht am: *04 - März - 2025*
Weitere Informationen finden Sie unter:
https://www.bfarm.de/DE/Aktuelles/Statistiken/Arzneimittelzulassung/offene-Zulassungsantraege/_artikel.html?nn=986770

Arzneimittel-Lieferengpassbekämpfungs- und Versorgungs-verbesserungs-gesetz (ALBVVG)
Veröffentlicht am: *04 - März - 2025*
Weitere Informationen finden Sie unter:
https://www.bfarm.de/DE/Arzneimittel/Arzneimittelinformationen/Lieferengpaesse/ALBVVG/_artikel.html?nn=986770

PSUR Single Assessment (PSUSA)
Veröffentlicht am: *05 - März - 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

Gemeinsame Ringvorlesung Wintersemester 2024/2025 - Vortragsfolien
Veröffentlicht am: *04 - März - 2025*
Weitere Informationen finden Sie unter:
https://www.bfarm.de/DE/Aktuelles/Veranstaltungen/Ringvorlesung/Termine/Ringvorlesung_2024-2025.html?nn=986770

Humanarzneimittel - Österreich

Gebührentarif_01.03.2025 Neu
Veröffentlicht am: *26 - Februar - 2025*
Weitere Informationen finden Sie unter:
Gebührentarif

PSUR outcome: Tacrolimus (systemische Darreichungsformen) Neu
Veröffentlicht am: *24 - Februar - 2025*
Weitere Informationen finden Sie unter:
Link zur Website der Europäischen Kommission

PSUR outcome: Fluticasonfuroat Neu
Veröffentlicht am: *25 - Februar - 2025*
Weitere Informationen finden Sie unter:
Mustertext Fluticasonfuroat
Link zur Website der Europäischen Kommission

PSUR outcome: Spironolacton Neu
Veröffentlicht am: *06 - März - 2025*
Weitere Informationen finden Sie unter:
Link zur Website der Europäischen Kommission

Humanarzneimittel - Schweiz

Einführung der Leitlinie ICH GCP E6 (R3)
Veröffentlicht am: *24 - Februar - 2025*
Weitere Informationen finden Sie unter:
https://www.swissmedic.ch/swissmedic/de/home/news/mitteilungen/einfuehrung-leitlinie-ich-gcp-e6-r3.html

Neue Informationsplattform Abgrenzungsfragen Humanbereich
Veröffentlicht am: *28 - Februar - 2025*
Weitere Informationen finden Sie unter:
https://www.swissmedic.ch/swissmedic/de/home/services/delimitation/humanbereich/infoplattform.html

Swissmedic Journal
Veröffentlicht am: *06 - März - 2025*
Weitere Informationen finden Sie unter:
https://www.swissmedic.ch/swissmedic/de/home/ueber-uns/publikationen/swissmedic-journal.html

Übersicht internationale Arzneimittelzulassungen
Veröffentlicht am: *07 - März - 2025*
Weitere Informationen finden Sie unter:
https://www.swissmedic.ch/swissmedic/de/home/news/mitteilungen/uebersicht-interanationale-am-zulassungen.html

Aktualisierte Vorgabedokumente
Veröffentlicht am: *01 - März - 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

Klinische Prüfung: BfArM trifft...!
Ort: *online*
Termin: *26 - März - 2025*
Weitere Informationen finden Sie unter:
https://www.bfarm.de/DE/Aktuelles/Veranstaltungen/Termine/2025-03-26-klinische-pruefung-austausch.html?nn=986770

Workshop der Arbeitsgruppe Chemometrics and Quality Assurance zur Datenvisualisierung
Ort: *Paul-Ehrlich-Institut, Langen*
Termin: *02 bis 03 - April - 2025*
Weitere Informationen finden Sie unter:
https://www.pei.de/SharedDocs/veranstaltungen-events/DE/2025/2025-04-02-gdch-workshop.html?nn=170994

Österreich

Keine Veranstaltungen veröffentlicht

Schweiz

Keine Veranstaltungen veröffentlicht

Europa

Certificates Processing System: Demo & Q&A session for industry stakeholders
Where: *online and European Medicines Agency, Amsterdam, the Netherlands*
Date: *13 - March - 2025 , 27 - March - 2025 and 10 -April - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/events/certificates-processing-system-demo-qa-session-industry-stakeholders
https://www.ema.europa.eu/en/events/certificates-processing-system-demo-qa-session-industry-stakeholders-hv-0
https://www.ema.europa.eu/en/events/certificates-processing-system-demo-qa-session-industry-stakeholders-hv

Veranstaltungen / Events – Behörden und andere Veranstalter

Q&A clinic on web-based electronic Application Form (eAF) functionalities for CAPs and non-CAPs variations
Where: *online and European Medicines Agency, Amsterdam, the Netherlands*
Date: *13 - March - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/events/qa-clinic-web-based-electronic-application-form-eaf-functionalities-caps-non-caps-variations

The European Health data Space (EHDS) - Unlocking Europe's Health Data Future Together
Where: *Hotel Le Plaza Brussels, 1000 Brussels, Belgium*
Date: *18 - March - 2025*
For more information, please refer to:
https://health.ec.europa.eu/events/european-health-data-space-ehds-unlocking-europes-health-data-future-together-2025-03-18_en

DIA Europe 2025
Where: *Congress Centre Basel, Switzerland*
Date: *18 to 20 - March - 2025*
For more information, please refer to:
https://www.edqm.eu/en/w/dia-europe-2025

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

Quarterly System Demo – Q1 2025
Where: *online and European Medicines Agency, Amsterdam, the Netherlands*
Date: *26 - March - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/events/quarterly-system-demo-q1-2025

EDQM Stakeholder Event on "Plasma Supply Continuity"
Where: *Congress Centre Basel, Switzerland*
Date: *26 to 27 - March - 2025*
For more information, please refer to:
https://www.edqm.eu/en/plasma-supply-continuity

SPOR and XEVMPD status update webinar
Where: *Live broadcast*
Date: *09 - April - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/events/spor-xevmpd-status-update-webinar

Veranstaltungen / Events – Behörden und andere Veranstalter

EMA Open Door Day
Where: *European Medicines Agency, Amsterdam, the Netherlands*
Date: *09 - May - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/events/ema-open-door-day

Product Management Service (PMS) information day 2025
Where: *online and European Medicines Agency, Amsterdam, the Netherlands*
Date: *21 - May - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/events/product-management-service-pms-information-day-2025