03. - 17. April 2025

MEGRA §

NEWSLETTER

HUMANARZNEIMITTEL - EMA **2**

Allgemeines – General *2*
Pharmakovigilanz – PRAC *2*
Zulassung – Regulatory Affairs *3*
Orphan Drugs und neuartige Therapierichtungen (ATMP) *4*
Qualität – Quality *4*
(Prä-) Klinische Forschung – Research and Development *4*
Kinderarzneimittel – Paediatrics *5*
Pflanzliche Arzneimittel – Herbal medicines *5*

EUROPEAN COMMISSION **6**

EDQM **7**

MEDIZINPRODUKTE **8**

CMDH **9**

HUMANARZNEIMITTEL - DEUTSCHLAND **10**

HUMANARZNEIMITTEL - ÖSTERREICH **11**

HUMANARZNEIMITTEL - SCHWEIZ **12**

FRAGEN AN DAS NETZWERK **13**

VERANSTALTUNGEN / EVENTS – BEHÖRDEN UND ANDERE VERANSTALTER **14**

DEUTSCHLAND 14
ÖSTERREICH 14
SCHWEIZ 14
EUROPA 14

Humanarzneimittel - EMA

Allgemeines – General

Real-world evidence
Published on: *08 - April - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/about-us/how-we-work/data-regulation-big-data-other-sources/real-world-evidence

List of industry subject matter experts and list of planned calls for industry subject matter experts
Published on: *10 - April - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/documents/other/list-industry-subject-matter-experts-list-planned-calls-industry-subject-matter-experts_en.pdf

News: Tackling vulnerabilities in the supply chain of radiopharmaceuticals in the EU
Published on: *10 - April - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/news/tackling-vulnerabilities-supply-chain-radiopharmaceuticals-eu

Fees payable to the European Medicines Agency
Published on: *15 - April - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/about-us/fees-payable-european-medicines-agency

Medicinal products for human use: monthly figures - March 2025
Published on: *16 - April - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/documents/report/medicinal-products-human-use-monthly-figures-march-2025_en.pdf

Pharmakovigilanz – PRAC

List of signals discussed at PRAC since September 2012
Published on: *07 - April - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/documents/other/list-signals-discussed-prac-september-2012_en.xlsx

Chapter 3.II: XEVPRM detailed user guidance on the electronic submission of information on medicinal products for human use by marketing authorisation holders to the EMA
Published on: *10 - April - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/documents/other/chapter-3ii-xevprm-detailed-user-guidance-electronic-submission-information-medicinal-products-human-use-marketing-authorisation-holders-ema_en.pdf

Humanarzneimittel - EMA

Guidance on the anonymisation of protected personal data and assessment of commercially confidential information during the preparation of RMPs (main body and annexes 4 and 6)
Published on: *11 - April - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/guidance-anonymisation-protected-personal-data-assessment-commercially-confidential-information-during-preparation-rmps-main-body-annexes-4-6_en.pdf

Zulassung – Regulatory Affairs

Substance Management System (SMS) guidance for external users
Published on: *04 - April - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/documents/other/sms-guidance-external-users_en.pdf

Recommendations on eligibility to PRIME scheme - Adopted at the CHMP meeting of 24-27 March 2025
Published on: *09 - April - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/documents/chmp-annex/recommendations-eligibility-prime-scheme-adopted-chmp-meeting-24-27-march-2025_en.pdf

PRIME: priority medicines
Published on: *09 - April - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/human-regulatory-overview/research-development/prime-priority-medicines

QRD Appendix V - Adverse-drug-reaction reporting details
Published on: *09 - April - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/documents/template-form/qrd-appendix-v-adverse-drug-reaction-reporting-details_en.docx

Electronic submission of Article 57(2) data: questions and answers
Published on: *10 - April - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/documents/other/electronic-submission-article-572-data-questions-answers_en.pdf

Questions & answers - Practical arrangements on the companion diagnostics consultation procedure to the European Medicines Agency by notified bodies - tracked changes
Published on: *11 - April - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/documents/other/questions-answers-practical-arrangements-companion-diagnostics-consultation-procedure-european-medicines-agency-notified-bodies-tracked-changes_en.pdf

Humanarzneimittel - EMA

Product-information (QRD) templates – Human
Published on: *14 - April - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/human-regulatory-overview/marketing-authorisation/product-information-requirements/product-information-qrd-templates-human

Nitrosamines Safety Operational Expert Group
Published on: *15 - April - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/committees/working-parties-other-groups/chmp/nitrosamines-safety-operational-expert-group

Orphan Drugs und neuartige Therapierichtungen (ATMP)

No news published

Qualität – Quality

Guidance on good manufacturing practice and good distribution practice: Questions and answers
Published on: *08 - April - 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

ICH Guideline M13B on bioequivalence for immediate-release solid oral dosage forms - additional strengths biowaiver - Scientific guideline, New
Published on: *09 - April - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/ich-guideline-m13b-bioequivalence-immediate-release-solid-oral-dosage-forms-additional-strengths-biowaiver-scientific-guideline

Non-clinical Working Party
Published on: *15 - April - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/committees/working-parties-other-groups/chmp/non-clinical-working-party

ICH M15 guideline on general principles for model-informed drug development - Step 2b - Scientific guideline
Published on: *16 - April - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/ich-m15-guideline-general-principles-model-informed-drug-development-step-2b-scientific-guideline

Humanarzneimittel - EMA

Kinderarzneimittel – Paediatrics

Procedural advice on paediatric applications
Published on: *15 - April - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/procedural-advice-paediatric-applications_en.pdf

Pflanzliche Arzneimittel – Herbal medicines

HMPC meeting report on European Union herbal monographs, guidelines and other activities - 17-19 March 2025
Published on: *10 - April - 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-march-2025_en.pdf

Procedures for monograph and list entry establishment
Published on: *15 - April - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/human-regulatory-overview/herbal-medicinal-products/procedures-monograph-list-entry-establishment

Herbal: Crataegi folium cum flore, F: Assessment finalized
Published on: *15 - April - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/medicines/herbal/crataegi-folium-cum-flore

Herbal: Arnicae flos, F: Assessment finalized
Published on: *15 - April - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/medicines/herbal/arnicae-flos

Herbal: Allii sativi bulbus, F: Assessment finalized
Published on: *15 - April - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/medicines/herbal/allii-sativi-bulbus

European Commission

EU-EEA EFTA negotiations on health emergency measures in medical countermeasures to strengthen European health security
Published on: *14 – April – 2025*
For more information, please refer to:
https://health.ec.europa.eu/latest-updates/eu-eea-efta-negotiations-health-emergency-measures-medical-countermeasures-strengthen-european-2025-04-14_en

Commission authorises medicine for treatment of early Alzheimer's disease
Published on: *15 – April – 2025*
For more information, please refer to:
https://ec.europa.eu/newsroom/sante/newsletter-archives/62476

Commission welcomes significant step towards Pandemic Agreement
Published on: *16 - April - 2025*
For more information, please refer to:
https://ec.europa.eu/commission/presscorner/detail/en/ip_25_1068

Health Technology Assessment: First joint clinical assessments begin
Published on: *16 – April – 2025*
For more information, please refer to:
https://ec.europa.eu/newsroom/sante/newsletter-archives/62551

EDQM

Outcome of the 181st session of the European Pharmacopoeia Commission, March 2025
Published on: *08 - April - 2025*
For more information, please refer to:
https://www.edqm.eu/en/-/outcome-of-the-181st-session-of-the-european-pharmacopoeia-commission-march-2025

EPC adopts groundbreaking chapter on cell-based preparations for human use
Published on: *08 - April - 2025*
For more information, please refer to:
https://www.edqm.eu/en/-/epc-adopts-groundbreaking-chapter-on-cell-based-preparations-for-human-use

Public consultation on revised general chapter 5.1.6. Alternative methods for control of microbiological quality in Pharmeuropa 37.2
Published on: *08 - April - 2025*
For more information, please refer to:
https://www.edqm.eu/en/-/public-consultation-on-revised-general-chapter-5.1.6.-alternative-methods-for-control-of-microbiological-quality-in-pharmeuropa-37.2

Certification monthly report of activities: End of March 2025
Published on: *10 - April - 2025*
For more information, please refer to:
https://www.edqm.eu/en/-/certification-monthly-report-of-activities-end-of-march-2025

Technical recommendation of the EDSForm WP: sulfamethoxazole-trimethoprim, paediatric products
Published on: *15 - April - 2025*
For more information, please refer to:
https://www.edqm.eu/en/-/technical-recommendation-of-the-edsform-wp-sulfamethoxazole-trimethoprim-paediatric-products

Medizinprodukte

New publication of Harmonised standards under the medical devices Regulations – April 2025
Published on: *10 - April - 2025*
For more information, please refer to:
https://health.ec.europa.eu/medical-devices-topics-interest/harmonised-standards_en

Medical devices
Published on: *11 - April - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/human-regulatory-overview/medical-devices

CMDh

AR template for paediatric studies submitted in accordance with Article 46 of Regulation (EC) No1901/2006
Published on: *09 - April - 2025*
For more information, please refer to:
https://www.hma.eu/human-medicines/cmdh/templates/assessment-reports/paediatric-data.html

CMDH PRESS RELEASES 2025
Published on: *09 - April - 2025*
For more information, please refer to:
https://www.hma.eu/human-medicines/cmdh/press-releases.html#c7615

HMPWG Reports
Published on: *08 - April - 2025*
For more information, please refer to:
https://www.hma.eu/about-hma/working-groups/homeopathic-medicinal-products-working-group/homeopathic-medicinal-products-working-group-hmpwg.html#c6613

Simultaneous National Scientific Advice (SNSA)
Published on: *10 - April - 2025*
For more information, please refer to:
https://www.hma.eu/about-hma/working-groups/eu-innovation-network-eu-in/eu-innovation-network-eu-in.html#c6787

UPDATE - AR template for paediatric studies submitted in accordance with Article 45 of Regulation (EC) No1901/2006
Published on: *09 – April – 2025*
For more information, please refer to:
https://view.officeapps.live.com/op/view.aspx?src=https%3A%2F%2Fwww.hma.eu%2Ffileadmin%2Fdateien%2FHuman_Medicines%2FCMD_h_%2FTemplates%2FAR%2FPaediatric_Data%2FCMDh_021_2009_Rev.6_2022_06_-_PAR_for_paediatric_studies_Art_45.doc&wdOrigin=BROWSELINK

UPDATE - Report from the meeting held on 25-26 March 2025
Published on: *09 – April – 2025*
For more information, please refert to:
https://www.hma.eu/fileadmin/dateien/Human_Medicines/CMD_h_/CMDh_pressreleases/2025/CMDh_press_release_-_March_2025.pdf

Concerned Member State's Comments on Lead Member State's Preliminary assessment report
Published on: *09 – April – 2025*
For more information, please refer to:
https://view.officeapps.live.com/op/view.aspx?src=https%3A%2F%2Fwww.hma.eu%2Ffileadmin%2Fdateien%2FHuman_Medicines%2FCMD_h_%2FTemplates%2FPSUR%2FCMDh_333_2015_Rev2_2025_04_clean_-_CMS_Comments_on_LMS_AR.docx&wdOrigin=BROWSELINK

Humanarzneimittel - Deutschland

Maßnahmen des BfArM und ergänzende Informationen zu Lieferengpässen
Veröffentlicht am: *07 - April - 2025*
Weitere Informationen finden Sie unter:
https://www.bfarm.de/DE/Arzneimittel/Arzneimittelinformationen/Lieferengpaesse/Massnahmen-des-BfArM/_artikel.html?nn=986770

Informationen zu Einreichung und Genehmigung von Schulungsmaterial
Veröffentlicht am: *08 - April - 2025*
Weitere Informationen finden Sie unter:
https://www.bfarm.de/DE/Arzneimittel/Pharmakovigilanz/Risikoinformationen/Schulungsmaterial/Zusatzinformationen/_artikel.html?nn=986770

Nachträgliche Änderungen einer klinischen Prüfung
Veröffentlicht am: *08 - April - 2025*
Weitere Informationen finden Sie unter:
https://www.bfarm.de/DE/Arzneimittel/Klinische-Pruefung/Genehmigungsverfahren/Nachtraegliche-Aenderungen/_artikel.html?nn=986770

PSUR Single Assessment (PSUSA)
Veröffentlicht am: *15 - April - 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

Medizinforschungsgesetz
Veröffentlicht am: *16 - April - 2025*
Weitere Informationen finden Sie unter:
https://www.bfarm.de/DE/Medizinforschungsgesetz/_artikel.html?nn=986770

Aktuell laufende und bestätigte Arzneimittel-Härtefallprogramme
Veröffentlicht am: *16 - April - 2025*
Weitere Informationen finden Sie unter:
https://www.bfarm.de/DE/Arzneimittel/Klinische-Pruefung/Compassionate-Use/compUse-tabelle.html?nn=986770

Arzneimittel-Lieferengpass-bekämpfungs- und Versorgungs-verbesserungs-gesetz (ALBVVG)
Veröffentlicht am: *16 - April - 2025*
Weitere Informationen finden Sie unter:
https://www.bfarm.de/DE/Arzneimittel/Arzneimittelinformationen/Lieferengpaesse/ALBVVG/_artikel.html?nn=986770

Humanarzneimittel - Österreich

CHMP Meeting Highlights März 2025
Veröffentlicht am: *07 - April - 2025*
Weitere Informationen finden Sie unter:
https://www.basg.gv.at/marktbeobachtung/amtliche-nachrichten/detail/chmp-meeting-highlights-maerz-2025

0425_Bearbeitungsstand
Veröffentlicht am: *10 - April - 2025*
Weitere Informationen finden Sie unter:
Gute Herstellungs- / Vertriebspraxis (GMP/GDP)

0425_Register Arzneimittelvermittler
Veröffentlicht am: *10 - April - 2025*
Weitere Informationen finden Sie unter:
Arzneimittelvermittler

0425_Register bewilligter AM Betriebe Österreich
Veröffentlicht am: *10 - April - 2025*
Weitere Informationen finden Sie unter:
Arzneimittelbetriebe

Klinische Prüfungen von Arzneimitteln Neu
Veröffentlicht am: *11 - April - 2025*
Weitere Informationen finden Sie unter:
https://www.basg.gv.at/gesundheitsberufe/klinische-studien/klinische-pruefungen-von-arzneimitteln

Beratung durch das BASG
Veröffentlicht am: *15 - April - 2025*
Weitere Informationen finden Sie unter:
https://www.basg.gv.at/fuer-unternehmen/arzneimittel-informationen/beratung-durch-das-basg

PSUR outcome: Tiagabin
Veröffentlicht am: *07 - April - 2025*
Weitere Informationen finden Sie unter:
Link zur Website der EMA

PSUR outcome: Capecitabin
Veröffentlicht am: *15 - April - 2025*
Weitere Informationen finden Sie unter:
Mustertext Capecitabin
Link zur Website der Europäischen Kommission

PSUR outcome: Busulfan
Veröffentlicht am: *15 - April - 2025*
Weitere Informationen finden Sie unter:
Link zur Website der EMA

Humanarzneimittel - Schweiz

Aktualisierte Vorgabedokumente
Veröffentlicht am: *14 - April - 2025*
Weitere Informationen finden Sie unter:
https://www.swissmedic.ch/swissmedic/de/home/news/updates/updated_documents/april-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

BfArM im Dialog „D-A-CH-Anwenderforum SNOMED CT“
Ort: *BfArM Webex Event*
Termin: *20 – Mai - 2025*
Weitere Informationen finden Sie unter:
https://www.bfarm.de/DE/Aktuelles/Veranstaltungen/Termine/2025-05-20-snomed-anwenderforum.html?nn=986770

Österreich

BASG-Gespräch: Digitalisierung im regulatorischen Umfeld – Status und Neuigkeiten
Ort: online via Zoom
Termin: *11 – Juni - 2025*
Weitere Informationen finden Sie unter:
https://www.ages.at/ages/veranstaltungen/veranstaltungskalender/detail/basg-gespraech-digitalisierung-im-regulatorischen-umfeld-status-und-neuigkeiten-1

Schweiz

Keine Veranstaltungen veröffentlicht

Europa

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

Questions and answers clinic on Product Management Service (PMS) Product User Interface (PUI) and Application Programming Interface (API) - April 2025, May 2025 and June 2025
Where: *online and European Medicines Agency, Amsterdam, the Netherlands*
Date: *26 - April - 2025, 19 - May - 2025 and 17 - June - 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-april-2025
https://www.ema.europa.eu/en/events/questions-answers-clinic-product-management-service-pms-product-user-interface-pui-application-programming-interface-api-may-2025
https://www.ema.europa.eu/en/events/questions-answers-clinic-product-management-service-pms-product-user-interface-pui-application-programming-interface-api-june-2025

Veranstaltungen / Events – Behörden und andere Veranstalter

EMA traineeship programme informative session
Where: *online and European Medicines Agency, Amsterdam, the Netherlands*
Date: *14 - April - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/events/ema-traineeship-programme-informative-session-0

Second EMA / Alliance for Regenerative Medicine bilateral meeting
Where: *online and European Medicines Agency, Amsterdam, the Netherlands*
Date: *08 - May - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/events/second-ema-alliance-regenerative-medicine-bilateral-meeting

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

Clinical Trials Information System (CTIS): Walk-in clinic - May 2025
Where: *online and European Medicines Agency, Amsterdam, the Netherlands*
Date: *14 - May - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/events/clinical-trials-information-system-ctis-walk-clinic-may-2025

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

EUDAMED - 21 May Stuttgart Workshop registration is open
Where: online and Steigenberger Graf Zeppelin hotel, 70173 Stuttgart
Date: *21 - May - 2025*
For more information, please refer to:
https://www.eap-events.eu/ehome/index.php?eventid=200286344&

Clinical Trials Information System (CTIS): Information day
Where: *online and European Medicines Agency, Amsterdam, the Netherlands*
Date: *22 - May - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/events/clinical-trials-information-system-ctis-information-day-1

Veranstaltungen / Events – Behörden und andere Veranstalter

CPhI China 2025
Where: *Shanghai, China*
Date: *24 to 26 - June - 2025*
For more information, please refer to:
https://www.edqm.eu/en/cphi-china-2025

EMA's 30th anniversary scientific conference - Medicines, regulation and the future
Where: *European Medicines Agency, Amsterdam, the Netherlands*
Date: *25 - June - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/events/emas-30th-anniversary-scientific-conference-medicines-regulation-future