11. - 25. Oktober 2024

MEGRA NEWSLETTER

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Humanarzneimittel - EMA

Allgemeines – General

EMA's work on public health emergencies
Published on: *14 - October - 2024*
For more information, please refer to:
https://www.ema.europa.eu/en/human-regulatory-overview/public-health-threats/emas-work-public-health-emergencies

Quarterly System Demo - Q3 2024, Event – 18 - Sep - 2024
Presentations and Video recording available
Published on: *16 - October - 2024*
For more information, please refer to:
https://www.ema.europa.eu/en/events/quarterly-system-demo-q3-2024

Small and medium-sized enterprises info day, Event – 18 - Oct - 2024
Presentations and Video recording available
Published on: *25 - October - 2024*
For more information, please refer to:
https://www.ema.europa.eu/en/events/small-medium-sized-enterprises-info-day

Pharmakovigilanz – PRAC

Article 57 product data
Published on: *15 - October - 2024*
For more information, please refer to:
https://www.ema.europa.eu/en/documents/other/article-57-product-data_en.xlsx

Referral: Oxbryta
Published on: *17 - October - 2024*
For more information, please refer to:
https://www.ema.europa.eu/en/medicines/human/referrals/oxbryta

Nitrosamines Safety Operational Expert Group
Published on: *17 - October - 2024*
For more information, please refer to:
https://www.ema.europa.eu/en/committees/working-parties-other-groups/chmp/nitrosamines-safety-operational-expert-group

Pharmacovigilance Inspectors Working Group
Published on: *17 - October - 2024*
For more information, please refer to:
https://www.ema.europa.eu/en/human-regulatory-overview/marketing-authorisation/compliance-marketing-authorisation/pharmacovigilance-inspections-veterinary-medicines/pharmacovigilance-inspectors-working-group

Humanarzneimittel - EMA

List of European Union reference dates and frequency of submission of periodic safety update reports (PSURs)
Published on: *23 - October - 2024*
For more information, please refer to:
https://www.ema.europa.eu/en/documents/other/list-european-union-reference-dates-frequency-submission-periodic-safety-update-reports-psurs_en.xlsx

Zulassung – Regulatory Affairs

Joint HMA/EMA multi-stakeholder workshop on submission predictability, Event – 25 - Sep - 2024 Presentations and Video recording available
Published on: *15 - October - 2024*
For more information, please refer to:
https://www.ema.europa.eu/en/events/joint-hma-ema-multi-stakeholder-workshop-submission-predictability

Meeting highlights from the Committee for Medicinal Products for Human Use (CHMP) 14-17 October 2024
Published on: *18 - October - 2024*
For more information, please refer to:
https://www.ema.europa.eu/en/news/meeting-highlights-committee-medicinal-products-human-use-chmp-14-17-october-2024

Use of clinical study data in medicine evaluation
Published on: *18 - October - 2024*
For more information, please refer to:
https://www.ema.europa.eu/en/about-us/how-we-work/big-data/use-clinical-study-data-medicine-evaluation

Plasma master file certificates
Published on: *22 - October - 2024*
For more information, please refer to:
https://www.ema.europa.eu/en/human-regulatory-overview/plasma-master-file-pmf-certification/plasma-master-file-certificates

PRIME: priority medicines
Published on: *23 - October - 2024*
For more information, please refer to:
https://www.ema.europa.eu/en/human-regulatory-overview/research-development/prime-priority-medicines

Humanarzneimittel - EMA

SPOR and xEVMPD Stakeholder Engagement Webinars : Substance, product, organisation and referential (SPOR) application programming interface (API) - SPOR API, Event – 14 -Oct - 2024
Presentation available
Published on: *24 - October - 2024*
For more information, please refer to:
https://www.ema.europa.eu/en/events/spor-xevmpd-stakeholder-engagement-webinars-substance-product-organisation-referential-spor-application-programming-interface-api-spor-api

Fostering regulatory collaboration to improve access to mpox medicines
Published on: *25 - October - 2024*
For more information, please refer to:
https://www.ema.europa.eu/en/news/fostering-regulatory-collaboration-improve-access-mpox-medicines

Product Management Service (PMS) Product UI training (access and navigation), Event – 16 - Oct - 2024
Presentation available
Published on: *23 - October - 2024*
For more information, please refer to:
https://www.ema.europa.eu/en/documents/presentation/presentation-product-management-service-pms-product-ui-training-access-navigation_en.pdf-0

Info session on web-based electronic Application Form (eAF) add package, Event – 18 - Jul - 2024
Presentation, Q&A and Video recording available
Published on: *21 - October - 2024*
For more information, please refer to:
https://www.ema.europa.eu/en/events/info-session-web-based-electronic-application-form-eaf-add-package

Orphan Drugs und neuartige Therapierichtungen (ATMP)

CAT meeting minutes
Published on: *22 - October - 2024*
For more information, please refer to:
https://www.ema.europa.eu/en/documents/minutes/minutes-cat-meeting-22-24-may-2024_en.pdf
https://www.ema.europa.eu/en/documents/minutes/minutes-cat-meeting-19-21-june-2024_en.pdf
https://www.ema.europa.eu/en/documents/minutes/minutes-cat-meeting-17-19-july-2024_en.pdf

Qualität – Quality

No news published

Humanarzneimittel - EMA

(Prä-) Klinische Forschung – Research and Development

Non-clinical Working Party
Published on: *17 - October - 2024*
For more information, please refer to:
https://www.ema.europa.eu/en/committees/working-parties-other-groups/chmp/non-clinical-working-party

Kinderarzneimittel – Paediatrics

No news published

Pflanzliche Arzneimittel – Herbal medicines

Quality Drafting Group
Published on: *21 - October - 2024*
For more information, please refer to:
https://www.ema.europa.eu/en/committees/working-parties-other-groups/hmpc/quality-drafting-group

European Commission

Health Technology Assessment - Commission adopts rules for cooperation with the European Medicines Agency
Published on: *21 - October - 2024*
For more information, please refer to:
https://ec.europa.eu/newsroom/sante/newsletter-archives/56679

EDQM

Implementation of the European Pharmacopoeia Supplement 11.7 – Notification for CEP holders
Published on: *15 - October - 2024*
For more information, please refer to:
https://www.edqm.eu/en/-/implementation-of-the-european-pharmacopoeia-supplement-11.7-notification-for-cep-holders

Medizinprodukte

MDCG 2021-25 rev.1 - Application of MDR requirements to "legacy devices" and to devices placed on the market prior to 26 May 2021 - October 2024
Published on: *16 - October - 2024*
For more information, please refer to:
https://health.ec.europa.eu/latest-updates/mdcg-2021-25-rev1-application-mdr-requirements-legacy-devices-and-devices-placed-market-prior-26-may-2024-10-16_en

High-risk medical devices: consultation procedures and advice
Published on: *17 - October - 2024*
For more information, please refer to:
https://www.ema.europa.eu/en/high-risk-medical-devices-consultation-procedures-advice

First Expert Panels and Notified Bodies workshop, Event – 22 - Apr - 2024
Highlights available
Published on: *24 - October - 2024*
For more information, please refer to:
https://www.ema.europa.eu/en/events/highlights-first-expert-panels-notified-bodies-workshop

CMDh

Letter from the HMA Core Group for Medical Devices to the European Commission
Published on: *21 - October - 2024*
For more information, please refer to:
https://www.hma.eu/about-hma/recently-published.html#c7587

Recommendations on submission dates in 2025 for Applications of the MRP
Published on: *25 - October - 2024*
For more information, please refer to:
https://www.hma.eu/human-medicines/cmdh/procedural-guidance/application-for-ma/mrp/rup.html

Recommendations on submission dates in 2025 for Applications of the DCP
Published on: *25 - October - 2024*
For more information, please refer to:
https://www.hma.eu/human-medicines/cmdh/procedural-guidance/application-for-ma/dcp.html

Humanarzneimittel - Deutschland

Aktuell laufende und bestätigte Arzneimittel-Härtefallprogramme
Veröffentlicht am: *14 - Oktober - 2024*
Weitere Informationen finden Sie unter:
https://www.bfarm.de/DE/Arzneimittel/Klinische-Pruefung/Compassionate-Use/compUse-tabelle.html?nn=986770

Arzneibuch
Veröffentlicht am: *14 - Oktober - 2024*
Weitere Informationen finden Sie unter:
https://www.bfarm.de/DE/Arzneimittel/Zulassung/Zulassungsrelevante-Themen/Arzneibuch/_artikel.html?nn=986770

Arzneimittel-Lieferengpass-bekämpfungs- und Versorgungs-verbesserungs-gesetz (ALBVVG)
Veröffentlicht am: *15 - Oktober - 2024*
Weitere Informationen finden Sie unter:
https://www.bfarm.de/DE/Arzneimittel/Arzneimittelinformationen/Lieferengpaesse/ALBVVG/_artikel.html?nn=986770

Sachstandstabelle (sortiert nach Wirkstoffen A-Z) - aktualisiert (Buchstabe S)
Veröffentlicht am: *16 - Oktober - 2024*
Weitere Informationen finden Sie unter:
https://www.bfarm.de/DE/Arzneimittel/Zulassung/Zulassungsrelevante-Themen/Expertengruppe-Off-Label/sachstandstabelle.html?nn=986770

Informationen zu Einreichung und Genehmigung von Schulungsmaterial
Veröffentlicht am: *21 - Oktober - 2024*
Weitere Informationen finden Sie unter:
https://www.bfarm.de/DE/Arzneimittel/Pharmakovigilanz/Risikoinformationen/Schulungsmaterial/Zusatzinformationen/_artikel.html?nn=986770

Zentraler Terminologieserver für das Gesundheitswesen
Veröffentlicht am: *23 - Oktober - 2024*
Weitere Informationen finden Sie unter:
https://www.bfarm.de/DE/Kodiersysteme/Services/Terminologieserver/_artikel.html?nn=986770

PSUR Single Assessment (PSUSA)
Veröffentlicht am: *24 - Oktober - 2024*
Weitere Informationen finden Sie unter:
https://www.bfarm.de/DE/Arzneimittel/Pharmakovigilanz/Periodic-Safety-Update-Reports_PSURs/PSUR-Single-Assessment/_artikel.html?nn=986770

Antibiotika für Kinder
Veröffentlicht am: *24 - Oktober - 2024*
Weitere Informationen finden Sie unter:
https://www.bfarm.de/DE/Arzneimittel/Arzneimittelinformationen/Lieferengpaesse/Antibiotika.html?nn=986770

Humanarzneimittel - Österreich

Leitfaden: eService Inspektionen (L_I253)
Veröffentlicht am: *21 - Oktober - 2024*
Weitere Informationen finden Sie unter:
https://www.basg.gv.at/fileadmin/redakteure/01_Formulare_Listen/I/L_I253_Benutzerhandbuch_eService_Inspektionen.pdf

Humanarzneimittel - Schweiz

Anpassung Wegleitung Beschleunigtes Zulassungsverfahren und Wegleitung Befristete Zulassung Humanarzneimittel
Veröffentlicht am: *15 - Oktober - 2024*
Weitere Informationen finden Sie unter:
https://www.swissmedic.ch/swissmedic/de/home/humanarzneimittel/authorisations/informationen/anpassung-wl-beschleunigtes-zlverfahren-und-wl-befristete-zl.html

Medikamentenlieferungen in Konfliktgebiete
Veröffentlicht am: *17 - Oktober - 2024*
Weitere Informationen finden Sie unter:
https://www.swissmedic.ch/swissmedic/de/home/news/mitteilungen/medikamentenlieferungen-in-konfliktgebiete.html

HPC – Tierarzneimittel mit dem Wirkstoff Pentobarbital
Veröffentlicht am: *25 - Oktober - 2024*
Weitere Informationen finden Sie unter:
https://www.swissmedic.ch/swissmedic/de/home/tierarzneimittel/market-surveillance/dhpc-veterinary-medicines/hpc-tam-mit-ws-pentobarbital.html

Aktualisierte Vorgabedokumente
Veröffentlicht am: *25 - Oktober - 2024*
Weitere Informationen finden Sie unter:
https://www.swissmedic.ch/swissmedic/de/home/news/updates/updated_documents/okt-2024.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

"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
Termin: *28 - November - 2024*
Weitere Informationen finden Sie unter:
https://www.pei.de/SharedDocs/veranstaltungen-events/DE/2024/2024-11-28-workshop-manufacturing-translation-atmp.html?nn=170994

Österreich

BASG-Gespräch: Pharmakovigilanz Update 2024
Termin: *20 – November – 2024*
Weitere Informationen unter:
https://www.ages.at/ages/veranstaltungen/veranstaltungskalender/detail/basg-gespraech-pharmakovigilanz-update-2024-1

BASG-Gespräch: Die Gute Laborpraxis
Termin: *26 November 2024*
Weitere Informationen unter:
https://www.ages.at/ages/veranstaltungen/veranstaltungskalender/detail/basg-gespraech-die-gute-laborpraxis-1

Schweiz

Swissmedic Regulatory & Beyond 2024
Ort: Kursaal Bern
Termin: *26 - November - 2024*
Weitere Informationen finden Sie unter:
https://rb-swissmedicevents.ch/

Europa

HMA/EMA multi-stakeholder workshop on Artificial Intelligence
Where: *European Medicines Agency, Amsterdam, the Netherlands*
Date: *05 - November - 2024*
For more information, please refer to:
https://www.ema.europa.eu/en/events/hma-ema-multi-stakeholder-workshop-artificial-intelligence

Veranstaltungen / Events – Behörden und andere Veranstalter

Third European Medicines Agency (EMA) and European Confederation of Pharmaceutical Entrepreneurs (EUCOPE) bilateral meeting
Where: *European Medicines Agency, Amsterdam, the Netherlands*
Date: *07 - November - 2024*
For more information, please refer to:
https://www.ema.europa.eu/en/events/third-european-medicines-agency-ema-european-confederation-pharmaceutical-entrepreneurs-eucope-bilateral-meeting

Human variation electronic application form (eAF) training session and Q&A clinic
Where: *online and European Medicines Agency, Amsterdam, the Netherlands*
Date: *08 - November - 2024*
For more information, please refer to:
https://www.ema.europa.eu/en/events/human-variation-electronic-application-form-eaf-training-session-qa-clinic

Clinical Data Publication (Policy 0070) webinar - Step 2
Where: *online and European Medicines Agency, Amsterdam, the Netherlands*
Date: *14 - November - 2024*
For more information, please refer to:
https://www.ema.europa.eu/en/events/clinical-data-publication-policy-0070-webinar-step-2

Translating innovation into access for ATMPs: 3rd EU-Innovation network multi-stakeholder meeting
Where: *online and Rome, Italy*
Date: *15 - November - 2024*
For more information, please refer to:
https://www.ema.europa.eu/en/events/translating-innovation-access-atmps-3rd-eu-innovation-network-multi-stakeholder-meeting

Conversations on Cancer - Pediatric Cancers: Navigating the Challenges Together
Where: *online and European Medicines Agency, Amsterdam, the Netherlands*
Date: *19 - November - 2024*
For more information, please refer to:
https://www.ema.europa.eu/en/events/conversations-cancer-pediatric-cancers-navigating-challenges-together

European Medicines Agency (EMA) Patients' and Consumers' (PCWP) and Healthcare Professionals' (HCPWP) Working Parties meeting with all eligible organisations - 2024
Where: *online and European Medicines Agency, Amsterdam, the Netherlands*
Date: *20 - November - 2024*
For more information, please refer to:
https://www.ema.europa.eu/en/events/european-medicines-agency-ema-patients-consumers-pcwp-healthcare-professionals-hcpwp-working-parties-meeting-all-eligible-organisations-2024

Veranstaltungen / Events – Behörden und andere Veranstalter

Clinical Trials Information System (CTIS): Walk-in clinic - November 2024
Where: *online and European Medicines Agency, Amsterdam, the Netherlands*
Date: *20 - November - 2024*
For more information, please refer to:
https://www.ema.europa.eu/en/events/clinical-trials-information-system-ctis-walk-clinic-november-2024

European Shortages Monitoring Platform training session on routine shortage reporting for marketing authorisation holders of CAPs
Where: *online and European Medicines Agency, Amsterdam, the Netherlands*
Date: *20 - November - 2024*
For more information, please refer to:
https://www.ema.europa.eu/en/events/european-shortages-monitoring-platform-training-session-routine-shortage-reporting-marketing-authorisation-holders-caps

Everything you've always wanted to know about the certification (CEP) procedure
Where: *online*
Date: *21 - November - 2024*
For more information, please refer to:
https://www.edqm.eu/en/-webinar-cep-procedure

Thirteenth meeting of the industry stakeholder platform on the operation of the centralised procedure for human medicines
Where: *online and European Medicines Agency, Amsterdam, the Netherlands*
Date: *22 - November - 2024*
For more information, please refer to:
https://www.ema.europa.eu/en/events/thirteenth-meeting-industry-stakeholder-platform-operation-centralised-procedure-human-medicines

EU Health Policy Platform Annual Meeting
Where: *online*
Date: *26 - November - 2024*
For more information, please refer to:
https://health.ec.europa.eu/latest-updates/register-now-participate-onsite-or-online-eu-health-policy-platform-annual-meeting-26-november-and-2024-09-20_en

Advancements in gene therapy: the European Pharmacopoeia's new approach
Where: *online*
Date: *03 - December - 2024*
For more information, please refer to:
https://www.edqm.eu/en/advancements-in-gene-therapy-the-european-pharmacopoeia-s-new-approach