06. - 20.
Dezember 2024

MEGRA NEWSLETTER

Humanarzneimittel - EMA

Allgemeines – General

European Medicines Agency mid-year report 2024 (January-June 2024)
Published on: *09 - December - 2024*
For more information, please refer to:
https://www.ema.europa.eu/en/documents/report/european-medicines-agency-mid-year-report-2024-january-june-2024_en.pdf

EMA communication perception survey report 2024
Published on: *11 - December - 2024*
For more information, please refer to:
https://www.ema.europa.eu/en/documents/report/ema-communication-perception-survey-report-2024_en.pdf

Big data
Published on: *13 - December - 2024*
For more information, please refer to:
https://www.ema.europa.eu/en/about-us/how-we-work/big-data

Medicinal products for human use: Monthly figures - November 2024
Published on: *13 - December - 2024*
For more information, please refer to:
https://www.ema.europa.eu/en/documents/report/medicinal-products-human-use-monthly-figures-november-2024_en.pdf

Artificial intelligence (updated)
Published on: *13 - December - 2024*
For more information, please refer to:
https://www.ema.europa.eu/en/about-us/how-we-work/big-data/artificial-intelligence

Quarterly system demo - Q4 2024, Event 12 - December - 2024
Video recording and Presentation available
Published on: *17 - December - 2024*
For more information, please refer to:
https://www.ema.europa.eu/en/events/quarterly-system-demo-q4-2024

Fifth EMA/HMA Big Data Stakeholder Forum, Event 28 - November - 2024
Video recording and Presentations available
Published on: *18 - December - 2024*
For more information, please refer to:
https://www.ema.europa.eu/en/events/fifth-ema-hma-big-data-stakeholder-forum

A common EU approach to data transparency in medicine regulation
Published on: *18 - December - 2024*
For more information, please refer to:
https://www.ema.europa.eu/en/news/common-eu-approach-data-transparency-medicine-regulation

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New fee regulation (from 1 January 2025) (updated)
Published on: *18 - December - 2024*
For more information, please refer to:
https://www.ema.europa.eu/en/about-us/fees-payable-european-medicines-agency/new-fee-regulation-1-january-2025

Pharmakovigilanz – PRAC

Referral: Metamizole-containing medicinal products
Published on: *06 - December - 2024*
For more information, please refer to:
https://www.ema.europa.eu/en/medicines/human/referrals/metamizole-containing-medicinal-products-0

Referral: Ocaliva
Published on: *09 - December - 2024*
For more information, please refer to:
https://www.ema.europa.eu/en/medicines/human/referrals/ocaliva

Referral: Mysimba
Published on: *13 - December - 2024*
For more information, please refer to:
https://www.ema.europa.eu/en/medicines/human/referrals/mysimba

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

19th industry stakeholder platform - operation of European Union (EU) pharmacovigilance, Event 15 - November - 2024
Presentations available
Published on: *09 - December - 2024*
For more information, please refer to:
https://www.ema.europa.eu/en/events/19th-industry-stakeholder-platform-operation-european-union-eu-pharmacovigilance

List of medicines under additional monitoring (updated)
Published on: *10 - December - 2024*
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

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Signal management (updated)
Published on: *12 - December - 2024*
For more information, please refer to:
https://www.ema.europa.eu/en/human-regulatory-overview/post-authorisation/pharmacovigilance-post-authorisation/signal-management

Data access to medicinal products for human use - Chapter 5 Annex A: Product data elements accessible by stakeholder group
Published on: *17 - December - 2024*
For more information, please refer to:
https://www.ema.europa.eu/en/documents/other/data-access-medicinal-products-human-use-chapter-5-annex-product-data-elements-accessible-stakeholder-group_en.xlsx

Periodic safety update reports (updated)
Published on: *18 - December - 2024*
For more information, please refer to:
https://www.ema.europa.eu/en/human-regulatory-overview/post-authorisation/pharmacovigilance-post-authorisation/periodic-safety-update-reports-psurs

Article 57 product data (updated)
Published on: *19 - December - 2024*
For more information, please refer to:
https://www.ema.europa.eu/en/documents/other/article-57-product-data_en.xlsx

Zulassung – Regulatory Affairs

Medicine shortages and availability issues: guidance for companies (updated)
Published on: *09 - December - 2024*
For more information, please refer to:
https://www.ema.europa.eu/en/human-regulatory-overview/post-authorisation/medicine-shortages-availability-issues/medicine-shortages-availability-issues-guidance-companies

Applications for new human medicines under evaluation: December 2024
Published on: *09 - December - 2024*
For more information, please refer to:
https://www.ema.europa.eu/en/documents/report/applications-new-human-medicines-under-evaluation-december-2024_en.xlsx

Frequently asked questions on the European Shortages Monitoring Platform (updated)
Published on: *10 - December - 2024*
For more information, please refer to:
https://www.ema.europa.eu/en/documents/other/frequently-asked-questions-european-shortages-monitoring-platform-esmp_en.pdf

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Regulatory Procedure Management (RPM) for the Product Lifecycle Management (PLM) - Frequently asked questions (updated)
Published on: *10 - December - 2024*
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

IRIS guide for applicants - How to create and submit scientific applications, for industry and individual applicants (updated)
Published on: *10 - December - 2024*
For more information, please refer to:
https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/iris-guide-applicants_en.pdf

Products Management Services (PMS) - Implementation of International Organization for Standardization (ISO) standards for the identification of medicinal products (IDMP) in Europe - Chapter 1: Registration requirements (updated)
Published on: *12 - December - 2024*
For more information, please refer to:
https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/products-management-services-pms-implementation-international-organization-standardization-iso-standards-identification-medicinal-products-idmp-europe-chapter-1-registration-requirements_en.pdf

Procedural advice on paediatric applications (updated)
Published on: *13 - December - 2024*
For more information, please refer to:
https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/procedural-advice-paediatric-applications_en.pdf

Requesting certificates (updated)
Published on: *13 - December - 2024*
For more information, please refer to:
https://www.ema.europa.eu/en/human-regulatory-overview/post-authorisation/certification-medicinal-products/requesting-certificates

Availability of medicines before and during crises (updated)
Published on: *16 - December - 2024*
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

Medicine shortages and availability issues: guidance for regulators (updated)
Published on: *17 - December - 2024*
For more information, please refer to:
https://www.ema.europa.eu/en/human-regulatory-overview/post-authorisation/medicine-shortages-availability-issues/medicine-shortages-availability-issues-guidance-regulators

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Applying for marketing authorisation: orphan medicines (updated)
Published on: *16 - December - 2024*
For more information, please refer to:
https://www.ema.europa.eu/en/human-regulatory-overview/marketing-authorisation/orphan-designation-marketing-authorisation/applying-marketing-authorisation-orphan-medicines

Successful pilot paves the way for implementation of ePI
Published on: *16 - December - 2024*
For more information, please refer to:
https://www.ema.europa.eu/en/news/successful-pilot-paves-way-implementation-epi

European Medicines Agency procedural advice for users of the centralised procedure for generic / hybrid applications (updated)
Published on: *17 - December - 2024*
For more information, please refer to:
https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/european-medicines-agency-procedural-advice-users-centralised-procedure-generic-hybrid-applications_en.pdf

European Medicines Agency post-authorisation procedural advice for users of the centralised procedure (updated)
Published on: *17 - December - 2024*
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

Worksharing: questions and answers (updated)
Published on: *17 - December - 2024*
For more information, please refer to:
https://www.ema.europa.eu/en/human-regulatory-overview/post-authorisation/variations-including-extensions-marketing-authorisations/worksharing-questions-answers

Grouping of variations: questions and answers (updated)
Published on: *17 - December - 2024*
For more information, please refer to:
https://www.ema.europa.eu/en/human-regulatory-overview/post-authorisation/variations-including-extensions-marketing-authorisations/grouping-variations-questions-answers

Extensions of marketing authorisations: questions and answers (updated)
Published on: *17 - December - 2024*
For more information, please refer to:
https://www.ema.europa.eu/en/human-regulatory-overview/post-authorisation/variations-including-extensions-marketing-authorisations/extensions-marketing-authorisations-questions-answers

Transfer of marketing authorisation: questions and answers (updated)
Published on: *17 - December - 2024*
For more information, please refer to:
https://www.ema.europa.eu/en/human-regulatory-overview/post-authorisation/transfer-marketing-authorisation-questions-answers

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Product Management Service (PMS) – Frequently Asked Questions (updated)
Published on: *17 - December - 2024*
For more information, please refer to:
https://www.ema.europa.eu/en/documents/other/product-management-service-pms-frequently-asked-questions-faqs_en.pdf

Biosimilar medicines: marketing authorisation
Published on: *17 - December - 2024*
For more information, please refer to:
https://www.ema.europa.eu/en/human-regulatory-overview/marketing-authorisation/biosimilar-medicines-marketing-authorisation

Pre-authorisation guidance
Published on: *17 - December - 2024*
For more information, please refer to:
https://www.ema.europa.eu/en/human-regulatory-overview/marketing-authorisation/pre-authorisation-guidance

EMA recommendation on the procedural aspects and dossier requirements for the consultation of the EMA by a notified body on an ancillary medicinal substance or an ancillary human blood derivative incorporated in a medical device - Revision 2
Published on: *17 - December - 2024*
For more information, please refer to:
https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/ema-recommendation-procedural-aspects-dossier-requirements-consultation-ema-notified-body-ancillary-medicinal-substance-or-ancillary-human-blood-derivative-incorporated-medical-device-revision-2_en.pdf

EMA procedural advice for medicinal products intended exclusively for markets outside the European Union in the context of co-operation with the World Health Organisation (updated)
Published on: *17 - December - 2024*
For more information, please refer to:
https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/ema-procedural-advice-medicinal-products-intended-exclusively-markets-outside-european-union-context-co-operation-world-health-organisation-who_en.pdf

Frequently asked questions about parallel distribution (updated)
Published on: *18 - December - 2024*
For more information, please refer to:
https://www.ema.europa.eu/en/human-regulatory-overview/post-authorisation/parallel-distribution/frequently-asked-questions-about-parallel-distribution

Advancing regulatory science research, Event 18 - November - 2024
Video recording and Presentations available
Published on: *18 - December - 2024*
For more information, please refer to:
https://www.ema.europa.eu/en/events/public-event-advancing-regulatory-science-research

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Orphan Drugs und neuartige Therapierichtungen (ATMP)

Scientific recommendations on classification of advanced therapy medicinal products (updated)
Published on: *13 - December - 2024*
For more information, please refer to:
https://www.ema.europa.eu/en/documents/other/scientific-recommendations-classification-advanced-therapy-medicinal-products_en.xlsx

Procedural advice for orphan medicinal product designation: Guidance for sponsors (updated)
Published on: *16 - December - 2024*
For more information, please refer to:
https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/procedural-advice-orphan-medicinal-product-designation-guidance-sponsors_en.pdf

Procedural advice for post-orphan medicinal product designation activities: Guidance for sponsors (updated)
Published on: *16 - December - 2024*
For more information, please refer to:
https://www.ema.europa.eu/en/documents/other/procedural-advice-post-orphan-medicinal-product-designation-activities-guidance-sponsors_en.pdf

Qualität – Quality

Quality of medicines questions and answers: Part 1 (updated)
Published on: *06 - December - 2024*
For more information, please refer to:
https://www.ema.europa.eu/en/human-regulatory-overview/research-development/scientific-guidelines/quality-medicines-qa-introduction/quality-medicines-questions-answers-part-1

Investigation of bioequivalence - Scientific guideline (updated)
Published on: *12 - December - 2024*
For more information, please refer to:
https://www.ema.europa.eu/en/investigation-bioequivalence-scientific-guideline

Questions and answers for biological medicinal products (updated)
Published on: *13 - December - 2024*
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

Annual report of the Good Clinical Practice Inspectors Working Group 2023
Published on: *09 - December - 2024*
For more information, please refer to:
https://www.ema.europa.eu/en/documents/report/annual-report-good-clinical-practice-inspectors-working-group-2023_en.pdf

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Guidance on good manufacturing practice and good distribution practice: Questions and answers
Published on: *17 - December - 2024*
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

Co-ordinating good manufacturing practice (GMP) inspections for centrally authorised products
Published on: *17 - December - 2024*
For more information, please refer to:
https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/co-ordinating-good-manufacturing-practice-gmp-inspections-centrally-authorised-products_en.pdf

ICH Q4B Evaluation and recommendation of pharmacopoeial texts for use in the ICH regions - Scientific guideline
Published on: *18 - December - 2024*
For more information, please refer to:
https://www.ema.europa.eu/en/ich-q4b-evaluation-recommendation-pharmacopoeial-texts-use-ich-regions-scientific-guideline

(Prä-) Klinische Forschung – Research and Development

Clinical trial information system (CTIS) public portal full trial information (updated)
Published on: *10 - December - 2024*
For more information, please refer to:
https://www.ema.europa.eu/en/documents/other/clinical-trial-information-system-ctis-public-portal-full-trial-information_en.pdf

Clinical trial information system (CTIS) public portal trial results (updated)
Published on: *10 - December - 2024*
For more information, please refer to:
https://www.ema.europa.eu/en/documents/other/clinical-trial-information-system-ctis-public-portal-trial-results_en.pdf

Clinical Trial Information System (CTIS) structured data form - Initial application, additional Member State Concerned, substantial modification, non-substantial modification (updated)
Published on: *11 - December - 2024*
For more information, please refer to:
https://www.ema.europa.eu/en/documents/template-form/clinical-trial-information-system-ctis-structured-data-form-initial-application-additional-member-state-concerned-substantial-modification-non-substantial-modification_en.xlsx

Humanarzneimittel - EMA

FAQs: How to create, submit and withdraw a Clinical Trial Application - CTIS Training Programme - Module 10 (updated)
Published on: *16 - December - 2024*
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

Scientific advice and protocol assistance (updated)
Published on: *16 - December - 2024*
For more information, please refer to:
https://www.ema.europa.eu/en/human-regulatory-overview/research-development/scientific-advice-protocol-assistance

CTIS newsflash - 17 December 2024
Published on: *17 - December - 2024*
For more information, please refer to:
https://www.ema.europa.eu/en/documents/newsletter/ctis-newsflash-17-december-2024_en.pdf

Kinderarzneimittel – Paediatrics

2024 annual meeting of the members and Coordinating Group of the European network of paediatric research at the EMA (Enpr-EMA), Event 01 - October - 2024
Presentations available
Published on: *10 - December - 2024*
For more information, please refer to:
https://www.ema.europa.eu/en/events/2024-annual-meeting-members-coordinating-group-european-network-paediatric-research-ema-enpr-ema

2024 annual workshop of the European network of paediatric research at EMA (Enpr-EMA), Event 02 - October - 2024
Presentations and Report available
Published on: *10 - December - 2024*
For more information, please refer to:
https://www.ema.europa.eu/en/events/2024-annual-workshop-european-network-paediatric-research-ema-enpr-ema

Paediatric investigation plans: questions and answers
Published on: *13 - December - 2024*
For more information, please refer to:
https://www.ema.europa.eu/en/human-regulatory-overview/research-development/paediatric-medicines-research-development/paediatric-investigation-plans/paediatric-investigation-plans-questions-answers

Humanarzneimittel - EMA

Pflanzliche Arzneimittel – Herbal medicines

Herbal medicinal product: Combination: Species pectorales, D: Draft under discussion (updated)
Published on: *16 - December - 2024*
For more information, please refer to:
https://www.ema.europa.eu/en/medicines/herbal/combination-species-pectorales

European Commission

Second HERA Invest agreement signed to advance therapies against antimicrobial resistance
Published on: *09 - December - 2024*
For more information, please refer to:
https://health.ec.europa.eu/latest-updates/second-hera-invest-agreement-signed-advance-therapies-against-antimicrobial-resistance-2024-12-09_en

Health Technology Assessment - Commission adopts rules for joint scientific consultations on medicinal products for human use
Published on: *18 - December - 2024*
For more information, please refer to:
https://ec.europa.eu/newsroom/sante/newsletter-archives/58728

EDQM

Certification monthly report of activities: End of November 2024
Published on: *09 - December - 2024*
For more information, please refer to:
https://www.edqm.eu/en/-/certification-monthly-report-of-activities-end-of-november-2024

New addition to the work programme of the European Paediatric Formulary
Published on: *10 - December - 2024*
For more information, please refer to:
https://www.edqm.eu/en/-/new-addition-to-the-work-programme-of-the-european-paediatric-formulary

CEP Procedure: 30 years of scientific excellence
Published on: *12 - December - 2024*
For more information, please refer to:
https://www.edqm.eu/en/-/cep-procedure-30-years-of-scientific-excellence

European Pharmacopoeia Supplement 11.8 now available
Published on: *17 - December - 2024*
For more information, please refer to:
https://www.edqm.eu/en/-/european-pharmacopoeia-supplement-11.8-now-available

Compliance and safety of food contact materials and articles – New EDQM guide available
Published on: *20 - December - 2024*
For more information, please refer to:
https://www.edqm.eu/en/-/compliance-and-safety-of-food-contact-materials-and-articles-new-edqm-guide-available

Medizinprodukte

MDCG 2024-16: Manufacturer Information Form on Interruption or Discontinuation of Supply of certain medical devices and certain in vitro diagnostic medical devices
Published on: *06 - December - 2024*
For more information, please refer to:
https://health.ec.europa.eu/latest-updates/mdcg-2024-16-manufacturer-information-form-interruption-or-discontinuation-supply-certain-medical-2024-12-06_en

Commission launches a public consultation and a call for evidence for EU Medical Devices evaluation
Published on: *12 - December - 2024*
For more information, please refer to:
https://ec.europa.eu/newsroom/sante/newsletter-archives/58530

COMBINE programme for clinical trials and medical devices endorsed by Member States
Published on: *16 - December - 2024*
For more information, please refer to:
https://ec.europa.eu/newsroom/sante/newsletter-archives/58613

Guidance on the procedural aspects for the consultation to the European Medicines Agency by a notified body on companion diagnostics - Revision 1
Published on: *17 - December - 2024*
For more information, please refer to:
https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/guidance-procedural-aspects-consultation-european-medicines-agency-notified-body-companion-diagnostics-revision-1_en.pdf

Questions & answers - Practical arrangements on the companion diagnostics consultation procedure to the European Medicines Agency by notified bodies (updated)
Published on: *17 - December - 2024*
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_en.pdf

Questions and answers on the consultation procedure to the European Medicines Agency by notified bodies on an ancillary medicinal substance or an ancillary human blood derivative incorporated in a medical device (updated)
Published on: *17 - December - 2024*
For more information, please refer to:
https://www.ema.europa.eu/en/documents/other/questions-answers-consultation-procedure-european-medicines-agency-notified-bodies-ancillary-medicinal-substance-or-ancillary-human-blood-derivative-incorporated-medical-device_en.pdf

MDCG 2022-3 rev.1 - Verification of manufactured class D IVDs by notified bodies (December 2024)
Published on: *18 - December - 2024*
For more information, please refer to:
https://health.ec.europa.eu/latest-updates/mdcg-2022-3-rev1-verification-manufactured-class-d-ivds-notified-bodies-december-2024-2024-12-18_en

CMDh

12-14 November CMDh minutes
Published on: *16 - December - 2024*
For more information, please refer to:
https://www.hma.eu/human-medicines/cmdh/agendas-and-minutes.html

Report from the meeting held on 10-11 December 2024
Published on: *19 - December - 2024*
For more information, please refer to:
https://www.hma.eu/human-medicines/cmdh/press-releases.html

Meeting of a subgroup of CMDh with Interested Parties dedicated to the publication of outcomes of safety variations - 14 November 2024
Presentations available
Published on: *19 - December - 2024*
For more information, please refer to:
https://www.hma.eu/human-medicines/cmdh/about-cmdh/contacts-with-representative-organisations.html

Meeting with Interested Parties - 20 November 2024
Presentations available
Published on: *19 - December - 2024*
For more information, please refer to:
https://www.hma.eu/human-medicines/cmdh/about-cmdh/contacts-with-representative-organisations.html

Humanarzneimittel - Deutschland

Arzneibuch
Veröffentlicht am: *09 - Dezember - 2024*
Weitere Informationen finden Sie unter:
https://www.bfarm.de/DE/Arzneimittel/Zulassung/Zulassungsrelevante-Themen/Arzneibuch/_artikel.html?nn=986770

Vereinfachung der Einreichung von Schulungsmaterial nach Harmonisierung
Veröffentlicht am: *09 - Dezember - 2024*
Weitere Informationen finden Sie unter:
https://www.bfarm.de/DE/Arzneimittel/Pharmakovigilanz/Risikoinformationen/Schulungsmaterial/vereinfachte-einreichung.html?nn=986770

Fragen und Antworten (Q&A) zur Erstellung, Einreichung und Implementierung von angeordnetem Schulungsmaterial (Educational Material)
Veröffentlicht am: *09 - Dezember - 2024*
Weitere Informationen finden Sie unter:
https://www.bfarm.de/SharedDocs/Downloads/DE/Arzneimittel/Pharmakovigilanz/Risikoinformationen/EducationMaterial/faq-pdf.html?nn=986770

Meldeverpflichtungen
Veröffentlicht am: *10 - Dezember - 2024*
Weitere Informationen finden Sie unter:
https://www.bfarm.de/DE/Arzneimittel/Arzneimittelinformationen/Lieferengpaesse/Meldeverpflichtungen/_artikel.html?nn=986770

EU-Verordnung 536/2014
Veröffentlicht am: *10 - Dezember - 2024*
Weitere Informationen finden Sie unter:
https://www.bfarm.de/SharedDocs/Downloads/DE/Arzneimittel/KlinischePruefung/EU-Verordnung_536-2014.html?nn=986770

Parallelimport von Arzneimitteln
Veröffentlicht am: *10 - Dezember - 2024*
Weitere Informationen finden Sie unter:
https://www.bfarm.de/DE/Arzneimittel/Zulassung/Zulassungsverfahren/Parallelimport-von-Arzneimitteln/_artikel.html?nn=986770

Häufig gestellte Fragen (FAQ)
Veröffentlicht am: *11 - Dezember - 2024*
Weitere Informationen finden Sie unter:
https://www.bfarm.de/DE/Arzneimittel/_FAQ/Zulassung/Aenderungsanzeigen-Variations/Variations/_artikel.html?nn=986770

Hilfestellungen für das Antragsverfahren
Veröffentlicht am: *12 - Dezember - 2024*
Weitere Informationen finden Sie unter:
https://www.bfarm.de/DE/Medizinprodukte/Aufgaben/Klinische-Pruefungen-und-Leistungsstudien/Klinische-Pruefungen/Hilfestellungen-Antrag-KP/_artikel.html?nn=986770

Humanarzneimittel - Deutschland

Ansprechpersonen Klinische Prüfung
Veröffentlicht am: *10 - Dezember - 2024*
Weitere Informationen finden Sie unter:
https://www.bfarm.de/DE/Arzneimittel/Klinische-Pruefung/Ansprechpersonen/_artikel.html?nn=986770

Informationen zu Rote-Hand-Briefen und Informationsbriefen
Veröffentlicht am: *12 - Dezember - 2024*
Weitere Informationen finden Sie unter:
https://www.bfarm.de/DE/Arzneimittel/Pharmakovigilanz/Risikoinformationen/Rote-Hand-Briefe/Zusatzinformationen/_artikel.html?nn=986770

Mitteilungspflichten des Zulassungsinhabers nach § 29 Abs. 1g AMG seit dem 28. Oktober 2013
Veröffentlicht am: *12 - Dezember - 2024*
Weitere Informationen finden Sie unter:
https://www.bfarm.de/DE/Arzneimittel/Zulassung/Folgeverfahren/NeueMitteilungspflichten.html?nn=986770

Schriftlicher Verzicht
Veröffentlicht am: *12 - Dezember - 2024*
Weitere Informationen finden Sie unter:
https://www.bfarm.de/DE/Arzneimittel/Zulassung/Folgeverfahren/Schriftlicher-Verzicht/_artikel.html?nn=986770

Studienerfassung und DRKS-Account
Veröffentlicht am: *16 - Dezember - 2024*
Weitere Informationen finden Sie unter:
https://www.bfarm.de/DE/Das-BfArM/Aufgaben/Deutsches-Register-Klinischer-Studien/Studienerfassung/_artikel.html?nn=986770

Aktuelle Hinweise zur Slotvergabe
Veröffentlicht am: *17 - Dezember - 2024*
Weitere Informationen finden Sie unter:
https://www.bfarm.de/DE/Arzneimittel/Zulassung/Zulassungsverfahren/DCP_Decentralised-Procedure/slotvergabe.html?nn=986770

ATC-Klassifikation
Veröffentlicht am: *17 - Dezember - 2024*
Weitere Informationen finden Sie unter:
https://www.bfarm.de/DE/Kodiersysteme/Klassifikationen/ATC/_artikel.html?nn=986770

Versagungen und Rücknahmen BfArM Januar-November 2024
Veröffentlicht am: *17 - Dezember - 2024*
Weitere Informationen finden Sie unter:
https://www.bfarm.de/SharedDocs/Downloads/DE/Service/Statistik/AM-Statistik/versagungen-2024.html?nn=986770

Humanarzneimittel - Deutschland

Muster: Dokumentation „Supervisory Authority Inspektion“
Veröffentlicht am: *17 - Dezember - 2024*
Weitere Informationen finden Sie unter:
https://www.bfarm.de/SharedDocs/Downloads/DE/Arzneimittel/Pharmakovigilanz/Service/mitteil/muster-pharmakovigilanz-sa-inspektionen.html?nn=986770

Template: Documentation „Supervisory Authority Inspection“
Veröffentlicht am: *17 - Dezember - 2024*
Weitere Informationen finden Sie unter:
https://www.bfarm.de/SharedDocs/Downloads/DE/Arzneimittel/Pharmakovigilanz/Service/mitteil/muster-pharmakovigilanz-sa-inspektionen_en.html?nn=986770

Muster: Dokumentation „Nicht Supervisory Authority Inspektion“
Veröffentlicht am: *17 - Dezember - 2024*
Weitere Informationen finden Sie unter:
https://www.bfarm.de/SharedDocs/Downloads/DE/Arzneimittel/Pharmakovigilanz/Service/mitteil/muster-pharmakovigilanz-non-sa-inspektionen.html?nn=986770

Template: Documentation „Non-Supervisory Authority Inspection“
Veröffentlicht am: *17 - Dezember - 2024*
Weitere Informationen finden Sie unter:
https://www.bfarm.de/SharedDocs/Downloads/DE/Arzneimittel/Pharmakovigilanz/Service/mitteil/muster-pharmakovigilanz-non-sa-inspektionen_en.html?nn=986770

Statistiken
Veröffentlicht am: *17 - Dezember - 2024*
Weitere Informationen finden Sie unter:
https://www.bfarm.de/DE/Aktuelles/Statistiken/_artikel.html?nn=986770

Bekanntmachungen zu Packungsgrößen
Veröffentlicht am: *18 - Dezember - 2024*
Weitere Informationen finden Sie unter:
https://www.bfarm.de/DE/Arzneimittel/Arzneimittelinformationen/Packungsgroessen/bekanntmachungen.html?nn=986770

Aktuell laufende und bestätigte Arzneimittel-Härtefallprogramme
Veröffentlicht am: *19 - Dezember - 2024*
Weitere Informationen finden Sie unter:
https://www.bfarm.de/DE/Arzneimittel/Klinische-Pruefung/Compassionate-Use/compUse-tabelle.html?nn=986770

Arzneimittel-Lieferengpassbekämpfungs- und Versorgungsverbesserungsgesetz (ALBVVG)
Veröffentlicht am: *19 - Dezember - 2024*
Weitere Informationen finden Sie unter:
https://www.bfarm.de/DE/Arzneimittel/Arzneimittelinformationen/Lieferengpaesse/ALBVVG/_artikel.html?nn=986770

Humanarzneimittel - Deutschland

Maßnahmen des BfArM und ergänzende Informationen zu Lieferengpässen
Veröffentlicht am: *20 - Dezember - 2024*
Weitere Informationen finden Sie unter:
https://www.bfarm.de/DE/Arzneimittel/Arzneimittelinformationen/Lieferengpaesse/Massnahmen-des-BfArM/_artikel.html?nn=986770

PSUR Single Assessment (PSUSA)
Veröffentlicht am: *20 - Dezember - 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

Humanarzneimittel - Österreich

1224_Bearbeitungsstand
Veröffentlicht am: *10 - Dezember - 2024*
Weitere Informationen finden Sie unter:
https://www.basg.gv.at/fileadmin/redakteure/04_Marktbeobachtung/%C3%96ffentliche_Register/1224_Bearbeitungsstand.pdf

1224_Register Arzneimittelvermittler
Veröffentlicht am: *10 - Dezember - 2024*
Weitere Informationen finden Sie unter:
https://www.basg.gv.at/fileadmin/redakteure/04_Marktbeobachtung/%C3%96ffentliche_Register/1224_Register_Arzneimittelvermittler.pdf

1224_Register bewilligter AM Betriebe Österreich.xlsx
Veröffentlicht am: *10 - Dezember - 2024*
Weitere Informationen finden Sie unter:
https://www.basg.gv.at/fileadmin/redakteure/04_Marktbeobachtung/%C3%96ffentliche_Register/1224_Register_bewilligter_AM_Betriebe_%C3%96sterreich.pdf

ERA human
Veröffentlicht am: *11 - Dezember - 2024*
Weitere Informationen finden Sie unter:
https://www.basg.gv.at/fuer-unternehmen/zulassung-life-cycle/faq-zulassung-life-cycle/environmental-risk-assessment/era-human

Bevorratung national
Veröffentlicht am: *12 - Dezember - 2024*
Weitere Informationen finden Sie unter:
https://www.basg.gv.at/marktbeobachtung/meldewesen/bevorratung-national

Handbuch zur Befuellung des Suchtmittelnachweisungsformulars 2024 (L_I120)
Veröffentlicht am: *13 - Dezember - 2024*
Weitere Informationen finden Sie unter:
https://www.basg.gv.at/fileadmin/redakteure/01_Formulare_Listen/I/L_I120_Handbuch_zur_Befuellung_des_Suchtmittelnachweisungsformulars_12.pdf

Formulare – Stammdaten
Veröffentlicht am: *13 - Dezember - 2024*
Weitere Informationen finden Sie unter:
https://www.basg.gv.at/fuer-unternehmen/arzneimittel-informationen/suchtmittel/formulare-stammdaten

FAQ online Service
Veröffentlicht am: *16 - Dezember - 2024*
Weitere Informationen finden Sie unter:
https://www.basg.gv.at/fuer-unternehmen/online-service/leitfaeden-und-faq

Humanarzneimittel - Österreich

Leitfaden: Registrierung von Unternehmen/Organisationen (L_M39)
Veröffentlicht am: *16 - Dezember - 2024*
Weitere Informationen finden Sie unter:
https://www.basg.gv.at/fileadmin/redakteure/01_Formulare_Listen/M/L_M39_Leitfaden_Registrierung.pdf

Leitfaden: Externe Benutzeradministration (L_M58)
Veröffentlicht am: *16 - Dezember - 2024*
Weitere Informationen finden Sie unter:
https://www.basg.gv.at/fileadmin/redakteure/01_Formulare_Listen/M/L_M58_Leitfaden_zur_externen_Benutzeradministration.pdf

Gebührentarif_Verordnung_Nr.4-2024
Veröffentlicht am: *17 - Dezember - 2024*
Weitere Informationen finden Sie unter:
https://www.basg.gv.at/fileadmin/redakteure/02_Ueber_Uns/Geb%C3%BChrentarif/Geb%C3%BChrentarif_Verordnung_Nr.4-2024.pdf

Gebührentarif
Veröffentlicht am: *17 - Dezember - 2024*
Weitere Informationen finden Sie unter:
https://www.basg.gv.at/ueber-uns/gebuehrentarif

Geschäftsordnung
Veröffentlicht am: *17 - Dezember - 2024*
Weitere Informationen finden Sie unter:
https://www.basg.gv.at/ueber-uns/basg-veroeffentlichungen/geschaeftsordnung

Genehmigungsentwürfe
Veröffentlicht am: *17 - Dezember - 2024*
Weitere Informationen finden Sie unter:
https://www.basg.gv.at/ueber-uns/gebuehrentarif/genehmigungsentwuerfe

Antrag auf Infrastruktursicherungsbeitrag (ISB)
Veröffentlicht am: *17 - Dezember - 2024*
Weitere Informationen finden Sie unter:
https://www.basg.gv.at/fuer-unternehmen/online-service/antrag-auf-infrastruktursicherungsbeitrag

Life-Cycle
Veröffentlicht am: *18 - Dezember - 2024*
Weitere Informationen finden Sie unter:
https://www.basg.gv.at/fuer-unternehmen/zulassung-life-cycle/lifecycle

In Kraft treten der geänderten Verordnung 1234/2008/EC über die Prüfung von Änderungen der Zulassungen von Humanarzneimitteln mit 01.01.2025
Veröffentlicht am: *18 - Dezember - 2024*
Weitere Informationen finden Sie unter:
https://www.basg.gv.at/fuer-unternehmen/zulassung-life-cycle/lifecycle

Humanarzneimittel - Österreich

PSUR outcome: Sugammadex
Veröffentlicht am: *19 - Dezember - 2024*
Weitere Informationen finden Sie unter:
https://www.basg.gv.at/fileadmin/redakteure/07_Unternehmen/PV-Mustertexte/ab_2023/241219_CL_Sugammadex_sig.pdf

Link zur Webseite der EC

Humanarzneimittel - Schweiz

Aufsichtsabgabe 2024 – Selbstdeklaration
Veröffentlicht am: *06 - Dezember - 2024*
Weitere Informationen finden Sie unter:
https://www.swissmedic.ch/swissmedic/de/home/news/mitteilungen/aufsichtsabgabe-2024.html

Swissmedic: Zentrale Schaltstelle im gemeinsamen Kampf gegen Heilmittelkriminalität
Veröffentlicht am: *16 - Dezember - 2024*
Weitere Informationen finden Sie unter:
https://www.swissmedic.ch/swissmedic/de/home/humanarzneimittel/marktueberwachung/arzneimittel-aus-dem-internet/drug-safety-current-threats/zentrale-schaltstelle-gemeinsamer-kampf-gegen-heilmittelkriminalitaet.html

Erfolgreicher Einsatz bei Kontrollaktion gegen illegalen Arzneimittelhandel
Veröffentlicht am: *18 - Dezember - 2024*
Weitere Informationen finden Sie unter:
https://www.swissmedic.ch/swissmedic/de/home/humanarzneimittel/marktueberwachung/arzneimittel-aus-dem-internet/drug-safety-current-threats/einsatz-bei-kontrollaktion-gegen-illegale-am.html

Swissmedic Podcast #4: Klinische Versuche - Basis für qualitativ hochstehende Medikamente
Veröffentlicht am: *20 - Dezember - 2024*
Weitere Informationen finden Sie unter:
https://www.swissmedic.ch/swissmedic/de/home/ueber-uns/publikationen/podcast.html

Aktualisierte Vorgabedokumente
Veröffentlicht am: *16 - Dezember - 2024*
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.

Frage 1

Dear Colleagues,

I am reaching out to gather your insights on how your organizations handle discrepancies between the EU Reference Safety Information (EU-RSI) and the information documented in the Investigator's Brochure (IB) during safety reporting. Specifically, we have observed differences in how safety events are categorized between the DSUR and submissions. Submissions to Swissmedic for SUSARs are based on the expectedness in the IB, whereas the DSUR is aligned with the EU-RSI, following EU regulations. Since the IB is updated more frequently, discrepancies have been highlighted by Health Authorities, particularly noting cases listed in the DSUR SUSAR line listing that were not submitted to them (as submission occurs per IB expectedness).

Could you share how your company addresses this challenge? Do you align your expedited reporting with the IB or the EU-RSI, and how do you communicate or manage these discrepancies with Health Authorities?

Frage 2 (gekürzt wegen Kartellrecht)

Es gibt Firmen, die darauf spezialisiert sind, PV Audits durchzuführen und anschließend diese Auditberichte zum Verkauf anzubieten. Wie sind die Erfahrungen mit der Akzeptanz dieser Auditberichte durch die Behörden, v.a. in Bezug auf GVP?

(Bitte nennen Sie keine Firmenempfehlungen).

Offene Frage aus KW 48/49

In June 2024 the MAH received a centrally marketing authorization for its vaccine. For the preparedness of the launch, the MAH needs confirmation what local prerequisites exists for the access of a new pharmaceutical product/vaccine in Germany. The question concerns every aspect for the end customer being able to order the product following Marketing authorization. Below are the activities we have identified as necessary for starting selling a pharma product in Germany. Question: Are there any critical activities missing in below list? Serial numbers uploaded in DE NMVS

-IFA database updated with PZN and Price
-BfArM Packungsgrössenverordnung
-Rote Liste
-Update PharmNet Bund/AMIce/BfArM databases Register
-Stufenplanbeauftrager

Veranstaltungen / Events – Behörden und andere Veranstalter

Deutschland

Gemeinsame Ringvorlesung Wintersemester 2024/2025
Ort: online
Termin: *verschiedene 2024 - 2025*
Weitere Informationen finden Sie unter:
https://www.bfarm.de/DE/Aktuelles/Veranstaltungen/Ringvorlesung/Termine/Ringvorlesung_2024-2025.html?nn=986770

Klinische Prüfung: BfArM trifft...!
Ort: online
Termin: *10 - Januar - 2025*
Weitere Informationen finden Sie unter:
https://www.bfarm.de/DE/Aktuelles/Veranstaltungen/Termine/2025-01-10-klinische-pruefung-austausch.html?nn=986770

Österreich

Keine Veranstaltungen veröffentlicht

Schweiz

Keine Veranstaltungen veröffentlicht

Europa

Q&A Clinic on post-authorisation procedure management in IRIS
Where: *online*
Date: *08 - January - 2025, 17 - January - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/events/qa-clinic-post-authorisation-procedure-management-iris-0
https://www.ema.europa.eu/en/events/qa-clinic-post-authorisation-procedure-management-iris-17-jan-2025

SPOR Status Update
Where: *online and European Medicines Agency, Amsterdam, the Netherlands*
Date: *22 - January - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/events/spor-status-update-1

Veranstaltungen / Events – Behörden und andere Veranstalter

Clinical Trials Information System (CTIS): Walk-in clinic - January 2025
Where: *online and European Medicines Agency, Amsterdam, the Netherlands*
Date: *29 - January - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/events/clinical-trials-information-system-ctis-walk-clinic-january-2025

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: *27 to 31 - January - 2025, 24 to 28 - February - 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-46
https://www.ema.europa.eu/en/events/mandatory-use-iso-ich-e2br3-individual-case-safety-reporting-eu-hands-training-course-using-eudravigilance-system-47

eXtended EudraVigilance Medicinal Product Dictionary (XEVMPD) training course - February 2025
Where: *online*
Date: *10 to 12 - February - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/events/extended-eudravigilance-medicinal-product-dictionary-xevmpd-training-course-february-2025

ACT EU workshop on ICH E6 R3 (principles and Annex 1)
Where: *online and European Medicines Agency, Amsterdam, the Netherlands*
Date: *19 to 20 - February - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/events/act-eu-workshop-ich-e6-r3-principles-annex-1

Virtual live hands-on training course for clinical trials sponsors using EudraVigilance system
Where: *online and European Medicines Agency, Amsterdam, the Netherlands*
Date: *18 to 20 - February - 2025, 05 to 07 - May - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/events/virtual-live-hands-training-course-clinical-trials-sponsors-using-eudravigilance-system-february
https://www.ema.europa.eu/en/events/virtual-live-hands-training-course-clinical-trials-sponsors-using-eudravigilance-system-may