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Humanarzneimittel - EMA

Allgemeines – General

First version of the Union list of critical medicines agreed to help avoid potential shortages in the EU

Published on: 12 - December - 2023

For more information, please refer to:

<https://www.ema.europa.eu/en/news/first-version-union-list-critical-medicines-agreed-help-avoid-potential-shortages-eu>

Data Analysis and Real World Interrogation Network (DARWIN EU)

Published on: 12 - December - 2023

For more information, please refer to:

<https://www.ema.europa.eu/en/about-us/how-we-work/big-data/data-analysis-and-real-world-interrogation-network-darwin-eu>

Big data

Published on: 18 - December - 2023

For more information, please refer to:

<https://www.ema.europa.eu/en/about-us/how-we-work/big-data>

Pharmakovigilanz – PRAC

Global regulators strengthen efforts to ensure continuous availability of safe and high-quality medicines

Published on: 08 - December - 2023

For more information, please refer to:

<https://www.ema.europa.eu/en/news/global-regulators-strengthen-efforts-ensure-continuous-availability-safe-and-high-quality-medicines>

Expected publication dates of PRAC recommendations on safety signals

Published on: 11 - December - 2023

For more information, please refer to:

https://www.ema.europa.eu/en/documents/other/expected-publication-dates-prac-recommendations-safety-signals_en.pdf

Referral: Havrix , Article 30 referrals, Review started (updated)

Published on: 15 - December - 2023

For more information, please refer to:

For more information, please refer to:

<https://www.ema.europa.eu/en/medicines/human/referrals/havrix>

Referral: Synapse Article-31 referral - Synapse Labs Pvt. Ltd: EMA recommends suspension of medicines over flawed studies

Published on: 15 - December - 2023

For more information, please refer to:

For more information, please refer to:

<https://www.ema.europa.eu/en/medicines/human/referrals/synapse>

Humanarzneimittel - EMA

Risk management plans (RMP) in post-authorisation phase: questions and answers

Published on: 18 - December - 2023

For more information, please refer to:

For more information, please refer to:

<https://www.ema.europa.eu/en/human-regulatory-overview/post-authorisation/pharmacovigilance-post-authorisation/risk-management-plans-rmp-post-authorisation-phase-questions-and-answers>

List of European Union reference dates and frequency of submission of periodic safety update reports (PSURs)

Published on: 19 - December - 2023

For more information, please refer to:

For more information, please refer to:

https://www.ema.europa.eu/en/documents/other/list-european-union-reference-dates-and-frequency-submission-periodic-safety-update-reports-psurs_en.xlsx

Article 57 product data

Published on: 21 - December - 2023

For more information, please refer to:

For more information, please refer to:

https://www.ema.europa.eu/en/documents/other/article-57-product-data_en.xlsx

18th industry stakeholder platform - operation of European Union (EU) pharmacovigilance, Event - 22 - November - 2023 (updated)

Presentation available

Published on: 21 - December - 2023

For more information, please refer to:

For more information, please refer to:

<https://www.ema.europa.eu/en/events/18th-industry-stakeholder-platform-operation-european-union-eu-pharmacovigilance>

EudraVigilance training and support

Published on: 21 - December - 2023

For more information, please refer to:

For more information, please refer to:

<https://www.ema.europa.eu/en/human-regulatory-overview/research-and-development/pharmacovigilance-research-and-development/eudravigilance/eudravigilance-training-and-support>

Zulassung – Regulatory Affairs

CHMP: Agendas, minutes and highlights

Published on: 11 - December - 2023

For more information, please refer to:

<https://www.ema.europa.eu/en/committees/committee-medicinal-products-human-use-chmp>

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Data Quality Framework for EU medicines regulation

Published on: 11 - December - 2023

For more information, please refer to:

https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/data-quality-framework-eu-medicines-regulation_en.pdf

Abbreviations used in EMA scientific committees and CMD documents, and in relation to EMA's regulatory activities

Published on: 12 - December - 2023

For more information, please refer to:

https://www.ema.europa.eu/en/documents/other/abbreviations-used-ema-scientific-committees-and-cmd-documents-and-relation-emas-regulatory-activities_en.pdf

EMA confirms recommendation for non-renewal of authorisation of multiple myeloma medicine Blenrep

Published on: 15 - December - 2023

For more information, please refer to:

<https://www.ema.europa.eu/en/news/ema-confirms-recommendation-non-renewal-authorisation-multiple-myeloma-medicine-blenrep>

Guideline on the acceptability of names for human medicinal products processed through the centralised procedure - Scientific guideline

Published on: 15 - December - 2023

For more information, please refer to:

<https://www.ema.europa.eu/en/guideline-acceptability-names-human-medicinal-products-processed-through-centralised-procedure-scientific-guideline>

Q & A on implementation of Ph.Eur. Medicinal Product Monographs

Published on: 15 - December - 2023

For more information, please refer to:

https://www.ema.europa.eu/en/documents/other/q-implementation-pheur-medicinal-product-monographs_en.pdf

Pre-authorisation guidance

Published on: 18 - December - 2023

For more information, please refer to:

<https://www.ema.europa.eu/en/human-regulatory-overview/marketing-authorisation/pre-authorisation-guidance>

European Medicines Agency pre-authorisation procedural advice for users of the centralised procedure

Published on: 18 - December - 2023

For more information, please refer to:

https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/european-medicines-agency-pre-authorisation-procedural-advice-users-centralised-procedure_en.pdf

Humanarzneimittel - EMA

European Medicines Agency post-authorisation procedural advice for users of the centralised procedure

Published on: 18 - December - 2023

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

Assessment of SmPC section 5.1: A Guide for Assessors of Centralised Applications - Scientific guideline

Published on: 18 - December - 2023

For more information, please refer to:

<https://www.ema.europa.eu/en/assessment-smpc-section-51-guide-assessors-centralised-applications-scientific-guideline>

Regulatory requirements for the development of medicinal products for Acute Kidney Injury (AKI) - Scientific guideline

Published on: 18 - December - 2023

For more information, please refer to:

<https://www.ema.europa.eu/en/regulatory-requirements-development-medicinal-products-acute-kidney-injury-aki-scientific-guideline>

Reflection papers on regulatory requirements for the development of medicinal products for chronic non-infectious liver diseases (PBC, PSC, NASH) - Scientific guideline

Published on: 19 - December - 2023

For more information, please refer to:

<https://www.ema.europa.eu/en/reflection-papers-regulatory-requirements-development-medicinal-products-chronic-non-infectious-liver-diseases-pbc-psc-nash-scientific-guideline>

International Council on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH)

Published on: 20 - December - 2023

For more information, please refer to:

<https://www.ema.europa.eu/en/partners-networks/international-activities/multilateral-coalitions-and-initiatives/international-council-harmonisation-technical-requirements-registration-pharmaceuticals-human-use-ich>

Plasma master file certificates (updated)

Published on: 04 - January - 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>

Humanarzneimittel - EMA

Orphan Drugs und neuartige Therapierichtungen (ATMP)

COMP agendas, minutes and meeting reports

Published on: 22 - December - 2023

For more information, please refer to:

<https://www.ema.europa.eu/en/committees/committee-orphan-medicinal-products-comp>

Qualität - Quality

ICH Q2(R2) Validation of analytical procedures - Scientific guideline

Published on: 22 - December - 2023

For more information, please refer to:

<https://www.ema.europa.eu/en/ich-q2r2-validation-analytical-procedures-scientific-guideline>

ICH E6 (R2) Good clinical practice - Scientific guideline

Published on: 22 - December - 2023

For more information, please refer to:

<https://www.ema.europa.eu/en/ich-e6-r2-good-clinical-practice-scientific-guideline>

ICH Q5A(R2) Guideline on viral safety evaluation of biotechnology products derived from cell lines of human or animal origin - Step 5

Published on: 03 - January - 2024

For more information, please refer to:

https://www.ema.europa.eu/en/documents/scientific-guideline/ich-q5ar2-guideline-viral-safety-evaluation-biotechnology-products-derived-cell-lines-human-or-animal-origin-step-5_en.pdf

(Prä-) Klinische Forschung – Research and Development

Clinical Trials Information System (CTIS): Walk-in clinic, Event - 15 - November - 2023 (updated)

Video recording available

Published on: 11 - December - 2023

For more information, please refer to:

<https://www.ema.europa.eu/en/events/clinical-trials-information-system-ctis-walk-clinic-november-2023>

CTIS newsflash - 8 December 2023

Published on: 12 - December - 2023

For more information, please refer to:

https://www.ema.europa.eu/en/documents/newsletter/ctis-newsflash-8-december-2023_en.pdf

Biologicals: finished product

Published on: 19 - December - 2023

For more information, please refer to:

<https://www.ema.europa.eu/en/human-regulatory-overview/research-and-development/scientific-guidelines/biological-guidelines/biologicals-finished-product>

Humanarzneimittel - EMA

Stakeholder workshop on support to quality development in early access approaches, such as PRIME and Breakthrough Therapies, Event - 26 - November - 2018 (updated)

Report available

Published on: 19 - December - 2023

For more information, please refer to:

<https://www.ema.europa.eu/en/events/stakeholder-workshop-support-quality-development-early-access-approaches-such-prime-and-breakthrough-therapies>

Opinions and letters of support on the qualification of novel methodologies for medicine development

Published on: 21 - December - 2023

For more information, please refer to:

<https://www.ema.europa.eu/en/human-regulatory-overview/research-and-development/scientific-advice-and-protocol-assistance/opinions-and-letters-support-qualification-novel-methodologies-medicine-development>

Development and manufacture of human medicinal products specifically designed for phage therapy - Scientific guideline

Published on: 22 - December - 2023

For more information, please refer to:

<https://www.ema.europa.eu/en/development-and-manufacture-human-medicinal-products-specifically-designed-phage-therapy-scientific-guideline>

Kinderarzneimittel – Paediatrics

Guidance on paediatric submissions

Published on: 12 - December - 2023

For more information, please refer to:

https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/guidance-paediatric-submissions_en.pdf

New treatment for young children with parasitic disease schistosomiasis

Published on: 15 - December - 2023

For more information, please refer to:

<https://www.ema.europa.eu/en/news/new-treatment-young-children-parasitic-disease-schistosomiasis>

Notification of discontinuation of an agreed PIP decision

Published on: 19 - December - 2023

For more information, please refer to:

https://www.ema.europa.eu/en/documents/template-form/notification-discontinuation-agreed-pip-decision_en.doc

Humanarzneimittel - EMA

Paediatric investigation plans: submitting documents

Published on: 20 - December - 2023

For more information, please refer to:

<https://www.ema.europa.eu/en/human-regulatory-overview/research-and-development/paediatric-medicines-research-and-development/paediatric-investigation-plans/paediatric-investigation-plans-submitting-documents>

Letter of support for a composite endpoint method for acceptability evaluation of oral drug formulations in the paediatric population

Published on: 20 - December - 2023

For more information, please refer to:

https://www.ema.europa.eu/en/documents/other/letter-support-composite-endpoint-method-acceptability-evaluation-oral-drug-formulations-paediatric-population_en.pdf

PDCO work plan 2024

Published on: 03 - January - 2024

For more information, please refer to:

https://www.ema.europa.eu/en/documents/work-programme/pdco-work-plan-2024_en.pdf

Pflanzliche Arzneimittel – Herbal medicines

Procedures for monograph and list entry establishment

Published on: 11 - December - 2023

For more information, please refer to:

<https://www.ema.europa.eu/en/human-regulatory-overview/herbal-medicinal-products/procedures-monograph-and-list-entry-establishment>

HMPc: overview of assessment work - priority list

Published on: 11 - December - 2023

For more information, please refer to:

https://www.ema.europa.eu/en/documents/other/hmpc-overview-assessment-work-priority-list_en.pdf

HMPc: agendas, minutes and meeting reports

Published on: 14 - December - 2023

For more information, please refer to:

<https://www.ema.europa.eu/en/committees/committee-herbal-medicinal-products-hmpc>

European Commission

SCHEER - Request for a scientific Opinion on the Memorandum on weight of evidence and uncertainties – Revision 2024

Published on: 08 - December - 2023

For more information, please refer to:

https://health.ec.europa.eu/latest-updates/scheer-request-scientific-opinion-memorandum-weight-evidence-and-uncertainties-revision-2024-2023-12-08_en

Study on the coherence, complementarity, and continued relevance of actions in the Council

Recommendation on strengthened cooperation against vaccine-preventable diseases

Published on: 12 - December - 2023

For more information, please refer to:

https://health.ec.europa.eu/publications/study-coherence-complementarity-and-continued-relevance-actions-council-recommendation-strengthened_en

Commission report - Final evaluation of the third Health Programme 2014-2020

Published on: 13 - December - 2023

For more information, please refer to:

https://health.ec.europa.eu/publications/commission-report-final-evaluation-third-health-programme-2014-2020_en

Medicines for children 2022 annual report

Published on: 20 - December - 2023

For more information, please refer to:

https://health.ec.europa.eu/latest-updates/medicines-children-2022-annual-report-2023-12-20_en

HERA 2024 Work Plan

Published on: 22 - December - 2023

For more information, please refer to:

https://health.ec.europa.eu/publications/hera-2024-work-plan_en

Outcome of the 177th session of the European Pharmacopoeia Commission, November 2023

Published on: 08 - December - 2023

For more information, please refer to:

<https://www.edqm.eu/en/-/outcome-of-the-177th-session-of-the-european-pharmacopoeia-commission-november-2023>

European Pharmacopoeia welcomes Egyptian Drug Authority as observer

Published on: 11 - December - 2023

For more information, please refer to:

<https://www.edqm.eu/en/-/european-pharmacopoeia-welcomes-egyptian-drug-authority-as-observer>

Information for CEP applicants - EDQM-DCEP non-working days in 2024

Published on: 11 - December - 2023

For more information, please refer to:

<https://www.edqm.eu/en/-/information-for-cep-applicants-edqm-dcep-non-working-days-in-2024>

The CEP 2.0 guideline on requirements for the content of the dossier has been updated

Published on: 13 - December - 2023

For more information, please refer to:

<https://www.edqm.eu/en/-/the-cep-2.0-guideline-on-requirements-for-the-content-of-the-dossier-has-been-updated>

Implementation of pharmaceutical care in daily practice in South-eastern Europe Health Network (SEEHN) member states

Published on: 14 - December - 2023

For more information, please refer to:

<https://www.edqm.eu/en/-/implementation-of-pharmaceutical-care-in-daily-practice-in-south-eastern-europe-health-network-seehn-member-states-1>

European Pharmacopoeia Supplement 11.5 now available

Published on: 15 - December - 2023

For more information, please refer to:

<https://www.edqm.eu/en/-/european-pharmacopoeia-supplement-11.5-now-available>

General chapters on powder characterisation techniques modernized

Published on: 18 - December - 2023

For more information, please refer to:

<https://www.edqm.eu/en/-/general-chapters-on-powder-characterisation-techniques-modernised>

Production, Distribution and Reception Operators

Published on: 18 - December - 2023

For more information, please refer to:

<https://www.edqm.eu/en/-/production-distribution-and-reception-operators>

BSP study outcome published online – Heparin Low-Molecular-Mass CRS batches 4 & 5

Published on: 18 - December - 2023

For more information, please refer to:

<https://www.edqm.eu/en/-/bsp-study-outcome-published-online-heparin-for-low-molecular-mass-crs-batches-4-5>

Implementation of the European Pharmacopoeia Supplement 11.5 – Notification for CEP holders

Published on: 19 - December - 2023

For more information, please refer to:

<https://www.edqm.eu/en/-/implementation-of-the-european-pharmacopoeia-supplement-11.5-notification-for-cep-holders>

New general chapter on comparability of alternative analytical procedures published in European Pharmacopoeia

Published on: 18 - December - 2023

For more information, please refer to:

<https://www.edqm.eu/en/-/new-general-chapter-on-comparability-of-alternative-analytical-procedures-published-in-european-pharmacopoeia>

EDQM welcomes EU Parliament and Council's political agreement on enhanced safety and quality for substances of human origin

Published on: 20 - December - 2023

For more information, please refer to:

<https://www.edqm.eu/en/-/edqm-welcomes-eu-parliament-and-council-s-political-agreement-on-enhanced-safety-and-quality-for-substances-of-human-origin>

8 replacement batches released in December 2023

Published on: 02 - January - 2024

For more information, please refer to:

<https://www.edqm.eu/en/-/8-replacement-batches-released-in-december-2023>

Cannabis flower for system suitability HRS and cannabidiol for cannabis CRS now available

Published on: 03 - January - 2024

For more information, please refer to:

<https://www.edqm.eu/en/-/cannabis-flower-for-system-suitability-hrs-and-cannabidiol-for-cannabis-crs-now-available>

Pharmeuropa 36.1 just released

Published on: 05 - January - 2024

For more information, please refer to:

<https://www.edqm.eu/en/-/pharmeuropa-36.1-just-released>

Medizinprodukte

Update - MDCG 2021-6 - Rev.1 - Regulation (EU) 2017/745 – Questions & Answers regarding clinical investigation - December 2023

Published on: 12 - December - 2023

For more information, please refer to:

https://health.ec.europa.eu/latest-updates/update-mdcg-2021-6-rev1-regulation-eu-2017745-questions-answers-regarding-clinical-investigation-2023-12-12_en

MDCG 2023-5 - Guidance on qualification and classification of Annex XVI products - A guide for manufacturers and notified bodies - December 2023

Published on: 14 - December - 2023

For more information, please refer to:

https://health.ec.europa.eu/latest-updates/mdcg-2023-5-guidance-qualification-and-classification-annex-xvi-products-guide-manufacturers-and-2023-12-14_en

MDCG 2023-6 - Guidance on demonstration of equivalence for Annex XVI products - A guide for manufacturers and notified bodies - December 2023

Published on: 14 - December - 2023

For more information, please refer to:

https://health.ec.europa.eu/latest-updates/mdcg-2023-6-guidance-demonstration-equivalence-annex-xvi-products-guide-manufacturers-and-notified-2023-12-14_en

Update - MDCG 2021-27 - Rev.1 - Questions and Answers on Articles 13 & 14 of Regulation (EU) 2017/745 and Regulation (EU) 2017/746 - December 2023

Published on: 19 - December - 2023

For more information, please refer to:

https://health.ec.europa.eu/latest-updates/update-mdcg-2021-27-rev1-questions-and-answers-articles-13-14-regulation-eu-2017745-and-regulation-2023-12-19_en

Update - MDCG 2019-7 - Rev.1 - Guidance on article 15 of the medical device regulation (MDR) and in vitro diagnostic device regulation (IVDR) on a PRRC - December 2023

Published on: 19 - December - 2023

For more information, please refer to:

https://health.ec.europa.eu/latest-updates/update-mdcg-2019-7-rev1-guidance-article-15-medical-device-regulation-mdr-and-vitro-diagnostic-2023-12-19_en

Questions and answers on implementation of the medical devices and in vitro diagnostic medical devices Regulations ((EU) 2017/745 and (EU) 2017/746)

Published on: 20 - December - 2023

For more information, please refer to:

https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/questions-and-answers-implementation-medical-devices-and-vitro-diagnostic-medical-devices-regulations-eu-2017-745-and-eu-2017-746_en.pdf

Updated version - Information on the applications for designation as a notified body (short overview)

Published on: 21 - December - 2023

For more information, please refer to:

https://health.ec.europa.eu/latest-updates/updated-version-information-applications-designation-notified-body-short-overview-2023-12-21_en

Medizinprodukte

MDCG 2023-7 - Guidance on exemptions from the requirements to perform clinical investigations pursuant to Article 61(4)-(6) MDR - December 2023

Published on: 21 - December - 2023

For more information, please refer to:

https://health.ec.europa.eu/latest-updates/mdcg-2023-7-guidance-exemptions-requirements-perform-clinical-investigations-pursuant-article-614-6-2023-12-21_en

CMDh

UPDATE - Data requested for New Applications in the MRP/DCP which are not stated in the current EU legislation and/or in Volume 2B, Presentation and format of the dossier Common Technical Document (CTD) and/or in the EEA approved Guidelines/Recommendation papers - correction

Published on: 12 - December - 2023

For more information, please refer to:

<https://www.hma.eu/human-medicines/cmdh/procedural-guidance/variation.html#c2512>

NEW - 7-8 November 2023 CMDh minutes

Published on: 19 - December - 2023

For more information, please refer to:

<https://www.hma.eu/human-medicines/cmdh/agendas-and-minutes.html#c7146>

NEW - Report from the meeting held on 12-14 December 2023

Published on: 20 - December - 2023

For more information, please refer to:

<https://www.hma.eu/human-medicines/cmdh/press-releases.html#c7155>

NEW - SmAR on Human normal immunoglobulin IV

Published on: 20 - December - 2023

For more information, please refer to:

<https://www.hma.eu/human-medicines/cmdh/pharmacovigilance/psur/outcome-of-informal-psur-worksharing-procedures.html#c7443>

NEW - SmAR on Ramipril/bisoprolol

Published on: 20 - December - 2023

For more information, please refer to:

<https://www.hma.eu/human-medicines/cmdh/pharmacovigilance/psur/outcome-of-informal-psur-worksharing-procedures.html#c7278>

UPDATE - Q&A - List for the submission of variations for human medicinal products according to Commission Regulation (EC) 1234/2008

Published on: 20 - December - 2023

For more information, please refer to:

<https://www.hma.eu/human-medicines/cmdh/questions-answers.html#c3193>

UPDATE - Chapter 6 - CMDh BPG for the processing of grouped applications in the Mutual Recognition Procedure

Published on: 20 - December - 2023

For more information, please refer to:

https://www.hma.eu/fileadmin/dateien/Human_Medicines/CMD_h_procedural_guidance/Variations/CMDh_296_2013_Rev.26_2023_12_clean - BPG_for_Variations - Chapter_6.pdf

UPDATE - Chapter 7 - CMDh BPG on Variation Worksharing

Published on: 20 - December - 2023

For more information, please refer to:

https://www.hma.eu/fileadmin/dateien/Human_Medicines/CMD_h_procedural_guidance/Variations/CMDh_297_2013_Rev.33_2023_12_clean - BPG_for_Variations - Chapter_7.pdf

Humanarzneimittel - Deutschland

OPS und ICD-10-GM: Vorschlagsverfahren für Versionen 2025 eröffnet

Veröffentlicht am: 08 - Dezember - 2023

Weitere Informationen finden Sie unter:

https://www.bfarm.de/DE/Kodiersysteme/News/OPS_und_ICD-10-GM_Vorschlagsverfahren_fuer_Version_2025_eroeffnet.html?nn=986770

Task Force zur Sicherstellung der medikamentösen Versorgung in der Intensivmedizin (ICU-Wirkstofflisten)

Veröffentlicht am: 12 - Dezember - 2023

Weitere Informationen finden Sie unter:

https://www.bfarm.de/DE/Arzneimittel/Arzneimittelinformationen/Lieferengpaesse/Task-Force-Intensivmedizin/_artikel.html?nn=986770

Ethik-Kommissionen

Veröffentlicht am: 12 - Dezember - 2023

Weitere Informationen finden Sie unter:

https://www.bfarm.de/DE/Arzneimittel/Klinische-Pruefung/Ethik-Kommissionen/_artikel.html?nn=986770

Geschäftsverteilungsplan der registrierten Ethik-Kommissionen für das Jahr 2024 (Teil I)

Veröffentlicht am: 12 - Dezember - 2023

Weitere Informationen finden Sie unter:

https://www.bfarm.de/SharedDocs/Downloads/DE/Arzneimittel/Zulassung/klin-pr/ethikKomm/GVPEthikKomm/GVP_2023.html?nn=986770

Informationen und Schulungsunterlagen

Veröffentlicht am: 13 - Dezember - 2023

Weitere Informationen finden Sie unter:

<https://www.bfarm.de/DE/Arzneimittel/Zulassung/Zulassungsrelevante-Themen/e-Submission/Pharmnet-Bund.html?nn=986770>

Ergebnisprotokolle der Expertengruppen Off-Label

Veröffentlicht am: 15 - Dezember - 2023

Weitere Informationen finden Sie unter:

https://www.bfarm.de/DE/Arzneimittel/Zulassung/Zulassungsrelevante-Themen/Expertengruppe-Off-Label/Ergebnisprotokolle_OLU.html?nn=986770

Versagungen und Rücknahmen BfArM Januar-November 2023

Veröffentlicht am: 15 - Dezember - 2023

Weitere Informationen finden Sie unter:

<https://www.bfarm.de/SharedDocs/Downloads/DE/Service/Statistik/AM-Statistik/versagungen-2023.html?nn=986770>

Maßnahmen des BfArM und ergänzende Informationen zu Lieferengpässen

Veröffentlicht am: 15 - Dezember - 2023

Weitere Informationen finden Sie unter:

https://www.bfarm.de/DE/Arzneimittel/Arzneimittelinformationen/Lieferengpaesse/Massnahmen-des-BfArM/_artikel.html?nn=986770

Humanarzneimittel - Deutschland

Arzneibuch

Veröffentlicht am: 18 - Dezember - 2023

Weitere Informationen finden Sie unter:

https://www.bfarm.de/DE/Arzneimittel/Zulassung/Zulassungsrelevante-Themen/Arzneibuch/_artikel.html?nn=986770

European Regulatory Oncology News – ERON

Veröffentlicht am: 19 - Dezember - 2023

Weitere Informationen finden Sie unter:

https://www.bfarm.de/DE/Das-BfArM/EU-und-Internationales/ERON/_artikel.html?nn=986770

Ergebnisprotokoll der Sitzungen der AG ICD Vorschlagsverfahren für die ICD-10-GM 2024

Veröffentlicht am: 19 - Dezember - 2023

Weitere Informationen finden Sie unter:

<https://www.bfarm.de/SharedDocs/Downloads/DE/Kodiersysteme/klassifikationen/icd-10-gm/version2024/icd-ergebnisprotokoll-2024.html?nn=986770>

Statistiken

Veröffentlicht am: 19 - Dezember - 2023

Weitere Informationen finden Sie unter:

https://www.bfarm.de/DE/Aktuelles/Statistiken/_artikel.html?nn=986770

Ergebnisprotokoll der Sitzungen der AG OPS Vorschlagsverfahren für den OPS 2024

Veröffentlicht am: 19 - Dezember - 2023

Weitere Informationen finden Sie unter:

<https://www.bfarm.de/SharedDocs/Downloads/DE/Kodiersysteme/klassifikationen/ops/version2024/ops-ergebnisprotokoll-2024.html?nn=986770>

ICD-10-GM-2024 - Bekanntmachung im Bundesanzeiger

Veröffentlicht am: 19 - Dezember - 2023

Weitere Informationen finden Sie unter:

<https://www.bfarm.de/DE/Kodiersysteme/Klassifikationen/ICD/ICD-10-GM/Historie/Versionsverlauf/ba-gm-2024.html?nn=986770>

Ergebnisprotokoll zur 32. Sitzung der Gemeinsamen Expertenkommission zur Einstufung von Stoffen

Veröffentlicht am: 19 - Dezember - 2023

Weitere Informationen finden Sie unter:

https://www.bfarm.de/DE/Arzneimittel/Zulassung/Zulassungsrelevante-Themen/Abgrenzung/Gemeinsame-Expertenkommission-zur-Einstufung-von-Stoffen/Sitzungen/32_Sitzung/protokoll_32.html?nn=986770

OPS 2024 - Bekanntmachung im Bundesanzeiger

Veröffentlicht am: 19 - Dezember - 2023

Weitere Informationen finden Sie unter:

<https://www.bfarm.de/DE/Kodiersysteme/Klassifikationen/OPS-ICHI/OPS/Historie-und-Ausblick/Versionsverlauf/ba-ops-2024.html?nn=986770>

Humanarzneimittel - Deutschland

CHMP Ausschuss für Humanarzneimittel

Veröffentlicht am: 20 - Dezember - 2023

Weitere Informationen finden Sie unter:

https://www.bfarm.de/DE/Das-BfArM/EU-und-Internationales/CHMP-Ausschuss/_artikel.html?nn=986770

Wissenswertes zu DiGA

Veröffentlicht am: 20 - Dezember - 2023

Weitere Informationen finden Sie unter:

https://www.bfarm.de/DE/Medizinprodukte/Aufgaben/DiGA-und-DiPA/DiGA/Wissenswertes/_artikel.html?nn=986770

Arzneibuchkommissionen

Veröffentlicht am: 20 - Dezember - 2023

Weitere Informationen finden Sie unter:

https://www.bfarm.de/DE/Arzneimittel/Zulassung/Zulassungsrelevante-Themen/Arzneibuch/Arzneibuchkommissionen/_artikel.html?nn=986770

ATC/DDD Version 2024

Veröffentlicht am: 20 - Dezember - 2023

Weitere Informationen finden Sie unter:

<https://www.bfarm.de/SharedDocs/Downloads/DE/Kodiersysteme/ATC/atc-ddd-amtlich-2024.html?nn=986770>

Workflow für 2025

Veröffentlicht am: 20 - Dezember - 2023

Weitere Informationen finden Sie unter:

<https://www.bfarm.de/SharedDocs/Downloads/DE/Kodiersysteme/ATC/arbeitsgruppe/2024/atc-workflow-2025.html?nn=986770>

Bulletin zur Arzneimittelsicherheit

Veröffentlicht am: 21 - Dezember - 2023

Weitere Informationen finden Sie unter:

https://www.bfarm.de/DE/Aktuelles/Publikationen/Bulletin/_artikel.html?nn=986770

Arzneimittelklassifikation: BfArM veröffentlicht amtliche Fassung der ATC-Klassifikation mit definierten Tagesdosen

Veröffentlicht am: 21 - Dezember - 2023

Weitere Informationen finden Sie unter:

<https://www.bfarm.de/SharedDocs/Pressemitteilungen/DE/2023/pm09-2023.html?nn=986770>

Statistik "Besondere Therapierichtungen und Traditionelle Arzneimittel"

Veröffentlicht am: 21 - Dezember - 2023

Weitere Informationen finden Sie unter:

https://www.bfarm.de/DE/Aktuelles/Statistiken/Arzneimittelzulassung/Besondere-Therapierichtungen/_artikel.html?nn=986770

Humanarzneimittel - Deutschland

ATC Downloads

Veröffentlicht am: 21 - Dezember - 2023

Weitere Informationen finden Sie unter:

https://www.bfarm.de/DE/Kodiersysteme/Klassifikationen/ATC/Downloads/_artikel.html?nn=986770

Liste der aktuell gültigen Monografien für Standardzulassungen – Humanarzneimittel: Stand 21.12.2023

Veröffentlicht am: 21 - Dezember - 2023

Weitere Informationen finden Sie unter:

https://www.bfarm.de/SharedDocs/Downloads/DE/Arzneimittel/Zulassung/ZulRelThemen/stdZul_und_Reg/aktuell_queltige_liste_standardzulassungen_stand_211223.html?nn=986770

Tagesordnungen und Ergebnisprotokolle

Veröffentlicht am: 22 - Dezember - 2023

Weitere Informationen finden Sie unter:

<https://www.bfarm.de/DE/Arzneimittel/Zulassung/Zulassungsrelevante-Themen/Abgrenzung/Gemeinsame-Expertenkommission-zur-Einstufung-von-Stoffen/Sitzungen/sitzungen.html?nn=986770>

Erstes Geneditierungsarzneimittel basierend auf der Genschere CRISPR/Cas erhält

Zulassungsempfehlung

Veröffentlicht am: 22 - Dezember - 2023

Weitere Informationen finden Sie unter:

<https://www.pei.de/DE/newsroom/hp-meldungen/2023/231222-zulassungsempfehlung-geneditierungsarzneimittel.html?nn=170852>

DiGA-Leitfaden (Stand: 28.12.2023, Version 3.5)

Veröffentlicht am: 28 - Dezember - 2023

Weitere Informationen finden Sie unter:

https://www.bfarm.de/SharedDocs/Downloads/DE/Medizinprodukte/diga_leitfaden.html?nn=986770

Formularserver / E-Belegverfahren

Veröffentlicht am: 01 - Januar - 2024

Weitere Informationen finden Sie unter:

https://www.bfarm.de/DE/Bundesopiumstelle/Betaeubungsmittel/Formularserver-und-E-Belegsverfahren/_artikel.html?nn=986770

Aktuell laufende und bestätigte Arzneimittel-Härtefallprogramme

Veröffentlicht am: 02 - Januar - 2024

Weitere Informationen finden Sie unter:

<https://www.bfarm.de/DE/Arzneimittel/Klinische-Pruefung/Compassionate-Use/compUsertabelle.html?nn=986770>

Humanarzneimittel - Deutschland

Arzneimittel-Festbeträge

Veröffentlicht am: 02 - Januar - 2024

Weitere Informationen finden Sie unter:

https://www.bfarm.de/DE/Arzneimittel/Arzneimittelinformationen/Festbetraege-und-Zuzahlungen/Festbetraege/_artikel.html?nn=986770

Pauschalangebote für die Datenbankrecherche

Veröffentlicht am: 02 - Januar - 2024

Weitere Informationen finden Sie unter:

https://www.bfarm.de/DE/Arzneimittel/Arzneimittelinformationen/Arzneimittel-recherchieren/Preise-und-Konditionen/_artikel.html?nn=986770

Sachstandstabelle (sortiert nach Wirkstoffen A-Z)

Veröffentlicht am: 03 - Januar - 2024

Weitere Informationen finden Sie unter:

<https://www.bfarm.de/DE/Arzneimittel/Zulassung/Zulassungsrelevante-Themen/Expertengruppe-Off-Label/sachstandstabelle.html?nn=986770>

Humanarzneimittel - Österreich

Gebührentarif 01.01.2024

Veröffentlicht am: 19 - Dezember - 2023

Weitere Informationen finden Sie unter:

https://www.basg.gv.at/fileadmin/redakteure/02_Ueber_Us/Geb%C3%BChrentarif/Geb%C3%BChrentarif_01.01.2024.pdf

Genehmigungsentwürfe

Veröffentlicht am: 19 - Dezember - 2023

Weitere Informationen finden Sie unter:

<https://www.basg.gv.at/ueber-uns/gebuehrentarif/genehmigungsentwuerfe>

CHMP Meeting Highlights Dezember 2023

Veröffentlicht am: 20 - Dezember - 2023

Weitere Informationen finden Sie unter:

<https://www.basg.gv.at/marktbeobachtung/amtliche-nachrichten/detail/chmp-meeting-highlights-dezember-2023>

Humanarzneimittel - Schweiz

Neues Arbeitsteilungsverfahren für prioritäre Gesuche im Rahmen des Access Consortiums

Veröffentlicht am: 13 - Dezember - 2023

Weitere Informationen finden Sie unter:

<https://www.swissmedic.ch/swissmedic/de/home/news/mitteilungen/neues-arbeitsteilungsverfahren-priotritaere-gesuche-access.html>

Regulierung der Desinfektionsmittel in der Schweiz

Veröffentlicht am: 14 - Dezember - 2023

Weitere Informationen finden Sie unter:

<https://www.swissmedic.ch/swissmedic/de/home/services/delimitation.html>

Gesuch für Covid-19-Impfstoff Nuvaxovid gegen Omikron-Variante XBB.1.5 zurückgezogen

Veröffentlicht am: 18 - Dezember - 2023

Weitere Informationen finden Sie unter:

<https://www.swissmedic.ch/swissmedic/de/home/news/coronavirus-covid-19/gesuch-impfstoff-nuvaxovid-omikron-variante-xbb-1-5-zurueckgezogen.html>

In Gesundheitseinrichtungen hergestellte und verwendete Produkte

Veröffentlicht am: 18 - Dezember - 2023

Weitere Informationen finden Sie unter:

<https://www.swissmedic.ch/swissmedic/de/home/medizinprodukte/regulierung-medizinprodukte/faq.html>

Identifikation von Arzneimitteln (IDMP)

Veröffentlicht am: 21 - Dezember - 2023

Weitere Informationen finden Sie unter:

<https://www.swissmedic.ch/swissmedic/de/home/services/submissions/idmp.html>

Swissmedic lässt Beyfortus zur RSV-Prophylaxe für Neugeborene, Säuglinge und Kleinkinder zu

Veröffentlicht am: 28 - Dezember - 2023

Weitere Informationen finden Sie unter:

<https://www.swissmedic.ch/swissmedic/de/home/news/mitteilungen/zulassung-beyfortus-zur-rsv-prophylaxe.html>

Nachtrag 11.3 der Europäischen Pharmakopöe in Kraft

Veröffentlicht am: 01 - Januar - 2024

Weitere Informationen finden Sie unter:

<https://www.swissmedic.ch/swissmedic/de/home/legal/pharmacopoea/wichtige-informationen/nachtrag-11-3-der-eu-pharmakopoe-in-kraft.html>

Neue Organisationsstruktur mit eigenem Bereich Überwachung Medizinprodukte – Eveline Trachsel wird Leiterin des Bereichs Zulassung und Vigilance Arzneimittel

Veröffentlicht am: 03 - Januar - 2024

Weitere Informationen finden Sie unter:

<https://www.swissmedic.ch/swissmedic/de/home/news/mitteilungen/neue-organisationsstruktur-mit-bereich-ueberwachung-mep.html>

Humanarzneimittel - Schweiz

Aktualisierte Vorgabedokumente

Veröffentlicht am: Dezember - 2023

Weitere Informationen finden Sie unter:

https://www.swissmedic.ch/swissmedic/de/home/news/updates/updated_documents/dez-2023.html

Aktualisierte Vorgabedokumente

Veröffentlicht am: Januar - 2024

Weitere Informationen finden Sie unter:

https://www.swissmedic.ch/swissmedic/de/home/news/updates/updated_documents/jan-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@mogra.org zur anonymen Publikation im nächsten Newsletter.*

*Bei der Beantwortung der Fragen handelt es sich um eine Zusammenfassung von persönlichen Meinungen und Erfahrungswerten der MEGRA Mitglieder mit keinem Anspruch auf Rechtssicherheit. Wir empfehlen zur Absicherung die Konsultation entsprechender zugrunde liegender Regularien.

Veranstaltungen / Events - Behörden und andere Veranstalter

Deutschland

Gemeinsame Ringvorlesung Wintersemester 2024

Ort: online

Termin: Januar - 2023

Weitere Informationen finden Sie unter:

https://www.bfarm.de/DE/Aktuelles/Veranstaltungen/Ringvorlesung/Termine/Ringvorlesung_2023-24.html?nn=936358

Update aus dem Zentrum für Seltene Erkrankungen Erlangen

Ort: Zentrum für Seltene Erkrankungen am Universitätsklinikum Erlangen, Erlangen

Termin: 17 - Januar - 2024

Weitere Informationen finden Sie unter:

<https://www.zseer.uk-erlangen.de/aktuelles/veranstaltungen/veranstaltungen/update-aus-dem-zseer-7896/>

Tag der Seltenen Erkrankungen am UKE: Der Weg zur Diagnose - Herausforderung bei Seltenen Erkrankungen

Ort: Universitätsklinikum Hamburg-Eppendorf, Hamburg

Termin: 28 - Februar - 2024

Weitere Informationen finden Sie unter:

https://www.uke.de/allgemein/veranstaltungen/veranstaltung_142208.html

Tag der Seltenen Erkrankungen am ZSE Düsseldorf: Wenn das Blut verrückt spielt

Ort: Universitätsklinikum Düsseldorf, Düsseldorf

Termin: 29 - Februar - 2024

Weitere Informationen finden Sie unter:

<https://www.uniklinik-duesseldorf.de/patienten-besucher/klinikeninstitutezentren/zentrum-fuer-seltene-erkrankungen/aktuelle-termine>

Österreich

BASG-Gespräch: Klinische Prüfung von Arzneimitteln 2024

Ort: Online

Termin: 24 - Januar - 2024

Weitere Informationen finden Sie unter:

<https://www.ages.at/ages/veranstaltungen/veranstaltungskalender/detail/basg-gespraech-klinische-pruefung-von-arezneimitteln-2024>

Veranstaltungen / Events - Behörden und andere Veranstalter

AGES-Seminar „Einführung in Geographische Informationssysteme (GIS)

Ort: AGES Wien 20

Termin: 11 - April - 2024

Weitere Informationen finden Sie unter:

<https://www.ages.at/ages/veranstaltungen/veranstaltungskalender/detail/ages-seminar-einfuehrung-in-geographische-informationssysteme-gis>

Schweiz

Keine Veranstaltungen veröffentlicht

Europa

Webinar on new general chapter Comparability of alternative analytical procedures (5.27)

Where: online

Date: 17 - January - 2024

For more information, please refer to:

<https://www.edqm.eu/en/webinar-on-new-general-chapter-comparability-of-alternative-analytical-procedures-5.27->

Clinical Trials Information System (CTIS): Walk-in clinic - January 2024

Where: Online and EMA, Amsterdam, the Netherlands

Date: 24 - January - 2024

For more information, please refer to:

<https://www.ema.europa.eu/en/events/clinical-trials-information-system-ctis-walk-clinic-january-2024>

ACT EU Clinical Trials Analytics Workshop - January 2024

Where: EMA, Amsterdam, the Netherlands

Date: 25 to 26 - January - 2024

For more information, please refer to:

<https://www.ema.europa.eu/en/events/act-eu-clinical-trials-analytics-workshop-january-2024>

Multi-stakeholder workshop on the guideline on clinical investigation of medicinal products in the treatment of epileptic disorders

Where: online

Date: 29 - January - 2024

For more information, please refer to:

<https://www.ema.europa.eu/en/events/multi-stakeholder-workshop-guideline-clinical-investigation-medicinal-products-treatment-epileptic>

Veranstaltungen / Events – Behörden und andere Veranstalter

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: 29 - January to 02 - February - 2024 , 04 to 08 - March - 2024

For more information, please refer to:

[https://www.ema.europa.eu/en/events/mandatory-use-iso-ich-e2b\(r3\)-individual-case-safety-reporting-eu-hands-training-course-using-eudravigilance-system-36](https://www.ema.europa.eu/en/events/mandatory-use-iso-ich-e2b(r3)-individual-case-safety-reporting-eu-hands-training-course-using-eudravigilance-system-36)

[https://www.ema.europa.eu/en/events/mandatory-use-iso-ich-e2b\(r3\)-individual-case-safety-reporting-eu-hands-training-course-using-eudravigilance-system-37](https://www.ema.europa.eu/en/events/mandatory-use-iso-ich-e2b(r3)-individual-case-safety-reporting-eu-hands-training-course-using-eudravigilance-system-37)

2024 EDQM virtual training programme: Independent modules on European Pharmacopoeia texts related to Biologicals and on Microbiology chapters

Where: online

Date: 30 - January to 01 - February - 2024

For more information, please refer to:

<https://www.edqm.eu/en/2024-edqm-virtual-training-programme-independent-modules-on-biologicals-in-the-european-pharmacopoeia>

Multistakeholder workshop on Patient Registries

Where: EMA, Amsterdam, the Netherlands

Date: 12 to 14 - February - 2024

For more information, please refer to:

<https://www.ema.europa.eu/en/events/multistakeholder-workshop-patient-registries>

Virtual live hands-on training course for clinical trials sponsors using EudraVigilance system

Where: online

Date: 26 to 28 - February - 2024

For more information, please refer to:

<https://www.ema.europa.eu/en/events/virtual-live-hands-training-course-clinical-trials-sponsors-using-eudravigilance-system-8>

Clinical Trials Information System (CTIS): Walk-in clinic - March 2024

Where: Online and EMA, Amsterdam, the Netherlands

Date: 12 - March - 2024

For more information, please refer to:

<https://www.ema.europa.eu/en/events/clinical-trials-information-system-ctis-walk-clinic-march-2024>

EMA multi-stakeholder workshop on psychedelics – Towards an EU regulatory framework

Where: online and EMA, Amsterdam, the Netherlands

Date: 16 to 17 - April - 2024

For more information, please refer to:

<https://www.ema.europa.eu/en/events/ema-multi-stakeholder-workshop-psychedelics-towards-eu-regulatory-framework>