

21. März -
04. April 2025



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Allgemeines – General

Data in regulation: Big data and other sources (updated)

Published on: 28 - March - 2025

For more information, please refer to:

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

Pharmakovigilanz – PRAC

PhV non-compliance notification contact points at National Competent Authority (NCA) level

Published on: 24 - March - 2025

For more information, please refer to:

https://www.ema.europa.eu/en/documents/other/phv-non-compliance-notification-contact-points-national-competent-authority-nca-level_en.xls

Periodic safety update reports (PSURs)

Published on: 25 - March - 2025

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>

Post-authorisation safety studies (PASS)

Published on: 25 - March - 2025

For more information, please refer to:

<https://www.ema.europa.eu/en/human-regulatory-overview/post-authorisation/pharmacovigilance-post-authorisation/post-authorisation-safety-studies-pass>

List of medicines under additional monitoring (updated)

Published on: 26 - March - 2025

For more information, please refer to:

<https://www.ema.europa.eu/en/human-regulatory-overview/post-authorisation/pharmacovigilance-post-authorisation/medicines-under-additional-monitoring/list-medicines-under-additional-monitoring>

MedDRA important medical event terms list - version 28.0

Published on: 26 - March - 2025

For more information, please refer to:

https://www.ema.europa.eu/en/documents/other/meddra-important-medical-event-terms-list-version-28-0_en.xlsx

New product information wording – Extracts from PRAC recommendations on signals adopted at the 28-31 October 2024 PRAC

Published on: 28 - March - 2025

For more information, please refer to:

https://www.ema.europa.eu/en/documents/prac-recommendation/new-product-information-wording-extracts-prac-recommendations-signals-adopted-28-31-october-2024-prac_en.pdf

Humanarzneimittel - EMA

Referral: Mysimba – updated

Published on: 28 - March - 2025

For more information, please refer to:

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

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

Published on: 02 - April - 2025

For more information, please refer to:

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

Zulassung – Regulatory Affairs

Q&A clinic on web-based electronic Application Form (eAF) functionalities for CAPs and non-CAPs variations, Event 06 & 13 March 2025

Video recording available

Published on: 21 & 24 - March - 2025

For more information, please refer to:

<https://www.ema.europa.eu/en/events/qa-clinic-web-based-electronic-application-form-eaf-functionalities-caps-non-caps-variations-0>

<https://www.ema.europa.eu/en/events/qa-clinic-web-based-electronic-application-form-eaf-functionalities-caps-non-caps-variations>

Guidance on the application of the amended Variations Regulation from 1 January 2025 (updated)

Published on: 25 - March - 2025

For more information, please refer to:

<https://www.ema.europa.eu/en/guidance-application-amended-variations-regulation-1-january-2025>

Extensions of marketing authorisations: questions and answers (updated)

Published on: 25 - March - 2025

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>

Type-IB variations: questions and answers (updated)

Published on: 25 - March - 2025

For more information, please refer to:

<https://www.ema.europa.eu/en/human-regulatory-overview/post-authorisation/variations-including-extensions-marketing-authorisations/type-ib-variations-questions-answers>

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Type-II variations: questions and answers (updated)

Published on: 25 - March - 2025

For more information, please refer to:

<https://www.ema.europa.eu/en/human-regulatory-overview/post-authorisation/variations-including-extensions-marketing-authorisations/type-ii-variations-questions-answers>

Worksharing: questions and answers (updated)

Published on: 25 - March - 2025

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: 25 - March - 2025

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>

Notifying a change of marketing status (updated)

Published on: 25 - March - 2025

For more information, please refer to:

<https://www.ema.europa.eu/en/human-regulatory-overview/post-authorisation/notifying-change-marketing-status>

European Medicines Agency procedural advice on recommendations on unforeseen variations according to Article 5 of Commission Regulation (EC) No 1234/2008 (updated)

Published on: 25 - March - 2025

For more information, please refer to:

https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/european-medicines-agency-procedural-advice-recommendations-unforeseen-variations-according-article-5-commission-regulation-ec-no-1234-2008_en.pdf

Product Management Service (PMS) roadmap (updated)

Published on: 26 - March - 2025

For more information, please refer to:

https://www.ema.europa.eu/en/documents/other/product-management-service-pms-roadmap_en.pdf

European Shortages Monitoring Platform (ESMP) (updated)

Published on: 27 - March - 2025

For more information, please refer to:

<https://www.ema.europa.eu/en/human-regulatory-overview/post-authorisation/medicine-shortages-availability-issues/european-shortages-monitoring-platform-esmp>

Humanarzneimittel - EMA

Product Management Service (PMS) webinar : Unlocking Integration – MAH & Software Developers to explore PMS API Machine-to-Machine Connection, Event 14 March 2025
Presentation and Video recording available

Published on: 27 - March - 2025

For more information, please refer to:

<https://www.ema.europa.eu/en/events/product-management-service-pms-webinar-unlocking-integration-mah-software-developers-explore-pms-api-machine-machine-connection>

European Shortages Monitoring Platform (ESMP) workshop on application programming interface (API) for marketing authorisation holders (MAHs), Event 24 March 2025

Presentation available

Published on: 28 - March - 2025

For more information, please refer to:

<https://www.ema.europa.eu/en/events/european-shortages-monitoring-platform-esmp-workshop-application-programming-interface-api-marketing-authorisation-holders-mahs>

Quarterly System Demo - Q1 2025, Event 26 March 2025

Presentation and Video recording available

Published on: 28 - March - 2025

For more information, please refer to:

<https://www.ema.europa.eu/en/events/quarterly-system-demo-q1-2025>

Meeting highlights from the Committee for Medicinal Products for Human Use (CHMP) 24-27 March 2025

Published on: 28 - March - 2025

For more information, please refer to:

<https://www.ema.europa.eu/en/news/meeting-highlights-committee-medicinal-products-human-use-chmp-24-27-march-2025>

List of centrally authorised products with safety-related changes to the product information (updated)

Published on: 31 - March - 2025

For more information, please refer to:

https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/list-centrally-authorized-products-safety-related-changes-product-information_en.xlsx

Electronic product information (ePI) (updated)

Published on: 31 - March - 2025

For more information, please refer to:

<https://www.ema.europa.eu/en/human-regulatory-overview/marketing-authorisation/product-information-requirements/electronic-product-information-epi>

Scientific guideline: Scientific data requirements for plasma master file (updated)

Published on: 31 - March - 2025

For more information, please refer to:

<https://www.ema.europa.eu/en/scientific-data-requirements-plasma-master-file-scientific-guideline>

Humanarzneimittel - EMA

Start of procedure: Type II variation - extension of indication under evaluation by the CHMP (28 February 2025 - 27 March 2025)

Published on: 01 - April - 2025

For more information, please refer to:

https://www.ema.europa.eu/en/documents/report/start-procedure-type-ii-variation-extension-indication-under-evaluation-chmp-28-february-2025-27-march-2025_en.xlsx

Start of procedure: Extension of marketing authorisation (28 February 2025 - 27 March 2025)

Published on: 01 - April - 2025

For more information, please refer to:

https://www.ema.europa.eu/en/documents/report/start-procedure-extension-marketing-authorisation-28-february-2025-27-march-2025_en.xlsx

SPOR and xEVMPD Stakeholder Engagement Webinars : Organisation Management Service (OMS), Event 09 October 2024 (updated)

Presentation and Video recording available

Published on: 01 - April - 2025

For more information, please refer to:

<https://www.ema.europa.eu/en/events/spor-xevmpd-stakeholder-engagement-webinars-organisation-management-service-oms>

SPOR and xEVMPD Stakeholder Engagement Webinars : SPOR Data Governance, Event 04 October 2024 (updated)

Presentation and Video recording available

Published on: 01 - April - 2025

For more information, please refer to:

<https://www.ema.europa.eu/en/events/spor-xevmpd-stakeholder-engagement-webinars-spor-data-governance>

SPOR and xEVMPD Stakeholder Engagement Webinars : Substance Management Service (SMS), Event 08 October 2024 (updated)

Presentation and Video recording available

Published on: 01 - April - 2025

For more information, please refer to:

<https://www.ema.europa.eu/en/events/spor-xevmpd-stakeholder-engagement-webinars-substance-management-service-sms>

SPOR and xEVMPD Stakeholder Engagement Webinars : Product Management Service (XEVMPD) for Sponsors, Event 11 October 2024 (updated)

Presentation and Video recording available

Published on: 01 - April - 2025

For more information, please refer to:

<https://www.ema.europa.eu/en/events/spor-xevmpd-stakeholder-engagement-webinars-product-management-service-xevmpd-sponsors>

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SPOR and xEVMPD Stakeholder Engagement Webinars : Product Management Service (XEVMPS) for MAH, Event 10 October 2024 (updated)

Presentation and Video recording available

Published on: 01 - April - 2025

For more information, please refer to:

<https://www.ema.europa.eu/en/events/spor-xevmpd-stakeholder-engagement-webinars-product-management-service-xevmpd-mah>

SPOR and xEVMPD Stakeholder Engagement Webinars : Referentials Management Service (RMS), Event 07 October 2024 (updated)

Presentation and Video recording available

Published on: 01 - April - 2025

For more information, please refer to:

<https://www.ema.europa.eu/en/events/spor-xevmpd-stakeholder-engagement-webinars-referentials-management-service-rms>

SPOR and xEVMPD Stakeholder Engagement Webinars : Substance, product, organisation and referential (SPOR) application programming interface (API) - SPOR API, Event 14 October 2024 (updated)

Presentation and Video recording available

Published on: 01 - April - 2025

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>

IRIS guide to registration and RPIs (update)

Published on: 01 - April - 2025

For more information, please refer to:

https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/iris-guide-registration-rpis_en.pdf

Plasma master file certificates (update)

Published on: 01 - April - 2025

For more information, please refer to:

<https://www.ema.europa.eu/en/human-regulatory-overview/plasma-master-file-pmf-certification/plasma-master-file-certificates>

Real-world evidence (update)

Published on: 03 - April - 2025

For more information, please refer to:

<https://www.ema.europa.eu/en/about-us/how-we-work/data-regulation-big-data-other-sources/real-world-evidence>

Orphan Drugs und neuartige Therapierichtungen (ATMP)

CAT meeting minutes (updated)

Published on: 24 - March - 2025

For more information, please refer to:

<https://www.ema.europa.eu/en/committees/committee-advanced-therapies-cat>

Qualität – Quality

Good Manufacturing Practice (GMP) / Distribution Practice Practice (GDP) Inspectors Working Group (updated)

Published on: 27 - March - 2025

For more information, please refer to:

<https://www.ema.europa.eu/en/human-regulatory-overview/research-development/compliance-research-development/good-manufacturing-practice/good-manufacturing-practice-gmp-distribution-practice-practice-gdp-inspectors-working-group>

Scientific guideline: Development of a guideline on the quality aspects of mRNA vaccines (updated)

Published on: 31 - March - 2025

For more information, please refer to:

<https://www.ema.europa.eu/en/development-guideline-quality-aspects-mrna-vaccines-scientific-guideline>

(Prä-) Klinische Forschung – Research and Development

Pre-authorisation guidance (updated)

Published on: 25 - March - 2025

For more information, please refer to:

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

CTIS newsflash - 25 March 2025

Published on: 25 - March - 2025

For more information, please refer to:

https://www.ema.europa.eu/en/documents/newsletter/ctis-newsflash-25-march-2025_en.pdf

Streamlining development and assessment of biosimilar medicines

Published on: 01 - April - 2025

For more information, please refer to:

<https://www.ema.europa.eu/en/news/streamlining-development-assessment-biosimilar-medicines>

Biosimilar medicines: Overview

Published on: 02 - April - 2025

For more information, please refer to:

<https://www.ema.europa.eu/en/human-regulatory-overview/biosimilar-medicines-overview>

Humanarzneimittel - EMA

Tolvaptan product-specific bioequivalence guidance

Published on: 02 - April - 2025

For more information, please refer to:

<https://www.ema.europa.eu/en/tolvaptan-product-specific-bioequivalence-guidance>

Clinical Trial Information System (CTIS) structured data form - Initial application, additional Member State Concerned, substantial modification, non-substantial modification (updated)

Published on: 01 - April - 2025

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

Clinical Trials Information System designated as WHO primary registry

Published on: 03 - April - 2025

For more information, please refer to:

<https://www.ema.europa.eu/en/news/clinical-trials-information-system-designated-who-primary-registry>

European Medicines Agency guidance for applicants seeking scientific advice and protocol assistance with track-changes

Published on: 04 - April - 2025

For more information, please refer to:

https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/european-medicines-agency-guidance-applicants-seeking-scientific-advice-protocol-assistance-track-changes_en.docx

Kinderarzneimittel – Paediatrics

Paediatric investigation plans: questions and answers

Published on: 24 - March - 2025

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>

Pflanzliche Arzneimittel – Herbal medicines

HMPC: overview of assessment work - priority list

Published on: 28 - March - 2025

For more information, please refer to:

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

Humanarzneimittel - EMA

Procedures for monograph and list entry establishment - 'Current and recent calls for scientific data' section updated

Published on: 01 - April - 2025

For more information, please refer to:

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

Herbal medicinal product: *Althaeae radix*, F: Assessment finalised (updated)

Published on: 01 - April - 2025

For more information, please refer to:

<https://www.ema.europa.eu/en/medicines/herbal/althaeae-radix>

Herbal medicinal product: *Carvi aetheroleum*, F: Assessment finalised (updated)

Published on: 01 - April - 2025

For more information, please refer to:

<https://www.ema.europa.eu/en/medicines/herbal/carvi-aetheroleum>

Herbal medicinal product: *Carvi fructus*, F: Assessment finalised (updated)

Published on: 01 - April - 2025

For more information, please refer to:

<https://www.ema.europa.eu/en/medicines/herbal/carvi-fructus>

Herbal medicinal product: Combination: *Valerianae radix and Lupuli flos*, F: Assessment finalised (updated)

Published on: 01 - April - 2025

For more information, please refer to:

<https://www.ema.europa.eu/en/medicines/herbal/valerianae-radix-lupuli-flos>

Herbal medicinal product: *Hamamelidis folium et cortex aut ramunculus destillatum*, F: Assessment finalised (updated)

Published on: 01 - April - 2025

For more information, please refer to:

<https://www.ema.europa.eu/en/medicines/herbal/hamamelidis-folium-et-cortex-aut-ramunculus-destillatum>

Herbal medicinal product: *Equiseti herba*, F: Assessment finalised (updated)

Published on: 01 - April - 2025

For more information, please refer to:

<https://www.ema.europa.eu/en/medicines/herbal/equiseti-herba>

Herbal medicinal product: *Hamamelidis folium*, F: Assessment finalised (updated)

Published on: 01 - April - 2025

For more information, please refer to:

<https://www.ema.europa.eu/en/medicines/herbal/hamamelidis-folium>

Herbal medicinal product: *Hamamelidis cortex*, F: Assessment finalised (updated)

Published on: 01 - April - 2025

For more information, please refer to:

<https://www.ema.europa.eu/en/medicines/herbal/hamamelidis-cortex>

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Herbal medicinal product: Harpagophyti radix, F: Assessment finalised (updated)

Published on: 01 - April - 2025

For more information, please refer to:

<https://www.ema.europa.eu/en/medicines/herbal/harpaqophyti-radix>

Herbal medicinal product: Psyllii semen, F: Assessment finalised (updated)

Published on: 01 - April - 2025

For more information, please refer to:

<https://www.ema.europa.eu/en/medicines/herbal/psyllii-semen>

Herbal medicinal product: Salicis cortex, F: Assessment finalised (updated)

Published on: 01 - April - 2025

For more information, please refer to:

<https://www.ema.europa.eu/en/medicines/herbal/salicis-cortex>

Update - MedEthicsEU report - Survey on National Part II Clinical Trial Application (CTA) requirements (March 2025)

Published on: 28 - March - 2025

For more information, please refer to:

https://health.ec.europa.eu/latest-updates/update-medethicseu-report-survey-national-part-ii-clinical-trial-application-cta-requirements-march-2025-03-28_en

EDQM On Air – The evolution of biologicals in the European Pharmacopoeia

Published on: 25 - March - 2025

For more information, please refer to:

<https://www.edqm.eu/en/-/edqm-on-air-the-evolution-of-biologicals-in-the-european-pharmacopoeia>

Modernising excipient monographs: revised identification techniques and new CRSs

Published on: 26 - March - 2025

For more information, please refer to:

<https://www.edqm.eu/en/-/modernising-excipient-monographs-revised-identification-techniques-and-new-crss>

Pharmeuropa 37.2 just released

Published on: 01 - April - 2025

For more information, please refer to:

<https://www.edqm.eu/en/-/pharmeuropa-37.2-just-released>

CEP holders invited to comment on draft monographs published in Pharmeuropa 37.2

Published on: 01 - April - 2025

For more information, please refer to:

<https://www.edqm.eu/en/-/cep-holders-invited-to-comment-on-draft-monographs-published-in-pharmeuropa-37.2>

EDQM reference standards monthly newsletter – March 2025

Published on: 04 - April - 2025

For more information, please refer to:

<https://www.edqm.eu/en/-/edqm-reference-standards-monthly-newsletter-march-2025>

Medizinprodukte

Medical devices (updated)

Published on: 24 - March - 2025

For more information, please refer to:

<https://www.ema.europa.eu/en/human-regulatory-overview/medical-devices>

EMA establishes regular procedure for scientific advice on certain high-risk medical devices (updated)

Published on: 24 - March - 2025

For more information, please refer to:

<https://www.ema.europa.eu/en/news/ema-establishes-regular-procedure-scientific-advice-certain-high-risk-medical-devices>

Template - Request for advice on the clinical development strategy or clinical data required for the clinical evaluation pursuant to Article 61(2) or Article 106(11) of Regulation (EU) 2017/745 and MDCG 2024-10 on from the Expert Panels (updated)

Published on: 01 - April - 2025

For more information, please refer to:

https://www.ema.europa.eu/en/documents/template-form/template-request-advice-clinical-development-strategy-or-clinical-data-required-clinical-evaluation-pursuant-article-612-or-article-10611-regulation-eu-2017-745-mdcq-2024-10-expert-panels_en.pdf

Template - Request for advice on the orphan device status pursuant to Article 61(2) of Regulation (EU) 2017/745 and MDCG 2024-10 (updated)

Published on: 01 - April - 2025

For more information, please refer to:

https://www.ema.europa.eu/en/documents/template-form/template-request-advice-orphan-device-status-pursuant-article-612-regulation-eu-2017-745-mdcq-2024-10_en.pdf

EU4Health call for tenders to develop point-of-care diagnostic medical devices for antimicrobial susceptibility testing

Published on: 25 - March - 2025

For more information, please refer to:

https://hadea.ec.europa.eu/news/eu4health-call-tenders-develop-point-care-diagnostic-medical-devices-antimicrobial-susceptibility-2025-03-24_en

QP declaration [Track version] (February 2025)

Published on: 21 - March - 2025

For more information, please refer to:

<https://www.hma.eu/human-medicines/cmdh/questions-answers.html#c5222>

Further guidance on eSubmissions can be found on the EMA website under eSubmission

Published on: 28 - March - 2025

For more information, please refer to:

<https://www.hma.eu/human-medicines/cmdh/procedural-guidance/esubmissions.html#c7631>

List of active substances and agreed SmPC wordings - EU work sharing procedure in the assessment of paediatric data

Published on: 01 - April - 2025

For more information, please refer to:

<https://www.hma.eu/human-medicines/cmdh/paediatric-regulation/article-45-and-previous-worksharing.html#c2202>

CMDH PRESS RELEASES 2025

Published on: 02 - April - 2025

For more information, please refer to:

<https://www.hma.eu/human-medicines/cmdh/press-releases.html#c7615>

Best Practice Guides (BPGs) for the Submission and Processing of Variations in the Mutual Recognition Procedure

Published on: 02 - April - 2025

For more information, please refer to:

<https://www.hma.eu/human-medicines/cmdh/procedural-guidance/variation.html#c2126>

Humanarzneimittel - Deutschland

Liste der Mitglieder der Gemeinsamen Expertenkommission

Veröffentlicht am: 24 - März - 2025

Weitere Informationen finden Sie unter:

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

Leitfaden zum Antrag auf Erteilung einer Erlaubnis nach § 4 Medizinal-Cannabisgesetz (MedCanG) zum Anbau von Cannabis zu medizinisch-wissenschaftlichen Zwecken

Veröffentlicht am: 25 - März - 2025

Weitere Informationen finden Sie unter:

https://www.bfarm.de/SharedDocs/Downloads/DE/Bundesopiumstelle/Cannabis/Leitfaden_Antrag_Anbau_med_wiss_Cannabis.html?nn=986770

Aktuell laufende und bestätigte Arzneimittel-Härtefallprogramme

Veröffentlicht am: 01 - April - 2025

Weitere Informationen finden Sie unter:

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

Fachausschüsse der Deutschen Arzneibuch-Kommission

Veröffentlicht am: 01 - April - 2025

Weitere Informationen finden Sie unter:

https://www.bfarm.de/DE/Arzneimittel/Zulassung/Zulassungsrelevante-Themen/Arzneibuch/Arzneibuchkommissionen/Deutsche-Arzneibuch-Kommission/fachausschuss_DAB-Kom-inhalt.html?nn=986770

Veröffentlichung gemäß § 34 Abs. 1b S. 2 AMG - offene ordnungsgemäß eingegangene Zulassungsanträge

Veröffentlicht am: 01 - April - 2025

Weitere Informationen finden Sie unter:

<https://www.bfarm.de/SharedDocs/Downloads/DE/Service/Statistik/AM-Statistik/OpenData/offene-ordnungsgemaess-eingegangene-zulantraege.html?nn=986770>

Arzneimittel-Lieferengpass-bekämpfungsgesetz und Versorgungverbesserungsgesetz (ALBVVG)

Veröffentlicht am: 01 - April - 2025

Weitere Informationen finden Sie unter:

<https://www.bfarm.de/DE/Arzneimittel/Arzneimittelinformationen/Lieferengpaesse/ALBVVG/artikel.html?nn=986770>

Offene ordnungsgemäß eingegangene Anträge auf Zulassung und Registrierung für Arzneimittel im Zuständigkeitsbereich des BfArM

Veröffentlicht am: 01 - April - 2025

Weitere Informationen finden Sie unter:

<https://www.bfarm.de/DE/Aktuelles/Statistiken/Arzneimittelzulassung/offene-Zulassungsantraege/artikel.html?nn=986770>

Humanarzneimittel - Deutschland

Maßnahmen des BfArM und ergänzende Informationen zu Lieferengpässen

Veröffentlicht am: 01 - April - 2025

Weitere Informationen finden Sie unter:

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

Organigramm des BfArM

Veröffentlicht am: 01 - April - 2025

Weitere Informationen finden Sie unter:

https://www.bfarm.de/SharedDocs/Downloads/DE/BfArM/Orq/bfarm_organigramm.html?nn=986770

Änderung / Variations (Aerosolzerstäuber)

Veröffentlicht am: 01 - April - 2025

Weitere Informationen finden Sie unter:

https://www.bfarm.de/DE/Arzneimittel/Zulassung/Folgeverfahren/Aenderungen_Variations/artikel.html?nn=986770

PSUR Single Assessment (PSUSA)

Veröffentlicht am: 03 - April - 2025

Weitere Informationen finden Sie unter:

https://www.bfarm.de/DE/Arzneimittel/Pharmakovigilanz/Periodic-Safety-Update-Reports_PSURs/PSUR-Single-Assessment/artikel.html?nn=986770

Abkürzungsverzeichnis der Darreichungsformen

Veröffentlicht am: 03 - April - 2025

Weitere Informationen finden Sie unter:

https://www.bfarm.de/SharedDocs/Downloads/DE/Arzneimittel/Zulassung/amInformationen/Festbetraege/2025/berechnungsgrundlage/quarter2/darreichungsformen-20250401_xls.html?nn=986770

Abkürzungsverzeichnis der Wirkstoffkürzel

Veröffentlicht am: 03 - April - 2025

Weitere Informationen finden Sie unter:

https://www.bfarm.de/SharedDocs/Downloads/DE/Arzneimittel/Zulassung/amInformationen/Festbetraege/2025/berechnungsgrundlage/quarter2/wirkstoffkuerzel-20250401_xls.html?nn=986770

Statistik "Besondere Therapierichtungen und Traditionelle Arzneimittel"

Veröffentlicht am: 04 - April - 2025

Weitere Informationen finden Sie unter:

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

Humanarzneimittel - Österreich

Fach- und Gebrauchsinformation

Veröffentlicht am: 25 - März - 2025

Weitere Informationen finden Sie unter:

<https://www.basq.gv.at/fuer-unternehmen/zulassung-life-cycle/faq-zulassung-life-cycle/fach-und-gebrauchsinformation>

Leitfaden: AT-Leitfaden Direct Healthcare Professional Communication (DHPC)/Educational Material (EM) (L_Z100)

Veröffentlicht am: 27 - März - 2025

Weitere Informationen finden Sie unter:

https://www.basq.gv.at/fileadmin/redakteure/01_Formulare_Listen/Z/L_Z100_Leitfaden_DHPC_EM.pdf

Leitfaden Pharmakovigilanz

Veröffentlicht am: 27 - März - 2025

Weitere Informationen finden Sie unter:

<https://www.basq.gv.at/fuer-unternehmen/pharmakovigilanz/leitfaeden>

AGES eValidator

Veröffentlicht am: 28 - März - 2025

Weitere Informationen finden Sie unter:

<https://www.basq.gv.at/fuer-unternehmen/zulassung-life-cycle/ages-evalidator>

RMS NEWS

Veröffentlicht am: 31 - März - 2025

Weitere Informationen finden Sie unter:

<https://www.basq.gv.at/fuer-unternehmen/zulassung-life-cycle/oesterreich-als-rms/rms-news>

PSUR outcome: Masern-Mumps-Röteln-Impfstoffe (lebend, attenuiert)

Veröffentlicht am: 02 - April - 2025

Weitere Informationen finden Sie unter:

[Link zur Website der Europäischen Kommission](#)

Leitfaden zur Elektronischen Einreichverordnung EEVO (L_Z45)

Veröffentlicht am: 03 - April - 2025

Weitere Informationen finden Sie unter:

https://www.basq.gv.at/fileadmin/redakteure/01_Formulare_Listen/Z/L_Z45_Leitfaden_zur_Elektronischen_Einreichverordnung_EEVO.pdf

Bevorratung national

Veröffentlicht am: 04 - April - 2025

Weitere Informationen finden Sie unter:

<https://www.basq.gv.at/marktbeobachtung/meldewesen/bevorratung-national>

Humanarzneimittel - Schweiz

Zulassungen und Arzneimittelsicherheit Tierarzneimittel 2024

Veröffentlicht am: 26 - März - 2025

Weitere Informationen finden Sie unter:

<https://www.swissmedic.ch/swissmedic/de/home/tierarzneimittel/zulassungen-tam/nce/jahresuebersichten.html>

Gefälschte Arzneimittel in der Lieferkette: Swissmedic intensiviert Kontrollen beim internationalen Handel mit Lieferanten aus nicht-EU-Ländern

Veröffentlicht am: 27 - März - 2025

Weitere Informationen finden Sie unter:

<https://www.swissmedic.ch/swissmedic/de/home/humanarzneimittel/marktueberwachung/arzneimittel-aus-dem-internet/drug-safety-current-threats/gefaelschte-am-in-lieferkette.html>

Anpassung Wegleitung Beschleunigtes Zulassungsverfahren und Wegleitung Befristete Zulassung Humanarzneimittel

Veröffentlicht am: 01 - April - 2025

Weitere Informationen finden Sie unter:

<https://www.swissmedic.ch/swissmedic/de/home/humanarzneimittel/authorisations/informationen/anpassung-wl-beschleunigtes-zlverfahren-wl-befristete-zl-ham.html>

Roundtable eSubmissions

Veröffentlicht am: 01 - April - 2025

Weitere Informationen finden Sie unter:

https://www.swissmedic.ch/swissmedic/de/home/ueber-uns/nationale-zusammenarbeit/roundtable_ectd.html

Anpassung der Wegleitung Firmenmeetings für Zulassungsverfahren

Veröffentlicht am: 01 - April - 2025

Weitere Informationen finden Sie unter:

<https://www.swissmedic.ch/swissmedic/de/home/humanarzneimittel/authorisations/informationen/anpassung-wl-firmenmeetings-zl-verfahren.html>

Erweiterung des Swissmedic Positionspapiers zu Real World Evidence

Veröffentlicht am: 01 - April - 2025

Weitere Informationen finden Sie unter:

<https://www.swissmedic.ch/swissmedic/de/home/humanarzneimittel/authorisations/informationen/erweiterung-positionspapier-rwe.html>

Nachtrag 11.7 der Europäischen Pharmakopöe in Kraft

Veröffentlicht am: 01 - April - 2025

Weitere Informationen finden Sie unter:

<https://www.swissmedic.ch/swissmedic/de/home/legal/pharmacopoea/wichtige-informationen/nachtrag-11-7-europaeischen-pharmakopoe.html>

Swissmedic Journal

Veröffentlicht am: 03 - April - 2025

Weitere Informationen finden Sie unter:

<https://www.swissmedic.ch/swissmedic/de/home/ueber-uns/publikationen/swissmedic-journal.html>

Humanarzneimittel - Schweiz

Swissmedic wird Mitglied des Management Committee des IMDRF

Veröffentlicht am: 03 - April - 2025

Weitere Informationen finden Sie unter:

<https://www.swissmedic.ch/swissmedic/de/home/news/mitteilungen/smc-mitglied-management-committee-imdrf.html>

Aktualisierte Vorgabedokumente

Veröffentlicht am: 03 - April - 2025

Weitere Informationen finden Sie unter:

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



Fragen an das Netzwerk

Falls Sie eine Frage haben, die Sie gerne in unserem Netzwerk diskutieren würden, senden Sie uns einfach eine E-Mail an info-as@megra.org zur anonymen Publikation im nächsten Newsletter.*

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

Veranstaltungen / Events – Behörden und andere Veranstalter

Deutschland

DMEA 2025 - enabling digital health

Ort: Messegelände in Berlin

Termin: 08 bis 10 - April - 2025

Weitere Informationen finden Sie unter:

<https://www.bfarm.de/DE/Aktuelles/Veranstaltungen/DMEA/artikel.html?nn=986770>

Österreich

BASG-Gespräch: Digitalisierung im regulatorischen Umfeld – Status und Neuigkeiten

Ort: online via Zoom

Termin: 11 – Juni - 2025

Weitere Informationen finden Sie unter:

<https://www.ages.at/ages/veranstaltungen/veranstaltungskalender/detail/basg-gespraech-digitalisierung-im-regulatorischen-umfeld-status-und-neuigkeiten-1>

Schweiz

Keine Veranstaltungen veröffentlicht

Europa

SPOR and XEVMPD status update webinar

Where: Live broadcast

Date: 09 - April - 2025

For more information, please refer to:

<https://www.ema.europa.eu/en/events/spor-xevmpd-status-update-webinar>

Questions and answers clinic on Product Management Service (PMS) Product User Interface (PUI) and Application Programming Interface (API) - April 2025, May 2025 and June 2025

Where: online and European Medicines Agency, Amsterdam, the Netherlands

Date: 26 - April - 2025, 19 - May - 2025 and 17 - June - 2025

For more information, please refer to:

<https://www.ema.europa.eu/en/events/questions-answers-clinic-product-management-service-pms-product-user-interface-pui-application-programming-interface-api-april-2025>

<https://www.ema.europa.eu/en/events/questions-answers-clinic-product-management-service-pms-product-user-interface-pui-application-programming-interface-api-may-2025>

<https://www.ema.europa.eu/en/events/questions-answers-clinic-product-management-service-pms-product-user-interface-pui-application-programming-interface-api-june-2025>

Veranstaltungen / Events – Behörden und andere Veranstalter

EMA traineeship programme informative session

Where: online and European Medicines Agency, Amsterdam, the Netherlands

Date: 14 - April - 2025

For more information, please refer to:

<https://www.ema.europa.eu/en/events/ema-traineeship-programme-informative-session-0>

Second EMA / Alliance for Regenerative Medicine bilateral meeting

Where: online and European Medicines Agency, Amsterdam, the Netherlands

Date: 08 - May - 2025

For more information, please refer to:

<https://www.ema.europa.eu/en/events/second-ema-alliance-regenerative-medicine-bilateral-meeting>

EMA Open Door Day

Where: European Medicines Agency, Amsterdam, the Netherlands

Date: 09 - May - 2025

For more information, please refer to:

<https://www.ema.europa.eu/en/events/ema-open-door-day>

Clinical Trials Information System (CTIS): Walk-in clinic - May 2025

Where: online and European Medicines Agency, Amsterdam, the Netherlands

Date: 14 - May - 2025

For more information, please refer to:

<https://www.ema.europa.eu/en/events/clinical-trials-information-system-ctis-walk-clinic-may-2025>

Product Management Service (PMS) information day 2025

Where: online and European Medicines Agency, Amsterdam, the Netherlands

Date: 21 - May - 2025

For more information, please refer to:

<https://www.ema.europa.eu/en/events/product-management-service-pms-information-day-2025>

Clinical Trials Information System (CTIS): Information day

Where: online and European Medicines Agency, Amsterdam, the Netherlands

Date: 22 - May - 2025

For more information, please refer to:

<https://www.ema.europa.eu/en/events/clinical-trials-information-system-ctis-information-day-1>

CPhI China 2025

Where: Shanghai, China

Date: 24 to 26 - June - 2025

For more information, please refer to:

<https://www.edqm.eu/en/cphi-china-2025>

Veranstaltungen / Events – Behörden und andere Veranstalter

EMA's 30th anniversary scientific conference - Medicines, regulation and the future

Where: European Medicines Agency, Amsterdam, the Netherlands

Date: 25 - June - 2025

For more information, please refer to:

<https://www.ema.europa.eu/en/events/emas-30th-anniversary-scientific-conference-medicines-regulation-future>