14. - 28. August 2026

MEGRA

NEWSLETTER

# Humanarzneimittel - EMA

## Allgemeines – General

***Artificial intelligence***
***"'Related scientific publications' section updated to highlight the article on 'Regulatory Research Priorities for AI Use in the Medicine Lifecycle: A European Perspective with Global Relevance"***
***Published on:*** *14 - August - 2026*
***For more information, please refer to:***
*https://www.ema.europa.eu/en/about-us/how-we-work/data-regulation-big-data-other-sources/artificial-intelligence*

***How to pay***
***Published on:*** *28 - August - 2026*
***For more information, please refer to:***
*https://www.ema.europa.eu/en/documents/other/how-pay-fees-charges-levied-ema-guidance-marketing-authorisation-holders-applicants_en.pdf*

## Pharmakovigilanz – PRAC

***International Pharmaceutical Abstracts (IPA) journals***
***Published on:*** *19 - August - 2026*
***For more information, please refer to:***
*https://www.ema.europa.eu/en/documents/other/international-pharmaceutical-abstracts-ipa-journals_en.xlsx*

***List of European Union reference dates (EURD) and frequency of submission of periodic safety update reports (PSURs)***
***Published on:*** *26 - August - 2026*
***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

***Draft data standards framework***
***Published on:*** *17 - August - 2026*
***For more information, please refer to:***
*https://www.ema.europa.eu/en/documents/other/draft-data-standards-framework_en.pdf*

***Pre-authorisation guidance***
***Published on:*** *19 - August - 2026*
***For more information, please refer to:***
*https://www.ema.europa.eu/en/human-regulatory-overview/marketing-authorisation/pre-authorisation-guidance*

# Humanarzneimittel - EMA

***Product Management Service (PMS) Public API – Frequently Asked Questions (FAQs)***
***Published on:*** *19 - August - 2026*
***For more information, please refer to:***
*https://www.ema.europa.eu/en/documents/other/product-management-service-pms-public-api-frequently-asked-questions-faqs_en.pdf*

***Guidance and template for industry on implementing Shortage Prevention Plans (SPP)***
***Published on:*** *20 - August - 2026*
***For more information, please refer to:***
*https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/guidance-template-industry-implementing-shortage-prevention-plans-spp_en.pdf*

***Medicines for human use under evaluation***
***Published on:*** *26 - August - 2026*
***For more information, please refer to:***
*https://www.ema.europa.eu/en/medicines/medicines-human-use-under-evaluation*

***Electronic product information (ePI)***
***Published on:*** *28 - August - 2026*
***For more information, please refer to:***
*https://www.ema.europa.eu/en/human-regulatory-overview/marketing-authorisation/product-information-requirements/electronic-product-information-epi*

## Orphan Drugs und neuartige Therapierichtungen (ATMP)

***CAT meeting minutes; May and June 2026***
***Published on:*** *26 - August - 2026*
***For more information, please refer to:***
*https://www.ema.europa.eu/en/committees/committee-advanced-therapies-cat*

## Qualität – Quality

***No news published***

## (Prä-) Klinische Forschung – Research and Development

***No news published***

## Kinderarzneimittel – Paediatrics

***No news published***

# Humanarzneimittel - EMA

## Pflanzliche Arzneimittel – Herbal medicines

***No news published***

## Events and Video recording

***EMA multi-stakeholder workshop on supporting innovation in cardiovascular medicines and medical devices in the EU, Event 01 to 02 - July - 2026***
*Presentations and Video recordings available*
***Published on:*** *19 - August - 2026*
***For more information, please refer to:***
*https://www.ema.europa.eu/en/events/ema-multi-stakeholder-workshop-supporting-innovation-cardiovascular-medicines-medical-devices-eu*

# European Commission

***New eligibility tool and updated guidance for early information for joint clinical assessments***
***Published on:*** *19 - August - 2026*
***For more information, please refer to:***
*https://ec.europa.eu/newsroom/sante/newsletter-archives/78397*

# EDQM

***Update to the guidance for electronic submissions of CEP applications***
***Published on:*** *19 - August - 2026*
***For more information, please refer to:***
*https://www.edqm.eu/en/-/update-to-the-guidance-for-electronic-submissions-of-cep-applications*

***Revised guidance about the use of a CEP to describe a material used in an application for another CEP***
***Published on:*** *27 - August - 2026*
***For more information, please refer to:***
*https://www.edqm.eu/en/-/revised-guidance-about-the-use-of-a-cep-to-describe-a-material-used-in-an-application-for-another-cep*

***Revised Guidance on applications for sister files***
***Published on:*** *27 - August - 2026*
***For more information, please refer to:***
*https://www.edqm.eu/en/-/revised-guidance-on-applications-for-sister-files*

# Medizinprodukte

***List of clinical evaluation consultation procedure (CECP) opinions issued for medical devices awaiting finalisation of conformity assessment***
***Published on:*** *26 - August - 2026*
***For more information, please refer to:***
*https://www.ema.europa.eu/en/documents/other/list-clinical-evaluation-consultation-procedure-cecp-opinions-issued-medical-devices-awaiting-finalisation-conformity-assessment_en.pdf*

# CMDh

***EU-Innovation Network (EU-IN)***
***Published on:*** *17 - August - 2026*
***For more information, please refer to:***
*https://www.hma.eu/about-hma/working-groups/eu-innovation-network-eu-in.html#c5571*

***CTCG News and Events***
***Published on:*** *20 - August - 2026*
***For more information, please refer to:***
*https://www.hma.eu/about-hma/working-groups/clinical-trials-coordination-group/clinical-trials-coordination-group.html#c7039*

# Humanarzneimittel - Deutschland

***Veröffentlichung auf dem Zentralen Terminologieserver: Klinische Dokumentenklassen-Liste (KDL) im FHIR-Format für den Datenaustausch im Kontext der elektronischen Patientenakte***
***Veröffentlicht am:*** *14 - August - 2026*
***Weitere Informationen finden Sie unter:***
*https://www.bfarm.de/DE/Kodiersysteme/News/Terminologieserver_Veroeffentlichung_KDL.html?nn=986770*

***Versagungen und Rücknahmen BfArM Januar - Juli 2026***
***Veröffentlicht am:*** *17 - August - 2026*
***Weitere Informationen finden Sie unter:***
*https://www.bfarm.de/SharedDocs/Downloads/DE/Service/Statistik/AM-Statistik/versagungen-2026.html?nn=986770*

***National Edition Germany für SNOMED CT wächst auf über 130.000 übersetzte Konzepte***
***Veröffentlicht am:*** *18 - August - 2026*
***Weitere Informationen finden Sie unter:***
*https://www.bfarm.de/DE/Kodiersysteme/News/SNOMED_Deutsche_National_Edition_August_2026.html?nn=986770*

***Statistiken***
***Veröffentlicht am:*** *24 - August - 2026*
***Weitere Informationen finden Sie unter:***
*https://www.bfarm.de/DE/Aktuelles/Statistiken/_artikel.html?nn=986770*

***Behördlich beauflagtes Schulungsmaterial - neue Webseitenstruktur***
***Veröffentlicht am:*** *28 - August - 2026*
***Weitere Informationen finden Sie unter:***
*https://www.bfarm.de/DE/Arzneimittel/Pharmakovigilanz/Risikoinformationen/Schulungsmaterial/neue-verteilerseite-info.html?nn=986770*

# Humanarzneimittel - Österreich

***PSUR outcome: Terbinafin***
***Veröffentlicht am:*** *17 - August - 2026*
***Weitere Informationen finden Sie unter:***
*Mustertext Terbinafin*
*Link zur Webseite der EMA*

***PSUR outcome: Carbidopa/Levodopa***
***Veröffentlicht am:*** *20 - August - 2026*
***Weitere Informationen finden Sie unter:***
*Mustertext Carbidopa/Levodopa*
*Link zur Webseite der EMA*

***PSUR outcome: Methotrexat***
***Veröffentlicht am:*** *26 - August - 2026*
***Weitere Informationen finden Sie unter:***
*Mustertext Methotrexat*
*Link zur Website der Europäischen Kommission*

***L_I260_Anleitung_Beantragung_Freiverkaufszertifikat***
***Veröffentlicht am:*** *18 - August - 2026*
***Weitere Informationen finden Sie unter:***
*https://www.basg.gv.at/fileadmin/redakteure/01_Formulare_Listen/I/L_I260_Anleitung_Beantragung_Freiverkaufszertifikat.pdf*
*https://www.basg.gv.at/fuer-unternehmen/medizinprodukte/freiverkaufszertifikate#c25419*

***Compassionate Use und Heilversuch/Named Patient Use***
***Veröffentlicht am:*** *21 - August - 2026*
***Weitere Informationen finden Sie unter:***
*https://www.basg.gv.at/fuer-unternehmen/arzneimittel-informationen/compassionate-use-1#c22989*

# Humanarzneimittel - Schweiz

***I-SMI.TI.10e Starting Material Identity Guarantee***
***Veröffentlicht am:*** *17 - August - 2026*
***Weitere Informationen finden Sie unter:***
*https://www.swissmedic.ch/swissmedic/de/home/humanarzneimittel/bewilligungen_zertifikate/betriebsbewilligungen/inspektorate.html*

***Swissmedic Portal Release Notes – 24.08.2026***
***Veröffentlicht am:*** *24 - August - 2026*
***Weitere Informationen finden Sie unter:***
*https://www.swissmedic.ch/swissmedic/de/home/services/egov-services/smc-portal/release-notes/release-note-240826.html*

***Aktualisierte Vorgabedokumente***
***Veröffentlicht am:*** *28 - August - 2026*
***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.

Heute eine Spezialfrage im Bereich Homöopathie:

Gibt es Erfahrungen in der Zulassung von Homöopathika in Deutschland, respektive Registrierungen auf der Basis von Monographien aus Drittländern respektive der Hom. Pharm. US (HPUS)?

Wir freuen uns auf zahlreiche Antworten, herzlichen Dank!

# Veranstaltungen / Events – Behörden und andere Veranstalter

## Deutschland

***Mit BfArM und PEI im Dialog: CTR und mehr***
***Ort:*** *online*
***Termin:*** *16 - September - 2026*
***Weitere Informationen finden Sie unter:***
*https://www.pei.de/SharedDocs/veranstaltungen-events/DE/2026/2026-09-16-ctr-dialog-bfarm-pei.html?nn=170994*

***SNOMED-CT-Basisschulung: ECL***
***Ort:*** *online*
***Termin:*** *17 - September - 2026*
***Weitere Informationen finden Sie unter:***
*https://www.bfarm.de/DE/Aktuelles/Veranstaltungen/Termine/2026-09-17-snomed-eclschulung.html?nn=986770*

***"The Product is the Process – Is it?" Manufacturing and Translation of ATMPs and Tissue- & Cell-based products***
***Ort:*** *Investitionsbank des Landes Brandenburg, Babelsberger Straße 21, 14473 Potsdam*
***Termin:*** *02 - Dezember - 2026*
***Weitere Informationen finden Sie unter:***
*https://www.pei.de/SharedDocs/veranstaltungen-events/DE/2026/2026-12-02-workshop-manufacturing-translation-atmp.html?nn=170994*

## Österreich

***BASG-GESPRÄCH: Klinische Prüfungen von Medizinprodukten und Leistungsstudien von In-Vitro Diagnostika 2026***
***Ort:*** *online*
***Termin:*** *24 – September - 2026*
***Weitere Informationen finden Sie unter:***
*https://akademie.ages.at/basg-gespraech_klinische_pruefungen_von_medizinprodukten_und_leistungsstudien_von_in-vitro_diagnostika_2026*

## Schweiz

***Save the Date: Regulatory & Beyond 2026***
***Ort:*** *Kursaal Bern*
***Termin:*** *16 - November - 2026*
***Weitere Informationen finden Sie unter:***
*https://www.swissmedic.ch/swissmedic/de/home/services/veranstaltungen/regulatory-beyond-2026.html*

# Veranstaltungen / Events – Behörden und andere Veranstalter

## Europa

***EMA risk management information day***
***Where:*** *European Medicines Agency, Amsterdam, the Netherlands*
***Date:*** *08 - September - 2026*
***For more information, please refer to:***
*https://www.diaglobal.org/en/ema/conference-listing/2026/09/ema-risk-management-information-day#showcontent*

***Q&A clinic on Substance, Organisation, Referentials Management Services - 2026***
***Where:*** *online and European Medicines Agency, Amsterdam, the Netherlands*
***Date:*** *09 - September - 2026, 07 - October - 2026, 11 - November - 2026, 09 - December - 2026*
***For more information, please refer to:***
*https://www.ema.europa.eu/en/events/qa-clinic-substance-organisation-referentials-management-services-september-2026*
*https://www.ema.europa.eu/en/events/qa-clinic-substance-organisation-referentials-management-services-october-2026*
*https://www.ema.europa.eu/en/events/qa-clinic-substance-organisation-referentials-management-services-november-2026*
*https://www.ema.europa.eu/en/events/qa-clinic-substance-organisation-referentials-management-services-december-2026*

***PMS Q&A Clinic on Product User Interface (PUI) and Application Programming Interface (API) - 2026***
***Where:*** *online*
***Date:*** *10 - September - 2026, 24 - September - 2026*
***For more information, please refer to:***
*https://www.ema.europa.eu/en/events/pms-qa-clinic-product-user-interface-pui-application-programming-interface-api-september-2026*
*https://www.ema.europa.eu/en/events/pms-qa-clinic-product-user-interface-pui-application-programming-interface-api-september-2026-0*

***Mandatory use of ISO/ICH E2B(R3) Individual Case Safety Reporting in the EU: Hands-on training course using the EudraVigilance System - 2026***
***Where:*** *online and European Medicines Agency, Amsterdam, the Netherlands*
***Date:*** *14 to 18 - September - 2026, 12 to 16 - October – 2026, 09 to 13 - November - 2026, 07 to 11 - December - 2026*
***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-55*
*https://www.ema.europa.eu/en/events/mandatory-use-iso-ich-e2br3-individual-case-safety-reporting-eu-hands-training-course-using-eudravigilance-system-56*
*https://www.ema.europa.eu/en/events/mandatory-use-iso-ich-e2br3-individual-case-safety-reporting-eu-hands-training-course-using-eudravigilance-system-57*
*https://www.ema.europa.eu/en/events/mandatory-use-iso-ich-e2br3-individual-case-safety-reporting-eu-hands-training-course-using-eudravigilance-system-58*

# Veranstaltungen / Events – Behörden und andere Veranstalter

***Quarterly System Demo - 2026***
***Where:*** *online and European Medicines Agency, Amsterdam, the Netherlands*
***Date:*** *17 - September - 2026, 10 - December - 2026*
***For more information, please refer to:***
*https://www.ema.europa.eu/en/events/quarterly-system-demo-q3-2026*
*https://www.ema.europa.eu/en/events/quarterly-system-demo-q4-2026*

***Health technology assessment: Webinar for patients and clinical experts***
***Where:*** *online*
***Date:*** *18 - September - 2026*
***For more information, please refer to:***
*https://health.ec.europa.eu/events/health-technology-assessment-webinar-patients-and-clinical-experts-2026-09-18_en*

***Joint European Commission (EC) / European Medicines Agency (EMA) multi-stakeholder workshop on regulatory sandbox***
***Where:*** *online and European Medicines Agency, Amsterdam, the Netherlands*
***Date:*** *21 - September - 2026*
***For more information, please refer to:***
*https://www.ema.europa.eu/en/events/joint-european-commission-ec-european-medicines-agency-ema-multi-stakeholder-workshop-regulatory-sandbox*

***Joint EDQM-USP International Symposium on Pharmaceutical Reference Standards***
***Where:*** *EDQM building, Strasbourg, France & Online*
***Date:*** *23 to 24 - September - 2026*
***For more information, please refer to:***
*https://www.edqm.eu/en/irss-event?p_l_back_url=%2Fen%2Fgroup%2Fedqm%2F%7E%2Fcontrol_panel%2Fmanage%3Fp_p_id%3Dcom_liferay_layout_admin_web_portlet_GroupPagesPortlet%26p_p_lifecycle%3D0%26p_p_state%3Dmaximized%26p_p_mode%3Dview%26_com_liferay_layout_admin_web_portlet_GroupPagesPortlet_tabs1%3Dpages%26_com_liferay_layout_admin_web_portlet_GroupPagesPortlet_privateLayout%3Dfalse%26_com_liferay_layout_admin_web_portlet_GroupPagesPortlet_displayStyle%3Dmiller-columns%26p_r_p_selPlid%3D2070%26p_r_p_layoutSetBranchId%3D0%26p_p_auth%3DLl4b0kgf*

***Regulatory Perspectives on Herbal Medicinal / Botanical Drug Product Development: Joint FDA / EMA Workshop***
***Where:*** *online and European Medicines Agency, Amsterdam, the Netherlands*
***Date:*** *25 - September - 2026*
***For more information, please refer to:***
*https://www.ema.europa.eu/en/events/regulatory-perspectives-herbal-medicinal-botanical-drug-product-development-joint-fda-ema-workshop*

# Veranstaltungen / Events – Behörden und andere Veranstalter

***CPhI Worldwide & CEP One-to-One Sessions***
***Where:*** *Fiera Milano, Milan, Italy*
***Date:*** *06 to 08 - October - 2026*
***For more information, please refer to:***
*https://www.edqm.eu/en/cphi-milan?p_l_back_url=%2Fen%2Fgroup%2Fedqm%2F%7E%2Fcontrol_panel%2Fmanage%3Fp_p_id%3Dcom_liferay_layout_admin_web_portlet_GroupPagesPortlet%26p_p_lifecycle%3D0%26p_p_state%3Dmaximized%26p_p_mode%3Dview%26_com_liferay_layout_admin_web_portlet_GroupPagesPortlet_tabs1%3Dpages%26_com_liferay_layout_admin_web_portlet_GroupPagesPortlet_privateLayout%3Dfalse%26_com_liferay_layout_admin_web_portlet_GroupPagesPortlet_displayStyle%3Dmiller-columns%26p_r_p_selPlid%3D2070%26p_r_p_layoutSetBranchId%3D0%26p_p_auth%3Dun7FrSXJ*

***Clinical Trials Information System (CTIS): Walk-in clinic October 2026***
***Where:*** *online and European Medicines Agency, Amsterdam, the Netherlands*
***Date:*** *07 - October - 2026*
***For more information, please refer to:***
*https://www.ema.europa.eu/en/events/clinical-trials-information-system-ctis-walk-clinic-october-2026*

***Mandatory use of ISO/ICH E2B(R3) Individual Case Safety Reporting in the EU: Hands-on training course using the EudraVigilance System - 2026***
***Where:*** *online and European Medicines Agency, Amsterdam, the Netherlands*
***Date:*** *06 to 08 - October - 2026, 24 to 26 - November - 2026*
***For more information, please refer to:***
*https://www.ema.europa.eu/en/events/virtual-live-hands-training-course-clinical-trials-sponsors-using-eudravigilance-system-october-2026*
*https://www.ema.europa.eu/en/events/virtual-live-hands-training-course-clinical-trials-sponsors-using-eudravigilance-system-november-2026*

***SAVE THE DATE! EDQM Symposium: Microbiology on the Move***
***Where:*** *Strasbourg, France*
***Date:*** *13 to 15 - October - 2026*
***For more information, please refer to:***
*https://www.edqm.eu/en/-/symposium-microbio*

***European platform for regulatory science research meeting: October 2026***
***Where:*** *online and European Medicines Agency, Amsterdam, the Netherlands*
***Date:*** *22 - October - 2026*
***For more information, please refer to:***
*https://www.ema.europa.eu/en/events/european-platform-regulatory-science-research-meeting-october-2026*

# 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:*** *Bucharest, Romania*
***Date:*** *26 to 28 - October - 2026*
***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-59*

***eXtended EudraVigilance Medicinal Product Dictionary (XEVMPD) training course (Bucharest) - October 2026***
***Where:*** *Hotel Capital Plaza Bucharest, Bucharest, Romania*
***Date:*** *29 to 30 - October - 2026*
***For more information, please refer to:***
*https://www.ema.europa.eu/en/events/extended-eudravigilance-medicinal-product-dictionary-xevmpd-training-course-bucharest-october-2026*

***Workshop on the use of external controls for evidence generation in regulatory decision-making***
***Where:*** *online and European Medicines Agency, Amsterdam, the Netherlands*
***Date:*** *03 - November - 2026*
***For more information, please refer to:***
*https://www.ema.europa.eu/en/events/workshop-use-external-controls-evidence-generation-regulatory-decision-making*

***HMA/EMA multistakeholder AI and Data forum: Build trustworthy AI on strong data foundations***
***Where:*** *online and European Medicines Agency, Amsterdam, the Netherlands*
***Date:*** *12 to 13 - November - 2026*
***For more information, please refer to:***
*https://www.ema.europa.eu/en/events/hma-ema-multistakeholder-ai-data-forum-build-trustworthy-ai-strong-data-foundations*

***Digitalisation and artificial Intelligence in pharmaceutical manufacturing: Quality Innovation Group (QIG) - Follow-up roundtable meeting***
***Where:*** *online and European Medicines Agency, Amsterdam, the Netherlands*
***Date:*** *18 to 19 - November - 2026*
***For more information, please refer to:***
*https://www.ema.europa.eu/en/events/digitalisation-artificial-intelligence-pharmaceutical-manufacturing-quality-innovation-group-qig-follow-roundtable-meeting*

# Veranstaltungen / Events – Behörden und andere Veranstalter

***CPHI India & CEP One-to-One Sessions***
***Where:*** *IICC, Yashobhoomi, Dwarka, Delhi*
***Date:*** *23 to 25 - November - 2026*
***For more information, please refer to:***
*https://www.edqm.eu/en/cphi-india-cep-one-to-one-sessions?p_l_back_url=%2Fen%2Fgroup%2Fedqm%2F~%2Fcontrol_panel%2Fmanage%3Fp_p_id%3Dcom_liferay_layout_admin_web_portlet_GroupPagesPortlet%26p_p_lifecycle%3D0%26p_p_state%3Dmaximized%26p_p_mode%3Dview%26_com_liferay_layout_admin_web_portlet_GroupPagesPortlet_tabs1%3Dpages%26_com_liferay_layout_admin_web_portlet_GroupPagesPortlet_privateLayout%3Dfalse%26_com_liferay_layout_admin_web_portlet_GroupPagesPortlet_displayStyle%3Dmiller-columns%26p_r_p_selPlid%3D2070%26p_r_p_layoutSetBranchId%3D0%26p_p_auth%3DHQfjd1mP*

***2026 EDQM virtual training programme: independent modules on the Ph. Eur., reference standards and the certification of suitability (CEP) procedure***
***Where:*** *online*
***Date:*** *30 - November to 11 - December - 2026*
***For more information, please refer to:***
*https://www.edqm.eu/en/2026-edqm-virtual-training-programme-independent-modules-on-the-ph.-eur.-reference-standards-and-the-certification-of-suitability-cep-procedure*