17. - 31. Juli 2026

MEGRA NEWSLETTER

Humanarzneimittel - EMA

Allgemeines – General

Podcast: Inside EMA
Published on: *27 - July - 2026*
For more information, please refer to:
https://www.ema.europa.eu/en/news-events/podcast-inside-ema

Pharmakovigilanz – PRAC

Guiding principles for the EMA - US FDA cluster teleconferences on Artificial Intelligence in Pharmacovigilance
Published on: *17 - July - 2026*
For more information, please refer to:
https://www.ema.europa.eu/en/documents/other/guiding-principles-ema-us-fda-cluster-teleconferences-artificial-intelligence-pharmacovigilance_en.pdf

Pharmacovigilance cluster – Terms of Reference
Published on: *17 - July - 2026*
For more information, please refer to:
https://www.ema.europa.eu/en/documents/other/pharmacovigilance-cluster-terms-reference_en.pdf

List of European Union reference dates (EURD) and frequency of submission of periodic safety update reports (PSURs)
Published on: *29 - July - 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

List of medicines under additional monitoring
Published on: *29 - July - 2026*
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

Zulassung – Regulatory Affairs

Meeting highlights from the Committee for Medicinal Products for Human Use (CHMP) 20-23 July 2026
Published on: *24 - July - 2026*
For more information, please refer to:
https://www.ema.europa.eu/en/news/meeting-highlights-committee-medicinal-products-human-use-chmp-20-23-july-2026

Humanarzneimittel - EMA

Medicines for human use under evaluation
Published on: *31 - July - 2026*
For more information, please refer to:
https://www.ema.europa.eu/en/medicines/medicines-human-use-under-evaluation

Orphan Drugs und neuartige Therapierichtungen (ATMP)

Terms of reference for the advanced therapy medicinal products cluster
Published on: *17 - July - 2026*
For more information, please refer to:
https://www.ema.europa.eu/en/documents/other/terms-reference-advanced-therapy-medicinal-products-cluster_en.pdf

Terms of reference for the European Medicines Agency and the United States Food and Drugs Administration cluster on orphan medicinal products
Published on: *17 - July - 2026*
For more information, please refer to:
https://www.ema.europa.eu/en/documents/other/terms-reference-european-medicines-agency-united-states-food-drugs-administration-cluster-orphan-medicinal-products_en.pdf

Qualität – Quality

No news published

(Prä-) Klinische Forschung – Research and Development

Questions and answers for biological medicinal products
Published on: *20 - July - 2026*
For more information, please refer to:
https://www.ema.europa.eu/en/human-regulatory-overview/research-and-development/scientific-guidelines/biological-guidelines/questions-answers-biological-medicinal-products

Kinderarzneimittel – Paediatrics

Pediatric cluster terms of reference
Published on: *17 - July - 2026*
For more information, please refer to:
https://www.ema.europa.eu/en/documents/other/pediatric-cluster-terms-reference_en.pdf-0

Humanarzneimittel - EMA

Pflanzliche Arzneimittel – Herbal medicines

Herbal medicinal product: Liquiritiae radix, D: Draft under discussion
Published on: *20 - July - 2026*
For more information, please refer to:
https://www.ema.europa.eu/en/medicines/herbal/liquiritiae-radix

HMPC meeting report on European Union herbal monographs, guidelines and other activities - 6-8 July 2026
Published on: *30 - July - 2026*
For more information, please refer to:
https://www.ema.europa.eu/en/documents/committee-report/hmpc-meeting-report-european-union-herbal-monographs-guidelines-other-activities-6-8-july-2026_en.pdf

Events and Video recording

Clinical Trials Information System (CTIS) bitesize talk: Annual safety report (ASR) new safety module
Presentation available
Published on: *30 - July - 2026*
For more information, please refer to:
https://www.ema.europa.eu/en/events/clinical-trials-information-system-ctis-bitesize-talk-annual-safety-report-asr-new-safety-module

European Commission

Monitoring of Notified Bodies: new MDR and IVDR reports
Published on: *20 - July - 2026*
For more information, please refer to:
https://health.ec.europa.eu/latest-updates/monitoring-notified-bodies-new-mdr-and-ivdr-reports-2026-07-20_en

EDQM

USP-EDQM Stakeholder Forum reinforces commitment to pharmacopoeial collaboration and global alignment
Published on: *27 - July - 2026*
For more information, please refer to:
https://www.edqm.eu/en/-/usp-edqm-stakeholder-forum-reinforces-commitment-to-pharmacopoeial-collaboration-and-global-alignment

Deployment of a new EDQM CEP database feature: full download of CEP data
Published on: *31 - July - 2026*
For more information, please refer to:
https://www.edqm.eu/en/-/deployment-of-a-new-edqm-cep-database-feature-full-download-of-cep-data

EDQM reference standards monthly newsletter – July 2026
Published on: *31 - July - 2026*
For more information, please refer to:
https://www.edqm.eu/en/-/edqm-reference-standards-monthly-newsletter-july-2026

Medizinprodukte

List of clinical evaluation consultation procedure (CECP) opinions issued for medical devices awaiting finalisation of conformity assessment
Published on: *17 - July - 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

New MDCG Position Paper: UDI assignment between manufacturers and distributors
Published on: *22 - July - 2026*
For more information, please refer to:
https://health.ec.europa.eu/medical-devices-sector/new-regulations/guidance-mdcg-endorsed-documents-and-other-guidance_en#sec18

CMDh

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

NEW - 23-25 June CMDh Minutes
Published on: *28 - July - 2026*
For more information, please refer to:
https://www.hma.eu/human-medicines/cmdh/agendas-and-minutes.html#c7861

NEW - Minutes of the 25 June 2026 meeting with Interested Parties
Published on: *28 - July - 2026*
For more information, please refer to:
https://www.hma.eu/human-medicines/cmdh/about-cmdh/contacts-with-representative-organisations.html

NEW - 2026 (Jan-Jun) - Statistics for New Applications (MRP/DCP), Variations, Referrals and Paediatric Worksharing procedures
Published on: *29 - July - 2026*
For more information, please refer to:
https://www.hma.eu/human-medicines/cmdh/statistics.html#c7903

UPDATE - Chapter 7 - CMDh BPG on Variation Worksharing; UPDATE - EMA/CMDh Explanatory notes on Variation Application Form - Human medicinal products only
Published on: *29 - July - 2026*
For more information, please refer to:
https://www.hma.eu/human-medicines/cmdh/procedural-guidance/variation.html#c2126

CMDH PRESS RELEASES 2026
Published on: *29 - July - 2026*
For more information, please refer to:
https://www.hma.eu/human-medicines/cmdh/press-releases.html

UPDATE - Template of letter of intent for the submission of a worksharing procedure
Published on: *29 - July - 2026*
For more information, please refer to:
https://www.hma.eu/human-medicines/cmdh/templates/variations.html#c2210

Humanarzneimittel - Deutschland

Rohdaten der Stoffbezeichnungen
Veröffentlicht am: *17 - Juli - 2026*
Weitere Informationen finden Sie unter:
https://www.bfarm.de/DE/Arzneimittel/Arzneimittelinformationen/Arzneimittel-recherchieren/Stoffbezeichnungen/_artikel.html?nn=986770

Erklärung zur Bereitstellung von harmonisiertem Schulungsmaterial (Educational Material)
Veröffentlicht am: *17 - Juli - 2026*
Weitere Informationen finden Sie unter:
https://www.bfarm.de/SharedDocs/Downloads/DE/Arzneimittel/Pharmakovigilanz/Risikoinformationen/EducationMaterial/leflunomid-harmonisiert-erklaerung-bereitstellung-word.html?nn=986770

Statistiken
Veröffentlicht am: *20 - Juli - 2026*
Weitere Informationen finden Sie unter:
https://www.bfarm.de/DE/Aktuelles/Statistiken/_artikel.html?nn=986770

Aktuell laufende und bestätigte Arzneimittel-Härtefallprogramme
Veröffentlicht am: *27 - Juli - 2026*
Weitere Informationen finden Sie unter:
https://www.bfarm.de/DE/Arzneimittel/Klinische-Pruefung/Compassionate-Use/compUse-tabelle.html?nn=986770

Informationen zu Einreichung und Genehmigung von Schulungsmaterial
Veröffentlicht am: *31 - Juli - 2026*
Weitere Informationen finden Sie unter:
https://www.bfarm.de/DE/Arzneimittel/Pharmakovigilanz/Risikoinformationen/Schulungsmaterial/Zusatzinformationen/_artikel.html?nn=986770

Humanarzneimittel - Österreich

FAQ Bewilligung
Veröffentlicht am: *22 - Juli - 2026*
Weitere Informationen finden Sie unter:
https://www.basg.gv.at/fuer-unternehmen/bewilligung-und-zertifizierung/gute-herstellungs-/-vertriebspraxis-gmp/gdp/faq-gmp/gdp/faq-bewilligung

Formular: Änderungsformblatt §24 (F_Z09) - Nationale Zulassung und Life-Cycle
Veröffentlicht am: *22 - Juli - 2026*
Weitere Informationen finden Sie unter:
https://www.basg.gv.at/fileadmin/redakteure/01_Formulare_Listen/Z/F_Z09_Aenderungsformblatt24.docx
https://www.basg.gv.at/fuer-unternehmen/formulare-arzneimittel/nationale-zulassung-und-life-cycle

Humanarzneimittel - Schweiz

Aktualisierte Vorgabedokumente
Veröffentlicht am: *31 - Juli - 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.

Veranstaltungen / Events – Behörden und andere Veranstalter

Deutschland

Internationales Paul-Ehrlich-Seminar (IPES)
Ort: *Stadthalle Langen (bei Frankfurt)*
Termin: *02 bis 05 - September - 2026*
Weitere Informationen finden Sie unter:
https://www.pei.de/DE/newsroom/hp-meldungen/2026/260216-ipes-2026-registrierung-gestartet.html?nn=170852

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

genomDE Symposium
Ort: *Bundeskunsthalle, Bonn*
Termin: *28 bis 29 - September - 2026*
Weitere Informationen finden Sie unter:
https://www.bfarm.de/DE/Aktuelles/Veranstaltungen/Termine/2026-09-28-genom.html?nn=986770

Österreich

Keine Veranstaltungen veröffentlicht

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

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

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

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

Veranstaltungen / Events – Behörden und andere Veranstalter

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

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