18. Februar - 04. März 2022

MEGRA NEWSLETTER

Humanarzneimittel - EMA

Allgemeines – General

Contact details of national competent authorities for requests to use a sticker to place the Unique Identifier on the outer/immediate packaging of centrally approved products (updated)
Published on: *18 - February - 2022*
For more information, please refer to:
https://www.ema.europa.eu/documents/other/contact-details-national-competent-authorities-requests-use-sticker-place-unique-identifier-outer/immediate-packaging-centrally-approved-products_en.pdf

Scientific publications (updated)
Published on: *21 - February - 2022*
For more information, please refer to:
https://www.ema.europa.eu/en/news-events/publications/scientific-publications

World Health Organization (WHO) (updated)
Published on: *21 - February - 2022*
For more information, please refer to:
https://www.ema.europa.eu/en/partners-networks/international-activities/multilateral-coalitions-initiatives/world-health-organization-who

What we do (updated)
Published on: *01 - March - 2022*
For more information, please refer to:
https://www.ema.europa.eu/en/about-us/what-we-do

Regulation on EMA's extended mandate becomes applicable
Published on: *01 - March - 2022*
For more information, please refer to:
https://www.ema.europa.eu/en/news/regulation-emas-extended-mandate-becomes-applicable

Pharmakovigilanz – PRAC

Referral: Nomegestrol and chlormadinone , nomegestrol, chlormadinone, Article 31 referrals, Under evaluation, 21/02/2022 (updated)
Published on: *21 - February - 2022*
For more information, please refer to:
https://www.ema.europa.eu/en/medicines/human/referrals/nomegestrol-chlormadinone

Referral: Terlipressin-containing medicinal products indicated in the treatment of hepatorenal syndrome , terlipressin, Article 31 referrals, Procedure started
Published on: *21 - February - 2022*
For more information, please refer to:
https://www.ema.europa.eu/en/medicines/human/referrals/terlipressin-containing-medicinal-products-indicated-treatment-hepatorenal-syndrome

Humanarzneimittel - EMA

Referral: Procaine benzylpenicillin , Article 82, Procedure started, 18/02/2022
Published on: *23 - February - 2022*
For more information, please refer to:
https://www.ema.europa.eu/en/medicines/veterinary/referrals/procaine-benzylpenicillin

Regulatory and procedural guideline: EU Individual Case Safety Report (ICSR) implementation guide business rules spreadsheets (updated)
Published on: *23 - February - 2022*
For more information, please refer to:
https://www.ema.europa.eu/documents/regulatory-procedural-guideline/eu-individual-case-safety-report-icsr-implementation-guide-business-rules-spreadsheets_en.zip

Regulatory and procedural guideline: EudraVigilance - EVWEB user manual - Version 1.6 (updated)
Published on: *23 - February - 2022*
For more information, please refer to:
https://www.ema.europa.eu/documents/regulatory-procedural-guideline/eudravigilance-evweb-user-manual-version-16_en.pdf

Hydroxyethyl-starch solutions for infusion recommended for suspension from the market
Published on: *25 - February - 2022*
For more information, please refer to:
https://www.ema.europa.eu/en/news/hydroxyethyl-starch-solutions-infusion-recommended-suspension-market

List of European Union reference dates and frequency of submission of periodic safety update reports (PSURs) (updated)
Published on: *02 - March - 2022*
For more information, please refer to:
https://www.ema.europa.eu/documents/other/list-european-union-reference-dates-frequency-submission-periodic-safety-update-reports-psurs_en.xls

Zulassung – Regulatory Affairs

Regulatory and procedural guideline: Member states contact points for translations review (updated)
Published on: *18 - February - 2022*
For more information, please refer to:
https://www.ema.europa.eu/documents/regulatory-procedural-guideline/member-states-contact-points-translations-review_en.pdf

Regulatory and procedural guideline: List of centrally authorised products requiring a notification of a change for update of annexes (updated)
Published on: *21 - February - 2022*
For more information, please refer to:
https://www.ema.europa.eu/documents/regulatory-procedural-guideline/list-centrally-authorised-products-requiring-notification-change-update-annexes_en.pdf

Humanarzneimittel - EMA

Regulatory and procedural guideline: European Medicines Agency guidance for applicants seeking scientific advice and protocol assistance (updated)
Published on: *24 - February - 2022*
For more information, please refer to:
https://www.ema.europa.eu/documents/regulatory-procedural-guideline/european-medicines-agency-guidance-applicants-seeking-scientific-advice-protocol-assistance_en.pdf

Regulatory and procedural guideline: Procedural advice – extended assessment time for initial marketing authorisation applications of 90 days
Published on: *25 - February - 2022*
For more information, please refer to:
https://www.ema.europa.eu/documents/regulatory-procedural-guideline/procedural-advice-extended-assessment-time-initial-marketing-authorisation-applications-90-days_en.pdf

Regulatory and procedural guideline: Substances considered as not falling within the scope of Regulation (EC) No. 470/2009, with regard to residues of veterinary medicinal products in foodstuffs of animal origin (updated)
Published on: *25 - February - 2022*
For more information, please refer to:
https://www.ema.europa.eu/documents/regulatory-procedural-guideline/substances-considered-not-falling-within-scope-regulation-ec-no-470/2009-regard-residues-veterinary-medicinal-products-foodstuffs-animal-origin_en.pdf

Regulatory and procedural guideline: Advice on the designation of antimicrobials or groups of antimicrobials reserved for treatment of certain infections in humans - in relation to implementing measures under Article 37(5) of Regulation (EU) 2019/6 on veterinary medicinal products
Published on: *01 - March - 2022*
For more information, please refer to:
https://www.ema.europa.eu/documents/regulatory-procedural-guideline/advice-designation-antimicrobials-groups-antimicrobials-reserved-treatment-certain-infections-humans/6-veterinary-medicinal-products_en.pdf

Union Product Database - FAQs - questions and answers for industry users (updated)
Published on: *18 - February - 2022*
For more information, please refer to:
https://www.ema.europa.eu/documents/other/union-product-database-faqs-questions-answers-industry-users_en.pdf

Agenda: Agenda - CHMP agenda of the 21-24 February 2022 meeting
Published on: *21 - February - 2022*
For more information, please refer to:
https://www.ema.europa.eu/documents/agenda/agenda-chmp-agenda-21-24-february-2022-meeting_en.pdf

Humanarzneimittel - EMA

Minutes: CHMP PROM minutes for the meeting on 17 January 2022
Published on: *23 - February - 2022*
For more information, please refer to:
https://www.ema.europa.eu/documents/minutes/chmp-prom-minutes-meeting-17-january-2022_en.pdf

Agenda: CHMP PROM agenda for the meeting on 17 January 2022
Published on: *23 - February - 2022*
For more information, please refer to:
https://www.ema.europa.eu/documents/agenda/chmp-prom-agenda-meeting-17-january-2022_en.pdf

Meeting highlights from the Committee for Medicinal Products for Human Use (CHMP) 21-24 February 2022
Published on: *25 - February - 2022*
For more information, please refer to:
https://www.ema.europa.eu/en/news/meeting-highlights-committee-medicinal-products-human-use-chmp-21-24-february-2022

Article 57 product data (updated)
Published on: *21 - February - 2022*
For more information, please refer to:
https://www.ema.europa.eu/documents/other/article-57-product-data_en.xlsx

European medicines regulatory network adopts EU common standard for electronic product information
Published on: *22 - February - 2022*
For more information, please refer to:
https://www.ema.europa.eu/en/news/european-medicines-regulatory-network-adopts-eu-common-standard-electronic-product-information

Product-information requirements (updated)
Published on: *22 - February - 2022*
For more information, please refer to:
https://www.ema.europa.eu/en/human-regulatory/marketing-authorisation/product-information-requirements

Agenda - Third European Medicines Agency and Association of the European Self-Medication Industry (AESGP) annual bilateral meeting
Published on: *23 - February - 2022*
For more information, please refer to:
https://www.ema.europa.eu/documents/agenda/agenda-third-european-medicines-agency-association-european-self-medication-industry-aesgp-annual_en.pdf

List of medicinal products under additional monitoring (updated)
Published on: *24 - February - 2022*
For more information, please refer to:
https://www.ema.europa.eu/documents/additional-monitoring/list-medicinal-products-under-additional-monitoring_en-0.pdf

Humanarzneimittel - EMA

European Medicines Agency's Data Protection Notice concerning the Multistakeholder Workshop on EMA extended mandate on 1 April 2022
Published on: *24 - February - 2022*
For more information, please refer to:
https://www.ema.europa.eu/documents/other/european-medicines-agency-data-protection-notice-concerning-multistakeholder-workshop-ema-extended_en.pdf

Presentation: Introducing DADI –The Digital Application Dataset Integration Network Project to replace electronic application forms
Published on: *24 - February - 2022*
For more information, please refer to:
https://www.ema.europa.eu/documents/presentation/presentation-introducing-dadi-digital-application-dataset-integration-network-project-replace_en.pdf

Interpretation of Article 18(7) of Regulation (EU) 2019/6 (updated)
Published on: *25 - February - 2022*
For more information, please refer to:
https://www.ema.europa.eu/en/interpretation-article-187-regulation-eu-2019-6

List of products granted eligibility to PRIME (updated)
Published on: *02 - March - 2022*
For more information, please refer to:
https://www.ema.europa.eu/documents/report/list-products-granted-eligibility-prime_en-0.xlsx

Orphan Drugs und neuartige Therapierichtungen (ATMP)

Agenda: Agenda - COMP agenda of the 15-17 February 2022 meeting
Published on: *21 - February - 2022*
For more information, please refer to:
https://www.ema.europa.eu/documents/agenda/agenda-comp-agenda-15-17-february-2022-meeting_en.pdf

Recommendations on eligibility to PRIME scheme - Adopted at the CHMP meeting of 21-24 February 2022
Published on: *02 - March - 2022*
For more information, please refer to:
https://www.ema.europa.eu/documents/chmp-annex/recommendations-eligibility-prime-scheme-adopted-chmp-meeting-21-24-february-2022_en.pdf

PRIME: Analysis of the first 5 years' experience
Published on: *03 - March - 2022*
For more information, please refer to:
https://www.ema.europa.eu/documents/report/prime-analysis-first-5-years-experience_en.pdf *und*
https://www.ema.europa.eu/documents/report/prime-5-years-experience_en.pdf

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PRIME enables earlier availability of life-changing medicines
Published on: *03 - March - 2022*
For more information, please refer to:
https://www.ema.europa.eu/en/news/prime-enables-earlier-availability-life-changing-medicines

Qualität – Quality

No news published

(Prä-) Klinische Forschung – Research and Development

CTIS newsflash - 18 February 2022
Published on: *23 - February - 2022*
For more information, please refer to:
https://www.ema.europa.eu/documents/newsletter/ctis-newsflash-18-february-2022_en.pdf

Principal documents taken into account for the preparation of procedures for GCP inspections requested by the CHMP (updated)
Published on: *18 - February - 2022*
For more information, please refer to:
https://www.ema.europa.eu/documents/other/principal-documents-taken-account-preparation-procedures-gcp-inspections-requested-chmp_en.pdf

Quick guide - Fill in the blanks exercise: Overview of CTIS workspaces and common system functionalities - CTIS Training Programme - Module 02
Published on: *01 - March - 2022*
For more information, please refer to:
https://www.ema.europa.eu/documents/other/quick-guide-fill-blanks-exercise-overview-ctis-workspaces-common-system-functionalities-ctis_en.pdf *and*
https://www.ema.europa.eu/documents/other/clinical-trials-information-system-ctis-common-features-ctis-training-programme-module-02_en.pdf

FAQs: Overview of CTIS workspaces and common system functionalities - CTIS Training Programme - Module 02 (updated)
Published on: *02 - March - 2022*
For more information, please refer to:
https://www.ema.europa.eu/documents/other/faqs-overview-ctis-workspaces-common-system-functionalities-ctis-training-programme-module-02_en.pdf

Presentation: Clinical Trials Information System (CTIS) bitesize talk: User access and role management
Published on: *01 - March - 2022*
For more information, please refer to:
https://www.ema.europa.eu/documents/presentation/presentation-clinical-trials-information-system-ctis-bitesize-talk-user-access-role-management_en.pdf

Humanarzneimittel - EMA

Newsletter: CTIS newsflash - 25 February 2022
Published on: *01 - March - 2022*
For more information, please refer to:
https://www.ema.europa.eu/documents/newsletter/ctis-newsflash-25-february-2022_en.pdf

Clinical Trials Information System (CTIS) - Technical requirements for optimal use
Published on: *03 - March - 2022*
For more information, please refer to:
https://www.ema.europa.eu/documents/other/clinical-trials-information-system-ctis-technical-requirements-optimal-use_en.pdf

Template or form: Innovation Task Force (ITF) briefing meeting request form (updated)
Published on: *03- March - 2022*
For more information, please refer to:
https://www.ema.europa.eu/documents/template-form/innovation-task-force-itf-briefing-meeting-request-form_en.docx

Kinderarzneimittel – Paediatrics

Minutes: PDCO monthly report of opinions on paediatric investigation plans and other activities 12-15 October 2021
Published on: *18 - February - 2022*
For more information, please refer to:
https://www.ema.europa.eu/documents/minutes/pdco-monthly-report-opinions-paediatric-investigation-plans-other-activities-12-15-october-2021_en.pdf

Work programme: PDCO work plan 2022
Published on: *21 - February - 2022*
For more information, please refer to:
https://www.ema.europa.eu/documents/work-programme/pdco-work-plan-2021_en.pdf

Agenda - PDCO agenda of the 22-25 February 2022 meeting
Published on: *25 - February - 2022*
For more information, please refer to:
https://www.ema.europa.eu/documents/agenda/agenda-pdco-agenda-22-25-february-2022-meeting_en.pdf

Minutes - PDCO minutes of the 7-10 September 2021 meeting
Published on: *02 - March - 2022*
For more information, please refer to:
https://www.ema.europa.eu/documents/minutes/minutes-pdco-minutes-7-10-september-2021-meeting_en.pdf

Humanarzneimittel - EMA

Pflanzliche Arzneimittel – Herbal medicines

No news published

European Commission

Eudralex Volume 4 - EU Guidelines for Good Manufacturing Practice for Medicinal Products for Human and Veterinary Use
Published on: *21 - February - 2022*
For more information, please refer to:
https://ec.europa.eu/health/latest-updates/eudralex-volume-4-eu-guidelines-good-manufacturing-practice-medicinal-products-human-and-veterinary-2022-02-21_en

Minutes - 1st drafting group meeting on managing AMR across the health system (28 January 2022)
Published on: *21 - February - 2022*
For more information, please refer to:
https://ec.europa.eu/health/latest-updates/minutes-1st-drafting-group-meeting-managing-amr-across-health-system-28-january-2022-2022-02-21_en

Factsheet - EU Action on Rare Diseases
Published on: *25 - February - 2022*
For more information, please refer to:
https://ec.europa.eu/health/latest-updates/factsheet-eu-action-rare-diseases-2022-02-25_en

EDQM

EDQM remote inspections: from pilot phase to a permanent element of EDQM's inspection scheme!
Published on: *23 - February - 2022*
For more information, please refer to:
https://www.edqm.eu/en/news/edqm-remote-inspections-pilot-phase-permanent-element-edqms-inspection-scheme

PDG 2021 autumn meeting held by videoconference
Published on: *01 - March - 2022*
For more information, please refer to:
https://www.edqm.eu/en/news/pdg-2021-autumn-meeting-held-videoconference

Update of application forms for Certificate of Suitability applications
Published on: *02 - March - 2022*
For more information, please refer to:
https://www.edqm.eu/en/news/update-application-forms-certificate-suitability-applications

Suspension of shipments
"*Due to the recent events in Ukraine, all carriers have suspended their activities in Belarus, Moldova, Russia and Ukraine until further notice. Therefore, the EDQM can no longer proceed with any shipments for Reference Standards, Publications or PTS to these countries.****"***
Published on: *02 - March - 2022*
For more information, please refer to:
https://www.edqm.eu/en/news/suspension-shipments

Medizinprodukte

No news published

CMDh

The 106th Heads of Medicines Agencies Meeting 23 - 24 November 2021 Highlights of the Meeting
Published on: *21 - February - 2022*
For more information, please refer to:
https://www.hma.eu/fileadmin/dateien/HMA_joint/03-Stakeholders_Info/Stakeholders_106th_HMA_Ljubljana_November_2021.pdf

HMA Procedures and Governance - For the Permanent Secretariat Support to the HMA Management Group (updated March 2022)
Published on: *03 - March - 2022*
For more information, please refer to:
https://www.hma.eu/about-hma/structure.html#c3940

Summary of CMDh Activities 2021
Published on: *03 - March - 2022*
For more information, please refer to:
https://www.hma.eu/human-medicines/cmdh/about-cmdh/cmdh-reports.html#c6973

Humanarzneimittel - Deutschland

Organigramm des BfArM - Stand 18.02.2022
Veröffentlicht am: *18 - Februar - 2022*
Weitere Informationen finden Sie unter:
https://www.bfarm.de/SharedDocs/Downloads/DE/BfArM/Org/bfarm_organigramm.html?nn=986770

Bearbeitungsstatistiken
Veröffentlicht am: *21 - Februar - 2022*
Weitere Informationen finden Sie unter:
https://www.bfarm.de/DE/Aktuelles/Statistiken/AM_statistik/statistik-bearbeitung.html

Statistik "Besondere Therapierichtungen und Traditionelle Arzneimittel"
„Die Statistiken zu den verkehrsfähigen Arzneimitteln der Besonderen Therapierichtungen (Phytopharmaka, Homöopathika, Anthroposophika) sowie traditioneller Arzneimittel, die erfolgreich ein (Nach-)Zulassungs- oder (Nach-)Registrierungsverfahren abgeschlossen haben, wurden aktualisiert."
Veröffentlicht am: *25 - Februar - 2022*
Weitere Informationen finden Sie unter:
https://www.bfarm.de/DE/Aktuelles/Statistiken/AM_statistik/Besondere_Therapierichtungen_statistik/statistik-bescheidzahlen.html

Arzneimittelzulassungen unter Verwendung von Studien der Firma GVK Biosciences in Indien: Ruhen der Zulassungen
„Wirkstoff: Verschiedene"
Veröffentlicht am: *22 - Februar - 2022*
Weitere Informationen finden Sie unter:
https://www.bfarm.de/SharedDocs/Risikoinformationen/Pharmakovigilanz/DE/RV_STP/q-l/gvk.html

Vorläufige Tagesordnung der 90. Routinesitzung am 15. März 2022
„Die 90. Routinesitzung nach § 63 AMG wird am 15. März 2022 ab 10:00 Uhr als Videokonferenz stattfinden."
Veröffentlicht am: *23 - Februar - 2022*
Weitere Informationen finden Sie unter:
https://www.bfarm.de/DE/Arzneimittel/Pharmakovigilanz/Ausschuesse-und-Gremien/Routinesitzung/Protokolle/90Sitzung/tagesordnung_90.html

Schreiben BMG vom 22.02.2022 - Versorgungsmangel tamoxifenhaltiger Arzneimittel
Veröffentlicht am: *23 - Februar - 2022*
Weitere Informationen finden Sie unter:
https://www.bfarm.de/SharedDocs/Downloads/DE/Arzneimittel/Zulassung/amInformationen/Lieferengpaesse/schreiben_bmg_tamoxifenhaltige_am_20220222.html?nn=986770

Bescheid vom 22.02.2022 - Anordnung gemäß § 52b Absatz 3d AMG für tamoxifenhaltige Arzneimittel
Veröffentlicht am: *23 - Februar - 2022*
Weitere Informationen finden Sie unter:
https://www.bfarm.de/SharedDocs/Downloads/DE/Arzneimittel/Zulassung/amInformationen/Lieferengpaesse/bescheid_52b_3d_tamoxifenhaltige_am.html?nn=986770

Humanarzneimittel - Deutschland

Vortragsfolien: Praktische Planung und Durchführung von klinischen Studien II
Veröffentlicht am: *23 - Februar - 2022*
Weitere Informationen finden Sie unter:
https://www.bfarm.de/SharedDocs/Downloads/DE/Service/Termine-und-Veranstaltungen/ringvorlesungen/2021_Winter/Praktische_Planung_Durchfuehrung_Coenen.pdf?__blob=publicationFile

Formular - Meldung von Vorkommnissen durch sonstige Inverkehrbringer sowie Betreiber und Anwender nach § 3 Abs. 2 bis 4 der Medizinprodukte Sicherheitsplanverordnung
Veröffentlicht am: *24 - Februar - 2022*
Weitere Informationen finden Sie unter:
https://www.bfarm.de/SharedDocs/Formulare/DE/Medizinprodukte/caVorkommnismeldungen-sonstige-Inverkehrbringer-PDF.html?nn=986770

Antrag auf Erlaubnis zur Teilnahme am Betäubungsmittelverkehr nach § 3 Betäubungsmittelgesetz (BtMG) für außeruniversitäre wissenschaftliche Einrichtungen und Behörden
Veröffentlicht am: *28 - Februar - 2022*
Weitere Informationen finden Sie unter:
https://www.bfarm.de/SharedDocs/Formulare/DE/Bundesopiumstelle/BtM/WissBehoerdenAntrag.html?nn=986770

Erlaubnis und Registrierung
„Jeder, der Grundstoffe der Kategorie 1 besitzt, in den Verkehr bringt, einführt, ausführt bzw. mit ihnen Vermittlungs- oder Streckengeschäfte betreibt, benötigt dafür eine Erlaubnis nach Artikel 3 Abs. 2 der Verordnung (EG) Nr. 273/2004 bzw. Artikel 6 Abs. 1 der Verordnung (EG) Nr. 111/2005.“
Veröffentlicht am: *28 - Februar - 2022*
Weitere Informationen finden Sie unter:
https://www.bfarm.de/DE/Bundesopiumstelle/Grundstoffe/Erlaubnis/_artikel.html?nn=986770

PEI-C Rebuild – Elektronische Zustellung der Chargenfreigabedokumente für weitere Produktgruppen
Veröffentlicht am: *28 - Februar - 2022*
Weitere Informationen finden Sie unter:
https://www.pei.de/SharedDocs/Downloads/DE/newsroom/mitteilungen/220228-elektronische-zustellung-chargenfreigabedokumente-2.pdf?__blob=publicationFile&v=2

Expertengruppen Off-Label
„Stellenausschreibung externe Sachverständige - Es liegen neue Arbeitsaufträge zur Vergabe vor.“
Veröffentlicht am: *03 - März - 2022*
Weitere Informationen finden Sie unter:
https://www.bfarm.de/DE/Arzneimittel/Zulassung/Zulassungsrelevante-Themen/Expertengruppen-Off-Label/_artikel.html

CHMP Ausschuss für Humanarzneimittel
Veröffentlicht am: *03 - März - 2022*
Weitere Informationen finden Sie unter:
https://www.bfarm.de/DE/Das-BfArM/Aufgaben/EU-und-Internationales/CHMP-Ausschuss/_artikel.html?nn=986770

Humanarzneimittel - Deutschland

Für den Fortschritt biomedizinischer Arzneimittel: Paul-Ehrlich-Institut im Gespräch mit dem Bundesverband der Pharmazeutischen Industrie (BPI)
Veröffentlicht am: *03 - März - 2022*
Weitere Informationen finden Sie unter:
https://www.pei.de/DE/newsroom/hp-meldungen/2022/220303-pei-bpi-meeting.html;jsessionid=ECA153456C0DB2FC5A76276DD9977E38.intranet221?nn=170852

Allergenimmuntherapie – viele Studien, wenige Zulassungen – woran liegt es?
Veröffentlicht am: *03 - März - 2022*
Weitere Informationen finden Sie unter:
https://www.pei.de/DE/newsroom/pm/jahr/2022/05-allergenimmuntherapie-viele-studien-viele-zulassungen-woran-liegt-es.html;jsessionid=F72E4D98A9005B4A08B1474A047FBEFD.intranet231?nn=172068

Humanarzneimittel - Österreich

PRAC signal recommendation - Pregabalin
Veröffentlicht am: *22 - Februar - 2021*
Weitere Informationen finden Sie unter:
https://www.basg.gv.at/fileadmin/redakteure/07_Unternehmen/PV-Mustertexte/220222_Mustertext_Pregabalin.pdf

PSUR-outcome - Azithromycin
Veröffentlicht am: *22 - Februar - 2021*
Weitere Informationen finden Sie unter:
https://www.basg.gv.at/fileadmin/redakteure/07_Unternehmen/PV-Mustertexte/220222_Mustertext_Azithromycin.pdf

PSUR-outcome - Tacrolimus (systemische Formulierungen)
Veröffentlicht am: *25 - Februar - 2021*
Weitere Informationen finden Sie unter:
https://ec.europa.eu/health/documents/community-register/html/ho27654.htm

96. Anlage der Geschäftsordnung des BASG
Veröffentlicht am: *23 - Februar - 2021*
Weitere Informationen finden Sie unter:
https://www.basg.gv.at/ueber-uns/basg-veroeffentlichungen/geschaeftsordnung#c3430

Vision, Werte und Strategie NEU
„Wir wollen eine der führenden Arzneimittelagenturen Europas sein.
Wir sind die zuständige nationale Aufsichtsbehörde für Arzneimittel, Medizinprodukte, Blut und Gewebe und Partner der zuständigen europäischen Aufsichtsbehörden und Agenturen.“
Veröffentlicht am: *03 - März - 2021*
Weitere Informationen finden Sie unter:
https://www.basg.gv.at/ueber-uns/vision-werte-und-strategie

Arzneimittel - Schweiz

Zulassungen von Humanarzneimitteln mit neuem Wirkstoff und Indikationserweiterungen 2021
Veröffentlicht am: *25 - Februar - 2022*
Weitere Informationen finden Sie unter:
https://www.swissmedic.ch/swissmedic/de/home/humanarzneimittel/authorisations/informationen/zl-ham-neue-ws-und-indiationserweiterungen-2021.html

Anpassung der VL Fachinformation TAM / Anpassung der VL Packungsbeilage TAM
„Die angepassten Vorlagen sind ab 1. März 2022 gültig“
Veröffentlicht am: *01 - März - 2022*
Weitere Informationen finden Sie unter:
https://www.swissmedic.ch/swissmedic/de/home/tierarzneimittel/informationen/anpassungen-vorlagen-fi-pi-tam.html

Medizinprodukte Datenbank
„Beachten Sie bitte die Informationen zur Medizinprodukte Datenbank“
Veröffentlicht am: *01 - März - 2022*
Weitere Informationen finden Sie unter:
https://www.swissmedic.ch/swissmedic/de/home/medizinprodukte/medizinprodukte-datenbank.html

Update Merkblatt - Einmalige Identifikationsnummer (CHRN – Swiss Single Registration Number)
Veröffentlicht am: *03 - März - 2022*
Weitere Informationen finden Sie unter:
https://www.swissmedic.ch/swissmedic/de/home/medizinprodukte/marktzugang/registriernummer-chrn.html

Aktualisierte Vorgabedokumente – Februar und März
„-ZL000_00_022d_WL Wegleitung Zulassung nach Art. 14 Abs. 1 Bst. abis-quater HMG HMV4 (28.02.2022)
-ZL000_00_023d_WL Wegleitung Pädiatrisches Prüfkonzept HMV4 (25.02.2022)
-BW630_10_003d_MB Einmalige Identifikationsnummer - CHRN (03.03.2022)
-BW690_00_002d_WL Exportzertifikate (03.03.2022)“
Veröffentlicht am: *03 - März - 2022*
Weitere Informationen finden Sie unter:
https://www.swissmedic.ch/swissmedic/de/home/news/updates/updated_documents/feb-2022.html und
https://www.swissmedic.ch/swissmedic/de/home/news/updates/updated_documents/maerz-2022.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

How to DiGA: Webinare mit Anforderungen, Erfahrungen und Tipps aus der DiGA-Antragsbewertung
Where: *Virtual meeting*
Date:
22 - März – 2022, 09:30 bis 12:30 Uhr, „Datensicherheit bei DiGA“
04 - Mai – 2022, 09:30 bis 12:30 Uhr, „Datensicherheit bei DiGA“
23 - September – 2022, 09:30 bis 12:30 Uhr, „Interoperabilität bei DiGA“
For more information, please refer to:
https://www.bfarm.de/DE/Medizinprodukte/Aufgaben/DiGA/Webinare/_artikel.html

BfArM im Dialog „Anwenderforum SNOMED CT“
Where: *Virtual meeting*
Date: *12- Mai – 2022, 10.00 – 14.00 Uhr*
For more information, please refer to:
https://www.bfarm.de/DE/Aktuelles/Veranstaltungen/Termine/snomed_anwenderforum_2022-05-12.html

Österreich

AGES Online-Course "R for Data Science – Basic" (2 days)
Where: *Virtual meeting*
Date: *06 to 07 - April – 2022, 09:00 bis 17:00 Uhr*
For more information, please refer to:
https://www.ages.at/ages/veranstaltungen/veranstaltungskalender/detail/ages-online-course-r-for-data-science-basic-2-days

Schweiz

Keine Veranstaltungen veröffentlicht

Europa

HPP webinar - The ‘State of Health in the EU’ in Slovakia (08 March 2022, 09:00 – 10:00 CET)
Where: *Online*
Date: *08 - March - 2022, 09:00 - 10:00 Amsterdam time (CEST)*
For more information, please refer to:
https://ec.europa.eu/health/latest-updates/hpp-webinar-state-health-eu-slovakia-08-march-2022-0900-1000-cet-2022-03-01_en

Veranstaltungen / Events – Behörden und andere Veranstalter

Introduction to Organisation Management Service (OMS) and Referentials Management Service (RMS) services and activities: Industry webinar
Where: *Online*
Date: *10 - March - 2022, 10:00 - 12:00 and 14:00 - 16:00 Amsterdam time (CEST)*
For more information, please refer to:
https://www.ema.europa.eu/en/events/introduction-organisation-management-service-oms-referentials-management-service-rms-services-0

System demo: digital application dataset integration (DADI) and Product Management Service (PMS)
Where: *Virtual meeting*
Date: *15 - March – 2022, 09:00 - 11:00 Amsterdam time (CET)*
For more information, please refer to:
https://www.ema.europa.eu/en/events/system-demo-digital-application-dataset-integration-dadi-product-management-service-pms

HPP Webinar - Addressing climate change impacts on health through national policies
Where: *Virtual meeting*
Date: *16 - March – 2022, 10:00 - 11:15 Amsterdam time (CET)*
For more information, please refer to:
https://ec.europa.eu/health/latest-updates/hpp-webinar-addressing-climate-change-impacts-health-through-national-policies-16-march-2022-1000-2022-02-18_en

Webinar on requesting access to and using EMA's substance, product, organisation and referential (SPOR) application programming interface (API)
Where: *Online*
Date: *18 - March - 2022, 14:00 - 16:00 Amsterdam time (CEST)*
For more information, please refer to:
https://www.ema.europa.eu/en/events/webinar-requesting-access-using-emas-substance-product-organisation-referential-spor-application

Clinical Trials Information System (CTIS) bitesize talk: Initial clinical trial application
Where: *Online*
Date: *23 - March - 2022*
For more information, please refer to:
https://www.ema.europa.eu/en/events/clinical-trials-information-system-ctis-bitesize-talk-initial-clinical-trial-application

HPP Webinar - Fighting access to health inequalities by improving health worker retention and task shifting policies (29 March 2022, 14.30 - 16.30 pm CET)
Where: *Online*
Date: *29 - March – 2022, 14:30 - 16:30 Amsterdam time (CEST)*
For more information, please refer to:
https://ec.europa.eu/health/latest-updates/hpp-webinar-fighting-access-health-inequalities-improving-health-worker-retention-and-task-shifting-2022-02-18_en

Veranstaltungen / Events – Behörden und andere Veranstalter

How to communicate efficiently with the EDQM on CEP applications
Where: *Virtual meeting*
Date: *29 - March – 2022, 10 a.m. to 11:15 a.m. (CEST)*
For more information, please refer to:
https://www.edqm.eu/en/events/how-communicate-efficiently-edqm-cep-applications

Multistakeholder workshop on EMA's extended mandate
Where: *Online*
Date: *01 - April - 2022, 09:00 a.m. - 16:15 p.m. Amsterdam time (CET)*
For more information, please refer to:
https://www.ema.europa.eu/en/events/multistakeholder-workshop-emas-extended-mandate

Getting the big picture: what has changed in the Ph. Eur. General Notices
Where: *Online*
Date: *07 - April - 2022, 2 p.m. to 3:15 p.m. (CEST)*
For more information, please refer to:
https://www.edqm.eu/en/events/getting-big-picture-what-has-changed-ph-eur-general-notices

Clinical Trials Information System (CTIS) bitesize talk: Modifications
Where: *Virtual meeting*
Date: *28 - April – 2022, 14:00 - 15:00 Amsterdam time (CET)*
For more information, please refer to:
https://www.ema.europa.eu/en/events/clinical-trials-information-system-ctis-bitesize-talk-modifications

CTIS sponsor user training programme - six separate courses
Where: *Online*
Dates:
05 - 08 April 2022, 14:00 - 18:30 (CEST)
10 - 13 May 2022, 09:00 - 13:30 (CEST)
20 - 23 June 2022, 14:00 - 18:30 (CEST)
For more information, please refer to:
https://www.ema.europa.eu/documents/agenda/programme-clinical-trials-information-system-ctis-sponsor-end-user-training-programme-2022_en.pdf

Mandatory use of ISO/ICH E2B(R3) individual case safety reporting in the EU: Hands-on training course on using the EudraVigilance system
Where: *Online meeting*
Dates:
14 to 18 - March - 2022
04 to 08 - April - 2022
18 to 20 - May - 2022
13 to 17 - June - 2022
04 to 08 - July - 2022
For more information, please refer to:
https://www.ema.europa.eu/en/human-regulatory/research-development/pharmacovigilance/eudravigilance/eudravigilance-training-support

Veranstaltungen / Events – Behörden und andere Veranstalter

Virtual live hands-on training course for Clinical Trials Sponsors using EudraVigilance system
Where: *Virtual meeting*
Date: *04 to 06 - May - 2022*
For more information, please refer to:
https://www.ema.europa.eu/en/events/virtual-live-hands-training-course-clinical-trials-sponsors-using-eudravigilance-system-0

SAVE THE DATE! Conference celebrating the publication of the 11th Edition of the European Pharmacopoeia
Where: *Virtual meeting*
Date: *19 to 20 - September - 2022*
For more information, please refer to:
https://www.edqm.eu/en/news/save-date-conference-celebrating-publication-11th-edition-european-pharmacopoeia-19-21