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<u>Urheberrechtshinweis:</u>	

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Allgemeines – General

The adjustment of the fees of the European Medicines Agency to the inflation rate with effect from 1 April 2022

“Regulatory and procedural guideline and Explanatory note are available”

Published on: 01 - April - 2022

For more information, please refer to:

https://www.ema.europa.eu/documents/other/explanatory-note-general-fees-payable-european-medicines-agency-01-april-2022_en.pdf and

https://www.ema.europa.eu/documents/regulatory-procedural-guideline/commission-regulation-eu-2022/510-29-march-2022-amending-council-regulation-ec-no-297/95-regards-adjustment-fees-european-medicines-agency-inflation-rate-effect-1-april-2022_en.pdf

PRIME: Analysis of the first 5 years' experience (updated)

Published on: 05 - April - 2022

For more information, please refer to:

https://www.ema.europa.eu/documents/report/prime-analysis-first-5-years-experience_en.pdf

Multistakeholder workshop on EMA's extended mandate, Online, from 01/04/2022 to 01/04/2022 (updated)

“Video records available”

Published on: 05 - April - 2022

For more information, please refer to:

<https://www.ema.europa.eu/en/events/multistakeholder-workshop-emas-extended-mandate>

Procurement (updated)

Published on: 11 - April - 2022

For more information, please refer to:

<https://www.ema.europa.eu/en/about-us/procurement>

Work programme: European collaboration between regulators and health technology assessment bodies - Joint work plan (2021-2023) between EMA and European HTA bodies facilitated through EUnetHTA21

Published on: 12 - April - 2022

For more information, please refer to:

https://www.ema.europa.eu/documents/work-programme/european-collaboration-between-regulators-health-technology-assessment-bodies-joint-work-plan-2021_en.pdf

Health technology assessment bodies (updated)

Published on: 12 - April - 2022

For more information, please refer to:

<https://www.ema.europa.eu/en/partners-networks/health-technology-assessment-bodies>

PRAC recommendations on signals adopted at the 7-10 March 2022 PRAC meeting

Published on: 04 - April - 2022

For more information, please refer to:

https://www.ema.europa.eu/documents/prac-recommendation/prac-recommendations-signals-adopted-7-10-march-2022-prac-meeting_en.pdf

EudraVigilance eXtended Medicinal Product Dictionary (XEVMPPD) (updated)

Published on: 06 - April - 2022

For more information, please refer to:

https://www.ema.europa.eu/documents/other/eudravigilance-extended-medicinal-product-dictionary-xevmpd-organisations_en.xls (organisations)

https://www.ema.europa.eu/documents/other/eudravigilance-extended-medicinal-product-dictionary-xevmpd-pharmaceutical-dose-forms_en.xls (pharmaceutical)

https://www.ema.europa.eu/documents/other/eudravigilance-extended-medicinal-product-dictionary-xevmpd-substances_en.xlsx (substances)

Meeting highlights from the Pharmacovigilance Risk Assessment Committee (PRAC) 4-7 April 2022

Published on: 08 - April - 2022

For more information, please refer to:

<https://www.ema.europa.eu/en/news/meeting-highlights-pharmacovigilance-risk-assessment-committee-prac-4-7-april-2022>

Referral: Terlipressin-containing medicinal products indicated in the treatment of hepatorenal syndrome , terlipressin, Article 31 referrals, Under evaluation, 11/04/2022 (updated)

Published on: 11 - April - 2022

For more information, please refer to:

<https://www.ema.europa.eu/en/medicines/human/referrals/terlipressin-containing-medicinal-products-indicated-treatment-hepatorenal-syndrome>

Referral: Nasolam and associated names , midazolam, Article 29(4) referrals, European Commission final decision, 27/01/2022, 01/04/2022, 12/04/2022 (updated)

Published on: 12 - April - 2022

For more information, please refer to:

<https://www.ema.europa.eu/en/medicines/human/referrals/nasolam-associated-names>

Regulatory and procedural guideline: Detailed guidance on ICSRs in the context of COVID-19 - Validity and coding of ICSRs (updated)

Published on: 13 - April - 2022

For more information, please refer to:

https://www.ema.europa.eu/documents/regulatory-procedural-guideline/detailed-guidance-icsrs-context-covid-19-validity-coding-icsrs_en.pdf

Zulassung – Regulatory Affairs

Regulatory and procedural guideline: European Medicines Agency guidance for applicants seeking scientific advice and protocol assistance (updated)

Published on: 04 - April - 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: Guidance on Irish language derogation ending on 1 January 2022 (updated)

Published on: 07 - April - 2022

For more information, please refer to:

https://www.ema.europa.eu/documents/regulatory-procedural-guideline/guidance-irish-language-derogation-ending-1-january-2022_en.pdf

Regulatory and procedural guideline: IRIS guide for applicants - How to create and submit scientific applications, for industry and individual applicants (updated)

Published on: 11 - April - 2022

For more information, please refer to:

https://www.ema.europa.eu/documents/regulatory-procedural-guideline/iris-guide-applicants-how-create-submit-scientific-applications-industry-individual-applicants_en.pdf

Template or form: PRIME eligibility request: applicant's justification template (updated)

Published on: 06 - April - 2022

For more information, please refer to:

https://www.ema.europa.eu/documents/template-form/prime-eligibility-request-applicants-justification-template_en.doc

Applications for new human medicines under evaluation by the CHMP: April 2022

Published on: 08 - April - 2022

For more information, please refer to:

https://www.ema.europa.eu/documents/report/applications-new-human-medicines-under-evaluation-chmp-april-2022_en.xlsx

Frequently asked questions about parallel distribution (updated)

Published on: 12 - April - 2022

For more information, please refer to:

<https://www.ema.europa.eu/en/human-regulatory/post-authorisation/parallel-distribution/frequently-asked-questions-about-parallel-distribution>

Orphan Drugs und neuartige Therapierichtungen (ATMP)

Minutes of the COMP meeting on 15-17 February 2022

Published on: 06 - April - 2022

For more information, please refer to:

https://www.ema.europa.eu/documents/minutes/minutes-comp-meeting-15-17-february-2022_en.pdf

Humanarzneimittel - EMA

Agenda - CAT agenda of the 11-13 April 2022 meeting

Published on: 11 - April - 2022

For more information, please refer to:

https://www.ema.europa.eu/documents/agenda/agenda-cat-agenda-11-13-april-2022-meeting_en.pdf

Agenda - COMP agenda of the 11-13 April 2022 meeting

Published on: 11 - April - 2022

For more information, please refer to:

https://www.ema.europa.eu/documents/agenda/agenda-comp-agenda-11-13-april-2022-meeting_en.pdf

Qualität – Quality

Good manufacturing practice (updated)

Published on: 06 - April - 2022

For more information, please refer to:

<https://www.ema.europa.eu/en/human-regulatory/research-development/compliance/good-manufacturing-practice>

(Prä-) Klinische Forschung – Research and Development

Roles and permissions matrix summary - CTIS Training Programme - Module 07 (updated)

Published on: 04 - April - 2022

For more information, please refer to:

https://www.ema.europa.eu/documents/other/roles-permissions-matrix-summary-authority-workspace-ctis-training-programme-module-07_en.pdf (Authority workspace)

https://www.ema.europa.eu/documents/other/roles-permissions-matrix-summary-sponsors-workspace-ctis-training-programme-module-07_en.pdf (Sponsors workspace)

https://www.ema.europa.eu/documents/other/sponsors-business-processes-roles-ctis-training-programme-module-07_en.pdf (Sponsors business processes and roles)

https://www.ema.europa.eu/documents/other/member-states-business-processes-roles-ctis-training-programme-module-07_en.pdf (Member states business processes and roles)

Good clinical practice (updated)

Published on: 06 - April - 2022

For more information, please refer to:

<https://www.ema.europa.eu/en/human-regulatory/research-development/compliance/good-clinical-practice>

Humanarzneimittel - EMA

Transition of trials from EudraCT to CTIS - CTIS Training Programme - Module 23 (updated)

Published on: 08 - April - 2022

For more information, please refer to:

https://www.ema.europa.eu/documents/other/member-states-guide-transition-trials-eudract-ctis-ctis-training-programme-module-23_en.pdf (Member states' guide)

https://www.ema.europa.eu/documents/other/faqs-transition-trials-eudract-ctis-ctis-training-programme-module-23_en.pdf (FAQs)

https://www.ema.europa.eu/documents/other/sponsors-guide-transition-trials-eudract-ctis-ctis-training-programme-module-23_en.pdf (Sponsors' guide)

FAQs: How to create, submit and withdraw a Clinical Trial Application - CTIS Training Programme - Module 10 (updated)

Published on: 11 - April - 2022

For more information, please refer to:

https://www.ema.europa.eu/documents/other/faqs-how-create-submit-withdraw-clinical-trial-application-ctis-training-programme-module-10_en.pdf

Draft guidance document on how to approach the protection of personal data and commercially confidential information in documents uploaded and published in the Clinical Trial Information System (CTIS)

Published on: 08 - April - 2022

For more information, please refer to:

https://www.ema.europa.eu/documents/other/draft-guidance-document-how-approach-protection-personal-data-commercially-confidential-information_en.pdf

Newsletter: CTIS newsflash - April 2022

Published on: 11 - April - 2022

For more information, please refer to:

https://www.ema.europa.eu/documents/newsletter/ctis-newsflash-1-april-2022_en.pdf (1 April)
and

https://www.ema.europa.eu/documents/newsletter/ctis-newsflash-8-april-2022_en.pdf (8 April)

Template or form: Innovation Task Force (ITF) briefing meeting request form (updated)

Published on: 11 - April - 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

Parallel joint scientific consultation with regulators and health technology assessment bodies (updated)

Published on: 12 - April - 2022

For more information, please refer to:

<https://www.ema.europa.eu/en/human-regulatory/research-development/scientific-advice-protocol-assistance/parallel-joint-scientific-consultation-regulators-health-technology-assessment-bodies>

Humanarzneimittel - EMA

Clinical trials in human medicines (updated)

Published on: 13 - April - 2022

For more information, please refer to:

<https://www.ema.europa.eu/en/human-regulatory/research-development/clinical-trials-human-medicines>

Impact of the war in Ukraine on methodological aspects of ongoing clinical trials

Published on: 13 - April - 2022

For more information, please refer to:

<https://www.ema.europa.eu/en/impact-war-ukraine-methodological-aspects-ongoing-clinical-trials>

Kinderarzneimittel – Paediatrics

Minutes: PDCO meeting report of opinions on paediatric investigation plans and other activities 18-21 January 2022

Published on: 04 - April - 2022

For more information, please refer to:

https://www.ema.europa.eu/documents/minutes/pdco-meeting-report-opinions-paediatric-investigation-plans-other-activities-18-21-january-2022_en.pdf

Scientific guideline: Draft ICH guideline E11A on pediatric extrapolation Step 2b

Published on: 06 - April - 2022

For more information, please refer to:

https://www.ema.europa.eu/documents/scientific-guideline/draft-ich-guideline-e11a-pediatric-extrapolation-step-2b_en.pdf

Paediatric medicines: Overview (updated)

Published on: 08 - April - 2022

For more information, please refer to:

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

Agenda - Enpr-EMA Coordinating Group and networks meeting

Published on: 11 - April - 2022

For more information, please refer to:

https://www.ema.europa.eu/documents/agenda/agenda-enpr-ema-coordinating-group-networks-meeting_en.pdf

Report: PDCO meeting report of opinions on paediatric investigation plans and other activities 22-25 February 2022

Published on: 12 - April - 2022

For more information, please refer to:

https://www.ema.europa.eu/documents/report/pdco-meeting-report-opinions-paediatric-investigation-plans-other-activities-22-25-february-2022_en.pdf

Pflanzliche Arzneimittel – Herbal medicines

Herbal - Call for data: Call for scientific data for the periodic review of the monograph on Sideritis herba - Revision 1

Published on: 13 - April - 2022

For more information, please refer to:

https://www.ema.europa.eu/documents/herbal-call-data/call-scientific-data-periodic-review-monograph-sideritis-herba-revision-1_en.pdf

Herbal - Call for data: Call for scientific data for the periodic review of the monograph on Sisymbrii officinalis herba - Revision 1

Published on: 13 - April - 2022

For more information, please refer to:

https://www.ema.europa.eu/documents/herbal-call-data/call-scientific-data-periodic-review-monograph-sisymbrii-officinalis-herba-revision-1_en.pdf

Herbal - Call for data: Call for scientific data for the periodic review of the monograph on Symphyti radix - Revision 1

Published on: 13 - April - 2022

For more information, please refer to:

https://www.ema.europa.eu/documents/herbal-call-data/call-scientific-data-periodic-review-monograph-symphyti-radix-revision-1_en.pdf

HMPC meeting report on European Union herbal monographs, guidelines and other activities - 28-30 March 2022

Published on: 13 - April - 2022

For more information, please refer to:

https://www.ema.europa.eu/documents/report/hmpc-meeting-report-european-union-herbal-monographs-guidelines-other-activities-28-30-march-2022_en.pdf

European Commission

EU non-communicable diseases (NCDs) initiative: Frequently asked questions

Published on: 01 - April - 2022

For more information, please refer to:

https://ec.europa.eu/health/system/files/2022-04/ncd_initiative_faq_en.pdf

Healthier Together Initiative: call for best practices on non-communicable diseases

“To support EU countries with reducing the burden of non-communicable diseases and improving citizens’ health, the European Commission invites governmental and non-governmental actors to submit proposals for best practices via the EU Best Practice Portal by 15 May 2022 (midnight CET).”

Published on: 01 - April - 2022

For more information, please refer to:

<https://ec.europa.eu/newsroom/sante/newsletter-archives/37183>

Presentations - Meeting of the Subgroup on Cancer (24 March 2022)

Published on: 04 - April - 2022

For more information, please refer to:

https://ec.europa.eu/health/latest-updates/presentations-meeting-subgroup-cancer-24-march-2022-2022-04-04_en

Minutes - 3rd drafting group meeting on managing AMR across the health system (8 March 2022)

Published on: 05 - April - 2022

For more information, please refer to:

https://ec.europa.eu/health/latest-updates/minutes-3rd-drafting-group-meeting-managing-amr-across-health-system-8-march-2022-2022-04-05_en

EU develops strategic reserves for chemical, biological and radio-nuclear emergencies

Published on: 06 - April - 2022

For more information, please refer to:

https://ec.europa.eu/commission/presscorner/detail/en/ip_22_2218

Minutes - 21st meeting of the Board of Member States on ERNs (28 October 2021)

Published on: 07 - April - 2022

For more information, please refer to:

https://ec.europa.eu/health/latest-updates/minutes-21st-meeting-board-member-states-erns-28-october-2021-2022-04-07_en

Minutes - 22nd meeting of the Board of Member States on ERNs (26 November 2021)

Published on: 07 - April - 2022

For more information, please refer to:

https://ec.europa.eu/health/latest-updates/minutes-22nd-meeting-board-member-states-erns-26-november-2021-2022-04-07_en

Minutes - 23rd meeting of the Board of Member States on ERNs (26 January 2022)

Published on: 07 - April - 2022

For more information, please refer to:

https://ec.europa.eu/health/latest-updates/minutes-23rd-meeting-board-member-states-erns-26-january-2022-2022-04-07_en

Flash report - Meeting of the Sub-group on the EU NCD Initiative (8 April 2022)

Published on: 11 - April - 2022

For more information, please refer to:

https://ec.europa.eu/health/latest-updates/flash-report-meeting-sub-group-eu-ncd-initiative-8-april-2022-2022-04-11_en

Questions and Answers Document – Regulation (EU) 536/2014 – Version 6 April 2022)

Published on: 13 - April - 2022

For more information, please refer to:

https://ec.europa.eu/health/latest-updates/questions-and-answers-document-regulation-eu-5362014-version-6-april-2022-2022-04-13_en

Flash report - Meeting of the Subgroup on Cancer (24 March 2022)

Published on: 13 - April - 2022

For more information, please refer to:

https://ec.europa.eu/health/latest-updates/flash-report-meeting-subgroup-cancer-24-march-2022-2022-04-13_en

Pharmeuropa 34.2 just released

"All new European Pharmacopoeia (Ph. Eur.) texts and texts that have undergone technical revisions are published in Pharmeuropa for public consultation. The deadline for comments on Pharmeuropa 34.2 is 30 June 2022."

Published on: 04 - April - 2022

For more information, please refer to:

<https://www.edqm.eu/en/-/pharmeuropa-34.2-just-released>

Call for experts: join the Ph. Eur. network!

„The European Pharmacopoeia (Ph. Eur.) is seeking independent scientific experts to join its groups of experts and working parties.“

Published on: 06 - April - 2022

For more information, please refer to:

<https://www.edqm.eu/en/-/call-for-experts-join-the-ph.-eur.-network-2>

EDQM helping increase tissue donation thanks to a better understanding of post-mortem blood testing practices

Published on: 07 - April - 2022

For more information, please refer to:

<https://www.edqm.eu/en/-/edqm-helping-increase-tissue-donation-thanks-to-a-better-understanding-of-post-mortem-blood-testing-practices>

CEP holders invited to comment on draft monographs published in Pharmeuropa 34.2

"Holders of Certificates of suitability to the monographs of the European Pharmacopoeia (CEPs) are requested to consult the list of substances for which draft revised monographs of the European Pharmacopoeia (Ph. Eur.) have been published in Pharmeuropa 34.2."

Published on: 07 - April - 2022

For more information, please refer to:

<https://www.edqm.eu/en/-/cep-holders-invited-to-comment-on-draft-monographs-published-in-pharmeuropa-34.2>

Outcome of the 172nd session of the European Pharmacopoeia Commission, March 2022

„The European Pharmacopoeia (Ph. Eur.) Commission held its 172nd session on 22 and 23 March 2022. The Commission adopted 78 texts at this session, to be published in Ph. Eur. Supplement 11.1 and be effective as of 1 April 2023.“

Published on: 11 - April - 2022

For more information, please refer to:

<https://www.edqm.eu/en/-/outcome-of-the-172nd-session-of-the-european-pharmacopoeia-commission-march-2022-1>

EDQM sticker no longer to appear on Certificates of suitability

Published on: 12 - April - 2022

For more information, please refer to:

<https://www.edqm.eu/en/-/edqm-sticker-no-longer-to-appear-on-certificates-of-suitability>

New Pharmeuropa Bio & Scientific Notes article now online: Human immunoglobulin for ACA BRP

„A new scientific article on the outcome of a recently concluded Biological Standardisation Programme (BSP) study has been published in Pharmeuropa Bio & Scientific Notes 2022.“

Published on: 13 - April - 2022

For more information, please refer to:

<https://www.edqm.eu/en/-/new-pharmeuropa-bio-scientific-notes-article-now-online-human-immunoglobulin-for-aca-brp>

New general text on comparability of alternative analytical procedures: European Pharmacopoeia launches public consultation

Published on: 13 - April - 2022

For more information, please refer to:

<https://www.edqm.eu/en/-/new-general-text-on-comparability-of-alternative-analytical-procedures-european-pharmacopoeia-launches-public-consultation>

Medizinprodukte

Update - Joint implementation and preparedness plan for Regulation (EU) 2017/746 on in vitro diagnostic medical devices (IVDR)

Published on: 01 - April - 2022

For more information, please refer to:

https://ec.europa.eu/health/latest-updates/update-joint-implementation-and-preparedness-plan-regulation-eu-2017746-vitro-diagnostic-medical-2022-04-01_en

The EUDAMED UDI/Devices module updated technical documentation is available

Published on: 11 - April - 2022

For more information, please refer to:

https://ec.europa.eu/health/latest-updates/eudamed-udid-devices-module-updated-technical-documentation-available-2022-04-11_en

The EUDAMED NBs & Certificates module updated technical documentation is available

Published on: 11 - April - 2022

For more information, please refer to:

https://ec.europa.eu/health/latest-updates/eudamed-nbs-certificates-module-updated-technical-documentation-available-2022-04-11_en

Notice to Stakeholders EU-Turkey Customs Union Agreement in the field of medical devices

Published on: 13 - April - 2022

For more information, please refer to:

https://ec.europa.eu/health/latest-updates/notice-stakeholders-eu-turkey-customs-union-agreement-field-medical-devices-2022-04-13_en

Clinical Trials Coordination Group (CTCG)

Published on: 01 - April - 2022

For more information, please refer to:

<https://www.hma.eu/about-hma/working-groups/clinical-trials-coordination-group.html#c7038>

Working Groups Human

Published on: 01 - April - 2022

For more information, please refer to:

<https://www.hma.eu/about-hma/working-groups.html#c4160>

CTCG RECOMMENDATION TO SPONSORS ON MANAGING THE IMPACT OF THE WAR IN UKRAINE ON CLINICAL TRIALS

Published on: 04 - April - 2022

For more information, please refer to:

<https://www.hma.eu/about-hma/recently-published.html#c7051>

CTCG News and events

Published on: 04 - April - 2022

For more information, please refer to:

<https://www.hma.eu/about-hma/working-groups/clinical-trials-coordination-group/clinical-trials-coordination-group.html#c7039>

HMA/EMA Joint Big Data Steering Group

Published on: 07 - April - 2022

For more information, please refer to:

<https://www.hma.eu/about-hma/working-groups/hma/ema-joint-big-data-steering-group.html#c5624>

CMDh Press Releases 2016/2017/2018/2019

Published on: 11 - April - 2022

For more information, please refer to:

<https://www.hma.eu/human-medicines/cmdh/press-releases/archive-2000-2019/2019.html#c6435>

<https://www.hma.eu/human-medicines/cmdh/press-releases/archive-2000-2019/2018.html#c6305>

<https://www.hma.eu/human-medicines/cmdh/press-releases/archive-2000-2019/2017.html#c5603>

<https://www.hma.eu/human-medicines/cmdh/press-releases/archive-2000-2019/2016.html#c6304>

Humanarzneimittel - Deutschland

Aktuell laufende und bestätigte Arzneimittel-Härtefallprogramme

Veröffentlicht am: 01 - April - 2022

Weitere Informationen finden Sie unter:

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

PSUR Single Assessment (PSUSA)

„Informationen und Hinweise zum Ergebnis einzelner Verfahren des PSUR Single Assessment (PSUSA).“

Veröffentlicht am: 01 - April - 2022

Weitere Informationen finden Sie unter:

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

Pharmakogenomik

„Das Forschungsgebiet Pharmakogenomik und individualisierte Pharmakotherapie beschäftigt sich mit der Variabilität von Arzneimittelwirkungen bei Patientinnen und Patienten, die durch angeborene genetische Unterschiede verursacht wird.“

Veröffentlicht am: 01 - April - 2022

Weitere Informationen finden Sie unter:

https://www.bfarm.de/DE/Das-BfArM/Aufgaben/Forschung/Pharmakogenomik/_artikel.html?nn=986770

Wirkstoffe und Arzneimittel, für die die Erstellung von Schulungsmaterialien beauftragt worden ist

Veröffentlicht am: 01 - April - 2022

Weitere Informationen finden Sie unter:

<https://www.bfarm.de/SharedDocs/Downloads/DE/Arzneimittel/Pharmakovigilanz/Risikoinformationen/EducationMaterial/Tabelle-educatmaterial.html?nn=986770>

Arzneimittel-Festbeträge

„Die neue Festbetragsdatei steht zur Verfügung.“

Veröffentlicht am: 05 - April - 2022

Weitere Informationen finden Sie unter:

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

Liste der PRAC-Empfehlungen zu Textanpassungen

„Textanpassungen“

Veröffentlicht am: 05 - April - 2022

Weitere Informationen finden Sie unter:

https://www.bfarm.de/SharedDocs/Downloads/DE/Arzneimittel/Pharmakovigilanz/Risikoinformationen/textanpassung/Signalbewertung/Textanpassung_PRAC-Empfehlung.html?nn=986770

Humanarzneimittel - Deutschland

Abkürzungsverzeichnis der Wirkstoffkürzel

Veröffentlicht am: 05 - April - 2022

Weitere Informationen finden Sie unter:

https://www.bfarm.de/SharedDocs/Downloads/DE/Arzneimittel/Zulassung/amInformationen/Festbeurteilung/2022/berechnungsgrundlage/quartal2/wirkstoffkuerzel-20220401_txt.html?nn=986770 und https://www.bfarm.de/SharedDocs/Downloads/DE/Arzneimittel/Zulassung/amInformationen/Festbeurteilung/2022/berechnungsgrundlage/quartal2/wirkstoffkuerzel-20220401_xls.html?nn=986770 (Excel-Format)

Liste der Veröffentlichungen von Zusammenfassungen von Risikomanagementplänen nach § 34 Abs. 1a AMG, Stand 01.04.2022

Veröffentlicht am: 05 - April – 2022

Weitere Informationen finden Sie unter:

<https://www.bfarm.de/SharedDocs/Downloads/DE/Arzneimittel/Pharmakovigilanz/Risikoinformationen/RMP/liste-rmp-summary.html?nn=986770>

Liste der versorgungskritischen Wirkstoffe gemäß § 52b Absatz 3c AMG

Veröffentlicht am: 07 - April – 2022

Weitere Informationen finden Sie unter:

https://www.bfarm.de/SharedDocs/Downloads/DE/Arzneimittel/Zulassung/amInformationen/Lieferengpaesse/Liste_versorgungskritischer_wirkstoffe.html?nn=986770

Niederschrift für die 25. Beratung der Deutschen Homöopathischen Arzneibuch-Kommission (2. Sitzung in der 6. Arbeitsperiode) am 26. Januar 2022 in Bonn

Veröffentlicht am: 13 - April – 2022

Weitere Informationen finden Sie unter:

https://www.bfarm.de/DE/Arzneimittel/Zulassung/Zulassungsrelevante-Themen/Arzneibuch/Arzneibuchkommissionen/Homoeopathische-Arzneibuch-Kommission/Protokolle/25_Niederschrift.html?nn=986770

Humanarzneimittel - Österreich

Referral: Etifoxin NEU

Veröffentlicht am: 01 - April – 2022

Weitere Informationen finden Sie unter:

<https://ec.europa.eu/health/documents/community-register/html/ho27690.htm>

Klinische Studien und der Krieg in der Ukraine NEU

„Klinische Studien und der Krieg in der Ukraine Neu Einleitung“

Veröffentlicht am: 05 - April – 2022

Weitere Informationen finden Sie unter:

<https://www.basq.gv.at/konsumentinnen/klinische-studien/klinische-studien-und-der-krieg-in-der-ukraine> und

<https://www.basq.gv.at/gesundheitsberufe/klinische-studien/klinische-pruefungen-under-krieg-in-der-ukraine>

97. Anlage der Geschäftsordnung des BASG NEU

Veröffentlicht am: 05 - April – 2022

Weitere Informationen finden Sie unter:

https://www.basq.gv.at/fileadmin/redakteure/01_Formulare_Listen/M/L_M72_Anlage_Geschaeftsordnung_97.pdf

PRAC signal recommendation: Calcineurin-Inhibitoren zur systemischen Anwendung (Ciclosporin, Tacrolimus) und Inhibitoren von mTOR (mammalian Target of Rapamycin) zur systemischen Anwendung (Everolimus, Sirolimus, Temsirolimus) NEU

Veröffentlicht am: 07 - April – 2022

Weitere Informationen finden Sie unter:

https://www.basq.gv.at/fileadmin/redakteure/07_Unternehmen/PV-Mustertexte/220407_Mustertext_Ciclosporin_Tacrolimus_Everolimus_Sirolimus_Temsirolimus.pdf und

<https://www.ema.europa.eu/en/human-regulatory/post-authorisation/pharmacovigilance/signal-management/prac-recommendations-safety-signals>

PSUR-outcome: Nimesulid (systemische Darreichungsformen) NEU

Veröffentlicht am: 12 - April – 2022

Weitere Informationen finden Sie unter:

https://www.ema.europa.eu/en/medicines/field_ema_web_categories%253Aname_field/Human/ema_group_types/ema_document-psusa/field_ema_regulatory_outcome%253Aname_field/Variation?sort=field_ema_computed_date_field&order=desc

PSUR-outcome: Tiagabin NEU

Veröffentlicht am: 12 - April – 2022

Weitere Informationen finden Sie unter:

https://www.ema.europa.eu/en/medicines/field_ema_web_categories%253Aname_field/Human/ema_group_types/ema_document-psusa/field_ema_regulatory_outcome%253Aname_field/Variation?sort=field_ema_computed_date_field&order=desc

Humanarzneimittel - Schweiz

Aktualisierung der Wegleitung PSUR / PBRER Information Einreichung

„Diese Wegleitung tritt am 01. April.2022 mit einer Übergangsfrist von 30 Tagen in Kraft.“

Veröffentlicht am: 01 - April - 2022

Weitere Informationen finden Sie unter:

<https://www.swissmedic.ch/swissmedic/de/home/humanarzneimittel/marktueberwachung/risk-management-rmps.html>

Swissmedic Journal Aktuelle Ausgabe - März 2022

Veröffentlicht am: 01 - April - 2022

Weitere Informationen finden Sie unter:

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

Ort: Virtual meeting

Termine:

04 - Mai – 2022, 09:30 bis 12:30 Uhr, „Datensicherheit bei DiGA“

23 - September – 2022, 09:30 bis 12:30 Uhr, „Interoperabilität bei DiGA“

Weitere Informationen finden Sie unter:

<https://www.bfarm.de/DE/Medizinprodukte/Aufgaben/DiGA/Webinare/artikel.html>

SNOMED-CT-Schulung für Entwicklerinnen und Entwickler

Ort: Virtual meeting

Termin: 04 - Mai – 2022, 09.00 – 16.00 Uhr

Weitere Informationen finden Sie unter:

https://www.bfarm.de/DE/Aktuelles/Veranstaltungen/Termine/snomed_entwicklerschulung_2022-05-04.html

IVDR: Neue Regelungen für IVD und therapiebegleitende Diagnostika (CDx) - Gemeinsame Dialogveranstaltung von PEI und BfArM

Ort: Maritim Hotel Bad Homburg, Deutschland

Termin: 11 - Mai – 2022 von 09.00 - 15.30 Uhr

Weitere Informationen finden Sie unter:

<https://www.bfarm.de/DE/Aktuelles/Veranstaltungen/Termine/2022-05-11-dialog-bfarm-pei.html?nn=986770>

BfArM im Dialog „Anwenderforum SNOMED CT“

Ort: Virtual meeting

Termin: 12 - Mai – 2022, 10.00 – 14.00 Uhr

Weitere Informationen finden Sie unter:

https://www.bfarm.de/DE/Aktuelles/Veranstaltungen/Termine/snomed_anwenderforum_2022-05-12.html

SNOMED-CT-Basiserschulung

Ort: Virtual meeting

Termin: 31 - Mai – 2022, 10.00 – 12.00 Uhr

Weitere Informationen finden Sie unter:

https://www.bfarm.de/DE/Aktuelles/Veranstaltungen/Termine/snomed_basiserschulung_2022-05-31.html

Veranstaltungen / Events – Behörden und andere Veranstalter

Österreich

BASG-Gespräch: Klinische Prüfungen von Medizinprodukten und Leistungsstudien von In-Vitro-Diagnostika Ort: Online

Termin: 27 - April - 2022 von 13:00 - 17:00 Uhr

Weitere Informationen finden Sie unter:

<https://www.ages.at/ages/veranstaltungen/veranstaltungskalender/detail/basg-gespraech-klinische-pruefungen-von-medizinprodukten-und-leistungsstudien-von-in-vitro-diagnostika>

BASG-Gespräch: Klinische Prüfung von Arzneimitteln

Ort: Online

Termin: 05 - Mai - 2022 von 13:00 - 17:00 Uhr

Weitere Informationen finden Sie unter:

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

BASG-Gespräch: Elektronische Meldung von Vertriebsbeschränkungen - Update 2022

Ort: Online

Termin: 09 - Juni - 2022 von 14:00 - 16:00 Uhr

Weitere Informationen finden Sie unter:

<https://www.ages.at/ages/veranstaltungen/veranstaltungskalender/detail/basg-gespraech-elektronische-meldung-von-vertriebseinschraenkungen-update-2022>

BASG-Gespräch: Gewebesicherheitsgesetz

Ort: Online

Termin: 21 - Juni - 2022 von 09:30 - 12:30 Uhr

Weitere Informationen finden Sie unter:

<https://www.ages.at/ages/veranstaltungen/veranstaltungskalender/detail/basg-gespraech-gewebesicherheitsgesetz>

GES Online-Kurs R for Data Science - Basiskurs

Ort: Online

Termin: 22 – 23 - Juni - 2022 von 09:00 - 17:00 Uhr

Weitere Informationen finden Sie unter:

<https://www.ages.at/ages/veranstaltungen/veranstaltungskalender/detail/ages-online-kurs-r-for-data-science-basiskurs>

GES Online-Kurs R for Data Science - Advanced

Ort: AGES Wien 20

Termine:

05 – 06 - Oktober - 2022 von 09:00 - 17:00 Uhr

09 – 10 – November - 2022 von 09:00 - 17:00 Uhr

Weitere Informationen finden Sie unter:

<https://www.ages.at/ages/veranstaltungen/veranstaltungskalender/detail/ages-kurs-r-for-data-science-advanced>

<https://www.ages.at/ages/veranstaltungen/veranstaltungskalender/detail/ages-online-course-r-for-data-science-advanced>

Veranstaltungen / Events – Behörden und andere Veranstalter

AGES Seminar „Einführung in Geographische Informationssysteme (GIS)“

Ort: AGES Wien 20

Termin: 13 - Oktober - 2022 von 09:00 - 17:00 Uhr

Weitere Informationen finden Sie unter:

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

Schweiz

Swissmedic Informationsveranstaltung «Regulatory & Beyond»

Ort: Hotel Allegro/Kursaal Bern

Termin: 20 - September - 2022 von 9.00 bis 17.30 Uhr

Weitere Informationen finden Sie unter:

<https://www.swissmedic.ch/swissmedic/de/home/services/veranstaltungen/regulatory-beyond.html>

Europa

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:

25 to 29 - 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>

Clinical Trials Information System (CTIS) bitesize talk: Requests for information (updated)

Where: Virtual meeting

Date: 28 - April – 2022, 14.00 – 15.30 CET

For more information, please refer to:

<https://www.ema.europa.eu/en/events/clinical-trials-information-system-ctis-bitesize-talk-requests-information>

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>

Veranstaltungen / Events – Behörden und andere Veranstalter

Enpr-EMA Coordinating Group and networks meeting (new)

Where: Online

Date: 03 - May – 2022, 14:00 - 15:30 Amsterdam time (CEST)

For more information, please refer to:

<https://www.ema.europa.eu/en/events/enpr-ema-coordinating-group-networks-meeting>

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>

Extended EudraVigilance medicinal product dictionary (XEVMPD) training course for clinical trial sponsors

Where: Online

Dates:

05 – May to 06 – May- 2022, 14:00 – 18:00 CEST

30 – June to 01 - July – 2022, 9:00 – 13.00 CEST

For more information, please refer to:

<https://www.ema.europa.eu/en/events/extended-eudravigilance-medicinal-product-dictionary-xevmpd-training-course-clinical-trial-sponsors-0>

<https://www.ema.europa.eu/en/events/extended-eudravigilance-medicinal-product-dictionary-xevmpd-training-course-clinical-trial-sponsors-1>

CTIS sponsor user training programme - six separate courses

Where: Online

Dates:

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

Quality requirements for nanomedicines: what role should the European Pharmacopoeia play?

Where: STRASBOURG, FRANCE

Date: 07 to 08 - June - 2022

For more information, please refer to:

<https://www.edqm.eu/en/news/new-edqm-event-quality-requirements-nanomedicines>

Veranstaltungen / Events – Behörden und andere Veranstalter

Save the date: 22 June 2022 - One-day conference on the new Regulation on Health Technology Assessment (HTA)

Where: Virtual meeting and on-site

Date: 22 - June - 2022

For more information, please refer to:

https://ec.europa.eu/health/latest-updates/save-date-22-june-2022-one-day-conference-new-regulation-health-technology-assessment-hta-2022-04-01_en

European Pharmacopoeia 11th Edition International Conference: early-bird registration now available

Where: Virtual meeting

Date: 19 to 20 - September - 2022

For more information, please refer to:

<https://www.edqm.eu/en/-/european-pharmacopoeia-11th-edition-international-conference-early-bird-registration-now-available>