20. – 31. Juli 2020

MEGRA NEWSLETTER

Humanarzneimittel - EU

Allgemeines – General

Launch of public consultation on joint network strategy to 2025

"EMA and the Heads of Medicines Agencies (HMA) have developed a joint strategy for the next five years that is released for a two-month public consultation today. The draft strategy details how the European medicines agencies' network can continue to enable the supply of safe and effective medicines that meet patients' needs in the face of challenges posed by ever-accelerating developments in science, medicine, digital technologies, globalisation as well as emerging health threats, such as the COVID-19 pandemic." […]

Published on: *06 - July - 2020*

For more information, please refer to:

Launch of public consultation on joint network strategy to 2025 | European Medicines Agency

COVID-19: What's new (updated)

Published on: *31 - July - 2020*

For more information, please refer to:

COVID-19: What's new | European Medicines Agency

Newsletters

Published on: *17 - July - 202*

For more information, please refer to:

Newsletters | European Medicines Agency

Pharmakovigilanz – PRAC

PRAC: Agendas, minutes and highlights

Published on: *31 - July - 2020*

For more information, please refer to:

PRAC: Agendas, minutes and highlights | European Medicines Agency

Regulatory and procedural guideline: EudraVigilance registration manual (updated) - EMA/13454/2020, Rev. 8

Published on: *23 – July – 2020*

For more information, please refer to:

https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/eudravigilance-registration-manual_en.pdf

List of medicines under additional monitoring (updated)

Published on: *29 – July – 2020*

For more information, please refer to:

List of medicines under additional monitoring | European Medicines Agency

Zulassung – Regulatory Affairs

Referral: Carbamazepin Tillomed , carbamazepin , Carbamazepin Tillomed,Carbamazepina Tillomed,Karbamazepin Tillomed,Karbamazepina Tillomed, Article 29(4) referrals, European Commission final decision, 30/04/2020, 25/06/2020, 21/07/2020 (updated)

"[…] Based on evaluation of the currently available data, the Agency concluded that the stricter limits were not needed for prolonged release formulations of carbamazepine medicines, since the slower release reduces variation in the blood levels of the medicine. The Agency therefore concluded that Carbamazepin Tillomed is bioequivalent to its reference medicine and that its benefits outweigh its

risks, and recommended that the marketing authorisation be granted in the concerned Member States." […]
***Pu*blished on**: *20 - July - 2020*
For more information, please refer to:
Carbamazepin Tillomed | European Medicines Agency

Referral: Fluorouracil and fluorouracil related substances (capecitabine, tegafur and flucytosine) containing medicinal products, capecitabine, fluorouracil, tegafur, flucytosine, Article 31 referrals, European Commission final decision, 30/04/2020, 07/07/2020, 23/07/2020 (updated)
"European Commission – final decision,
On 30 April 2020, EMA recommended that patients should be tested for the lack of the enzyme dihydropyrimidine dehydrogenase (DPD) before starting cancer treatment with fluorouracil given by injection or infusion (drip) or with the related medicines, capecitabine and tegafur.
As treatment for severe fungal infections with flucytosine (another medicine related to fluorouracil) should not be delayed, testing patients for DPD deficiency before they start treatment is not required. Patients who completely lack DPD must not be given any fluorouracil medicines. For patients with partial deficiency, the doctor may consider starting cancer treatment at lower doses than normal or stopping flucytosine treatment if severe side effects occur." […]
Pu*blished on: 23 - July - 2020*
For more information, please refer to:
Fluorouracil and fluorouracil related substances (capecitabine, tegafur and flucytosine) containing medicinal products | European Medicines Agency

Referral: Ibuprofen Kabi 400 mg Infusionslösung and associated names , ibuprofen , Ibuprofen Fresenius Kabi 400 mg oplossing voor infusie,Ibuprofen Fresenius Kabi 400 mg solution pour perfusion,Ibuprofen Kabi,Ibuprofen Kabi 400 mg oldatos infúzió,Ibuprofen Kabi 400 mg soluţie perfuzabilă,Ibuprofen Kabi 400 mg,Ibuprofen Kabi 400 mg raztopina za infundiranje,Ibuprofeno Kabi 400 mg solución para perfusion,Ibuprofen Kabi 400 mg Solution for Infusion, Article 29(4) referrals, Opinion provided by Committee for Medicinal Products for Human Use, 23/07/2020
"Current status: Opinion provided by Committee for Medicinal Products for Human Use" […]
***Pu*blished on**: *24 - July - 2020*
For more information, please refer to:
Ibuprofen Kabi 400 mg Infusionslösung and associated names | European Medicines Agency

Referral: Panexcell , Article 31 referrals, Opinion provided by Committee for Medicinal Products for Human Use, 27/02/2020, 24/07/2020 (updated)
" […]EMA and national authorities will continue working closely together to ensure that studies on EU medicines are carried out to the highest standards and that companies comply with all aspects of Good Clinical Practice (GCP). If companies do not meet required standards, authorities will take whatever measures necessary to ensure the integrity of data used to approve EU medicines.
The CHMP's recommendation is being sent to the European Commission for a legally binding decision." […]
***Published on:** 24 – July - 2020*
For more information, please refer to
Panexcell | European Medicines Agency

Referral: Yondelis, trabectedin, Article 20 procedures, Opinion provided by Committee for Medicinal Products for Human Use, 24/07/2020, 24/07/2020 (updated)
"Current status: Opinion provided by Committee for Medicinal Products for Human Use" […]
***Published on:** 24 – July - 2020*

Humanarzneimittel - EU

For more information, please refer to
Yondelis | European Medicines Agency

Referral: Picato , ingenol mebutate , Article 20 procedures, European Commission final decision, 30/04/2020, 02/07/2020, 27/07/2020 (updated)
"It was noted that recent data from a study on the effectiveness of actinic keratosis treatments supported the previous observation, detailed in the medicine's product information, that Picato's effectiveness decreases over time.
Picato is no longer authorised in the EU as the marketing authorisation was withdrawn on 11 February 2020 at the request of LEO Laboratories Ltd, the company that marketed the medicine." […]
Published on: *27 – July - 2020*
For more information, please refer to
Picato | European Medicines Agency
Guidance for medicine developers and companies on COVID-19 (updated)
Published on: 27 *– July - 2020*
For more information, please refer to
Guidance for medicine developers and companies on COVID-19 | European Medicines Agency

Referral: Leuprorelin-containing depot medicinal products , leuprorelin , Daronda,Depo-Eligard,Eligard,Eligard Depot,Eligard Mensua,Eligard Semestral,Eligard Trimestral,Elityran 1 Month Depot (Dps),Elityran 3 Month Depot (Dps),Enanton Depot Dual,Enanton Depot Set,Enantone,Enantone L.P,Enantone Lp,Enantone Monats-Depot,Ginecrin Depot,Klebrocid 3-Monats-Depot,Klebrocid Depot Zweikammerspritze,Leptoprol,Lerin,Leugon,Leuprex 3,Leuprol,Leuprolin Ratiopharm,Leuprone 1-Monatsdepot,Leuprone 3-Monatsdepot,Leuprorelin 1-Month Depot Gp-Pharm,Leuprorelin Hexal,Leuprorelin Sandoz,Leuprorelina Gp-Pharm,Leupro-Sandoz 1-Monats-Depot,Leupro-Sandoz 3-Monats-Depot,Leuprorelina Trimestral Sandoz,Leuprostin,Leuproreline Sandoz,Lucrin,Lucrin Depot,Lucrin Pds Depot,Lucrin Pds Depot 1 Maand,Lucrin Pds Depot 3 Maanden,Lucrin Pds Depot 6 Maanden,Lupron Depo,Lutrate 1 Month Depot,Lutrate 3 Month Depot,Lutrate Depo,Lutrate Depot,Lutrate Depot Trimestral,Politrate,Politrate Politrate Depot,Procren Depot,Procren Depot Pds,Procrin Mensual,Procrin Semestral,Procrin Trimestral,Prostap 3 Dcs,Prostap 6 Dcs,Prostap Sr Dcs,Prostaplant,Sixantone,Trenantone,Trenantone-Gyn,Zeulide,Елигард,Лутрат Депо, Article 31 referrals, CMDh final position, 24/06/2020, 31/07/2020 (updated)
Published on: *31 – July - 2020*
For more information, please refer to
Leuprorelin-containing depot medicinal products | European Medicines Agency

CHMP: Agendas, minutes and highlights
Published on: *31 – July - 2020*
For more information, please refer to
CHMP: Agendas, minutes and highlights | European Medicines Agency

Orphan Drugs und neuartige Therapierichtungen (ATMP)

CAT: Agendas, minutes and reports
Published on: *31 - July - 2020*
For more information, please refer to:
CAT: Agendas, minutes and reports | European Medicines Agency

COMP: Agendas, minutes and meeting reports

Humanarzneimittel - EU

Published on: *31 - July - 2020*
For more information, please refer to:
COMP: Agendas, minutes and meeting reports | European Medicines Agency

European Commission-DG Health and Food Safety and European Medicines Agency action plan on advanced therapy medicinal products (ATMPs) (updated)
Published on: *10 – July - 2020*
For more information, please refer to:
https://www.ema.europa.eu/en/documents/other/european-commission-dg-health-food-safety-european-medicines-agency-action-plan-advanced-therapy_en-0.pdf

Qualität – Quality

Quality of water for pharmaceutical use
"July 2020 update: The guideline has been updated to reflect changes in the European Pharmacopoeia including the revised monograph for Water for Injections allowing methods other than distillation for producing water of injectable quality. The guideline has also been updated to reflect current expectations for the minimum acceptable quality of water used in the manufacture of active substances and medicinal products for human and veterinary use. The updated guideline will be effective from 1 February 2021." […]
Published on: 20 - July - *2020*
For more information, please refer to:
Quality of water for pharmaceutical use | European Medicines Agency

Medizinprodukte - Medical Device / Health technology assessment

Medical Devices
"EMA intends to finalise the guideline in September 2020" […]
Published on: *31 - July - 2020*
For more information, please refer to:
Medical devices | European Medicines Agency

(Prä-) Klinische Forschung – Research and Development

Q&A: Good clinical practice (GCP) (updated)
"Update: EMA has published a notice for clinical trial sponsors to highlight the requirements for the qualification and validation of computerised systems used for managing clinical trial data. This is based on inspection findings and taking into account implications on the integrity, reliability, robustness and acceptability of data in marketing authorisation applications:
• Notice to sponsors on validation and qualification of computerised systems used in clinical trials
In line with this notice, EMA has also updated questions 8 and 9 on this page, which provide further related guidance on computerised systems." […]
Published on: *24 - July - 2020*
For more information, please refer to:
Q&A: Good clinical practice (GCP) | European Medicines Agency

Guidance for medicine developers and companies on COVID-19 (updated)
"Update: On 17 July 2020, the European Parliament and the Council of the EU adopted a Regulation on the conduct of clinical trials with treatments and vaccines against COVID-19 containing genetically modified organisms (GMOs).

The regulation aims to speed up the conduct of clinical trials by providing a temporary derogation from the mandatory environmental risk assessment for these substances during the COVID-19 pandemic. However, a COVID-19 vaccine or treatment containing GMOs would require an environmental risk assessment before it could be marketed in the EU." […]
***Published on:** 27 – July - 2020*
For more information, please refer to
Guidance for medicine developers and companies on COVID-19 | European Medicines Agency

Kinderarzneimittel – Paediatrics

PDCO: Agendas, minutes and meeting reports
***Published on:** 31 - July - 2020*
For more information, please refer to:
PDCO: Agendas, minutes and meeting reports | European Medicines Agency

Pflanzliche Arzneimittel – Herbal medicines

Herbal medicinal product: Menthae piperitae folium, Menthae piperitae folium, F: Assessment finalised (updated)
***Published on:** 24 - July - 2020*
For more information, please refer to:
Menthae piperitae folium | European Medicines Agency

Herbal medicinal product: Hippocastani semen, Hippocastani semen, F: Assessment finalised (updated)
***Published on:** 24 - July - 2020*
For more information, please refer to:
Hippocastani semen | European Medicines Agency

Herbal medicinal product: Menthae piperitae aetheroleum, Menthae piperitae aetheroleum, F: Assessment finalised (updated)
***Published on:** 24 - July - 2020*
For more information, please refer to:
Menthae piperitae aetheroleum | European Medicines Agency

Herbal medicinal product: Rhei radix, Rhei radix, F: Assessment finalised (updated)
***Published on:** 27 - July - 2020*
For more information, please refer to:
Rhei radix | European Medicines Agency

Herbal medicinal product: Sennae folium, Sennae folium, F: Assessment finalised (updated))
***Published on:** 27 - July - 2020*
For more information, please refer to:
Sennae folium | European Medicines Agency

Herbal medicinal product: Rhamni purshianae cortex, Rhamni purshianae cortex, F: Assessment finalised (updated)
***Published on:** 28 - July - 2020*
For more information, please refer to:
Rhamni purshianae cortex | European Medicines Agency

Humanarzneimittel - EU

Herbal medicinal product: Filipendulae ulmariae flos, Filipendulae ulmariae flos, F: Assessment finalised (updated)
Published on: *30 - July - 2020*
For more information, please refer to:
Filipendulae ulmariae flos | European Medicines Agency

Herbal medicinal product: Sennae fructus, Sennae fructus, F: Assessment finalised (updated)
Published on: *28 - July - 2020*
For more information, please refer to:
Sennae fructus | European Medicines Agency

Herbal medicinal product: Filipendulae ulmariae herba, Filipendulae ulmariae herba, F: Assessment finalised (updated)
Published on: *30 - July - 2020*
For more information, please refer to:
Filipendulae ulmariae herba | European Medicines Agency

Herbal medicinal product: Herniariae herba, Herniariae herba, F: Assessment finalised (updated)
Published on: *31 - July - 2020*
For more information, please refer to:
Herniariae herba | European Medicines Agency

Herbal medicinal product: Sabalis serrulatae fructus, Sabalis serrulatae fructus, C: ongoing call for scientific data (updated)
Published on: *31 - July - 2020*
For more information, please refer to:
Sabalis serrulatae fructus | European Medicines Agency

HMPC: Agendas, minutes and meeting reports
Published on: *31 - July - 2020*
For more information, please refer to:
HMPC: Agendas, minutes and meeting reports | European Medicines Agency

EDQM

Ten years at the service of consumer safety in Europe: over 600 analytical methods for cosmetics testing, 20 studies, 50 laboratories and more expected to join
"The experts of the European Committee for Cosmetics and Consumer Health (CD-P-COS) and the members of the Network of Official Cosmetics Control Laboratories (OCCLs) held a virtual meeting on 22 and 23 June to define steps for advancing consumer protection in Europe and for reinforcing cross-border co-operation and independent cosmetics testing. The meeting also marked the 10th anniversary of the Network of Official Cosmetics Control Laboratories (OCCLs), which supports laboratories across Europe and beyond in developing their market surveillance and enhancing product testing capacity." […]
Published on: *20 - July - 2020*
For more information, please refer to:
Ten years at the service of consumer safety in Europe: over 600 analytical methods for cosmetics testing, 20 studies, 50 laboratories and more expected to join | EDQM - European Directorate for the Quality of Medicines

Humanarzneimittel - EU

Clarification on the acceptability of requests for revision of CEP applications
"Following experience gained since the introduction of the revised EDQM Guideline on requirements for revision/renewal of certificates of suitability to the European Pharmacopoeia Monographs (PA/PH/CEP (04) 2, 7R corr) in January 2019, this announcement is intended to clarify a couple of items." […]
Published on: *21 - July - 2020*
For more information, please refer to:
Clarification on the acceptability of requests for revision of CEP applications | EDQM - European Directorate for the Quality of Medicines

Ph. Eur. Supplement 10.3: CEP holders are invited to update their applications
"Supplement 10.3 of the Ph. Eur is now available. CEP holders are invited to update their applications according to the revised monographs that will be implemented on the 1st of January 2021, and to follow the instructions given in the document." […]
Published on: *23 - July - 2020*
For more information, please refer to:
Ph. Eur. Supplement 10.3: CEP holders are invited to update their applications | EDQM - European Directorate for the Quality of Medicines

European Commission

Draft - Questions and Answers Document - Regulation (EU) 536/2014 – Version 2.4 (July 2020)
Published on: *06 - July- 2020*
For more information, please refer to:
https://ec.europa.eu/health/sites/health/files/files/eudralex/vol-10/regulation5362014_qa_en.pdf

Checklist for EN 17466 & Validation (Instructions for use for reusable & re-sterilisable medical devices)
Published on: **28** *- July - 2020*
For more information, please refer to:
https://ec.europa.eu/health/sites/health/files/md_sector/docs/md_checklists-iso-17664-14937_en.pdf

CMDh

UPDATE - Questions &Answers on QP declaration
Published on: *20 - July- 2020*
For more information, please refer to:
https://www.hma.eu/fileadmin/dateien/Human_Medicines/CMD_h_/Questions_Answers/CMDh_340_2015_Rev.6_2020_07_clean_-_QA_on_QP_Declaration_rev6_06_2020.pdf

UPDATE - Article 30 Tracking table;
Published on: *23 - July- 2020*
For more information, please refer to:
https://www.hma.eu/fileadmin/dateien/Human_Medicines/CMD_h_/Product_Information/Art30_Referrals/CMDh_140_2008_Rev45_2020_07_Status_Art30_SmPC_Harmonisation.xls

UPDATE - Data requested for Variations and/or Renewal Applications in the MRP/DCP which are not stated in the current EU legislation and/or in Volume 2B, Presentation and format of the dossier Common Technical Document (CTD) and/or in the EEA approved Guidelines / Recommendation papers;
Published on: *23 - July- 2020*
For more information, please refer to:
https://www.hma.eu/fileadmin/dateien/Human_Medicines/CMD_h_/procedural_guidance/Variations/CMDh_197_2010_Rev.7_2020_07_clean_-_Data_requested_for_Variations_andor_Renewal_Applications_MRP_DCP.pdf

NEW - Minutes from the CMDh meeting with IPs in May 2020
Published on: *24 - July- 2020*
For more information, please refer to:
https://www.hma.eu/fileadmin/dateien/Human_Medicines/CMD_h_/About_CMDh/Contact_with_Representatives_Organisations/Meeting_IP_May_2020/Minutes_CMDh_meeting_with_IPs_May_2020.pdf

NEW - Recommendations on common regulatory approaches for allergen products
Published on: *29 - July- 2020*
For more information, please refer to:
https://www.hma.eu/fileadmin/dateien/Human_Medicines/CMD_h_/procedural_guidance/01_General_Info/CMDh_423_2020_clean_2020_07.pdf

NEW - Art.46 Assessment report on fosrenol
Published on: *29 - July- 2020*
For more information, please refer to:
https://www.hma.eu/fileadmin/dateien/Human_Medicines/CMD_h_/Paediatric_Regulation/Assessment_Reports/Article_46_work-sharing/Fosrenol_Art._46_PAR.pdf

NEW - Art.45 Assessment report on valproic acid
Published on: *29 - July- 2020*
For more information, please refer to:
https://www.hma.eu/fileadmin/dateien/Human_Medicines/CMD_h_/Paediatric_Regulation/Assessment_Reports/Article_45_work-sharing/Valproic_Acid_Art._45_PAR.pdf

CMDh

NEW - Report from the meeting held on 21-22 July 2020
Published on:29 *- July- 2020*
For more information, please refer to:
https://www.hma.eu/fileadmin/dateien/Human_Medicines/CMD_h_/cmdh_pressreleases/2020/07_2020_CMDh_Press_Release.pdf

UPDATE - PSUR summary assessment report for doxylamine hydrogen succinate, pyridoxine hydrochloride
Published on: *31 - July- 2020*
For more information, please refer to:
Heads of Medicines Agencies: Outcome of informal PSUR worksharing procedures

NEW - Template for RMS Assessment Report on Similarity
UPDATE - RMS Day 70 Overview template
UPDATE - RMS Day 120 Overview template
Published on: *31 - July- 2020*
For more information, please refer to:
Heads of Medicines Agencies: Recently Published history

Humanarzneimittel - Deutschland

Bekanntmachung des Arzneibuchs
„Auflistung der zuletzt im Bundesanzeiger erschienenen Bekanntmachungen des Europäischen, Deutschen und Homöopathischen Arzneibuchs.“ […]
***Veröffentlicht am**: 21 - Juli - 2020*
Weitere Informationen finden Sie unter:
BfArM - Bekanntmachungen

Liste der am Pilotprojekt teilnehmenden Ethik-Kommissionen
„Liste der am Pilotprojekt "EU-Verordnung" teilnehmenden Ethik-Kommissionen“ [...]
***Veröffentlicht am**: 21 - Juli - 2020*
Weitere Informationen finden Sie unter:
BfArM - Pilotprojekt „EU-Verordnung“ - Liste der am Pilotprojekt teilnehmenden Ethik-Kommissionen

Stellungnahme (Nr. 01/2020) der Gemeinsamen Expertenkommission zur Einstufung von Stoffen
„Einstufung von Produkten der ayurvedischen Tradition.“ […]
***Veröffentlicht am**: 23 - Juli - 2020*
Weitere Informationen finden Sie unter:
https://www.bfarm.de/SharedDocs/Downloads/DE/Arzneimittel/Zulassung/ZulRelThemen/abgrenzung/Expertenkommission/stellungnahmen/2020-01.pdf?__blob=publicationFile&v=3

Aktuelle Bearbeitungsstatistik des Bundesinstituts für Arzneimittel und Medizinprodukte
„Die Arzneimittelzahlen und Statistiken wurden aktualisiert.“ […]
***Veröffentlicht am**: 23 - Juli - 2020*
Weitere Informationen finden Sie unter:
BfArM - Aktuelle Bearbeitungsstatistik des Bundesinstituts für Arzneimittel und Medizinprodukte

PSUR Single Assessment (PSUSA)
„Hier finden Sie Informationen und Hinweise zum Ergebnis einzelner Verfahren des PSUR Single Assessment (PSUSA).“ […]
***Veröffentlicht am**: 28 - Juli - 2020*
Weitere Informationen finden Sie unter:
BfArM - PSUR Single Assessment (PSUSA)

Informationen und Schulungsunterlagen
„Das BfArM hat die Webseite zum Schulungsangebot für die PharmNet.Bund-Anwendungen um die Schulungsunterlagen für PIT und SSC ergänzt.“ […]
***Veröffentlicht am**: 28 - Juli - 2020*
Weitere Informationen finden Sie unter:
BfArM - eSubmission - Informationen und Schulungsunterlagen

Beirat nach § 52b Abs. 3b AMG zu Liefer- und Versorgungsengpässen
„Beirat zu Liefer- und Versorgungsengpässen“ […]
***Veröffentlicht am**: 28 - Juli - 2020*
Weitere Informationen finden Sie unter:
BfArM - Beirat zu Liefer- und Versorgungsengpässen

Aktuelle Informationen zu Nitrosaminen in metforminhaltigen Arzneimitteln
„Aktuelle Informationen zu Nitrosaminen in metforminhaltigen Arzneimitteln.“ […]
***Veröffentlicht am**: 30 - Juli - 2020*
Weitere Informationen finden Sie unter:
BfArM - Weitere Arzneimittelrisiken - Aktuelle Informationen zu Nitrosaminen in metforminhaltigen Arzneimitteln

Paul-Ehrlich-Institut (PEI) - Beauflagtes Schulungsmaterial (Educational Material)
***Veröffentlicht am**: 31 - Juli - 2020*
Weitere Informationen finden Sie unter:
Paul-Ehrlich-Institut - Auflistung von genehmigtem Schulungsmaterial

PEI Lieferengpässe von Human-Impfstoffen:
***Veröffentlicht am**: 31- Juli - 2020*
Weitere Informationen finden Sie unter:
Paul-Ehrlich-Institut - Lieferengpässe

Sicherheitsinformationen
***Veröffentlicht am**: 31 - Juli- 2020*
Weitere Informationen finden Sie unter:
Paul-Ehrlich-Institut - Sicherheitsinformationen - Warnung vor dem Off-label-Einsatz von BCG-Präparaten

Coronavirus SARS-CoV-2
***Veröffentlicht am**:31 - Juli - 2020*
Weitere Informationen finden Sie unter:
BfArM - Coronavirus SARS-CoV-2

Humanarzneimittel - Österreich

FAQ Meldung Vertriebseinschränkung - Ist die Gebühr pro Meldung, pro Arzneispezialität oder pro Pharmazentralnummer (PZN) zu entrichten?
„Die Gebühr ist pro Meldung der Arzneispezialität und nicht pro gemeldeter Packungsgröße zu entrichten. Die Höhe der Gebühr entnehmen Sie bitte dem aktuellen Gebührentarif. Die Gebühr ist für Meldungen…“ […]
***Datum der Information**: 21 - Juli – 2020*
Weitere Informationen finden Sie unter:
FAQ Meldung Vertriebseinschränkung - BASG

Annual overview of GLP test facilities inspected
***Datum der Information:** 22 - Juli – 2020*
Weitere Informationen finden Sie unter:
https://www.basg.gv.at/fileadmin/redakteure/07_Unternehmen/GLP/Annual_overview_of_GLP_test_facilities_inspected.pdf

FAQ Suchtmittel - Als neuverblisternder Betrieb / Apotheke sehe ich Schwierigkeiten in der suchtmittelrechtlich vorgeschriebenen Dokumentation, insbesondere in der Befüllung der Nachweisungsformulare des BASG. Wie ist hier vorzugehen?
„Betriebe, im Sinne des § 2 Z 1 lit.c Neuverblisterungsbetriebsordnung oder öffentliche Apotheken oder Anstaltsapotheken (als Auftragnehmer), handeln als Erfüllungsgehilfen einer öffentlichen Apotheke…“. […]
***Veröffentlicht am:** 22 - Juli – 2020*
Weitere Informationen finden Sie unter:
FAQ Suchtmittel - BASG

Suchtmittel - Weiterführende Informationen unter:
„Formulare - Stammdaten FAQ Suchtmittel BMSGPK: Suchtmittelgebarung (Firmenverzeichnisse, Antragsformulare für Bewilligungen, Checkliste für die Suchtmittelüberprüfung der Apotheken)“ […]
***Veröffentlicht am:** 24 - Juli – 2020*
Weitere Informationen finden Sie unter:
Suchtmittel - BASG

Erstellung Barrierefreier Gebrauchsinformationen
„Wir haben aktualisierte Vorlagen für die barrierefreie humane Gebrauchsinformation und das QRD-Template veröffentlicht!“ […]
***Veröffentlicht am:** 27 - Juli– 2020*
Weitere Informationen finden Sie unter:
Erstellung Barrierefreier Gebrauchsinformationen - BASG
Und
Gebrauchsinformation barrierefrei - BASG
Und
Gebrauchsinformation barrierefrei - BASG

Verhaltenskodex (L_7962)
***Datum der Information:** 29 - Juli – 2020*
Weitere Informationen finden Sie unter:
Vision, Werte und Strategie - BASG

Humanarzneimittel - Österreich

COVID-19
Datum der Information: *31 - Juli – 2020*
Weitere Informationen finden Sie unter:
COVID-19 - BASG

Humanarzneimittel - Schweiz

Swissmedic Haemovigilance Jahresbericht
„Auswertung der Haemovigilance-Meldungen 2019“ […]
Veröffentlicht am: *22 – Juli – 2020*
Weitere Informationen finden Sie unter:
Publikationen

Umstellung auf elektronische Einreichung der Meldungen von wesentlichen Änderungen ab Herbst 2020
„Geplante Neuerungen für Betriebsbewilligungsinhaberinnen". […]
Veröffentlicht am: *23 - Juli– 2020*
Weitere Informationen finden Sie unter:
Umstellung auf elektronische Einreichung der Meldungen von wesentlichen Änderungen ab Herbst 2020

Medizinprodukte - Regulierung Medizinprodukte -Häufige Patientenfragen
Veröffentlicht am: *23 - Juli – 2020*
Weitere Informationen finden Sie unter:
Häufige Patientenfragen

Ausnahmebewilligungen für nicht konforme Medizinprodukte
„Medizinprodukte, welche in der Schweiz in Verkehr gebracht werden, müssen ein Konformitätsbewertungsverfahren durchgelaufen haben, durch welches die Konformität mit den grundlegenden Sicherheits- und Leistungsanforderungen überprüft wird.“ […]
Veröffentlicht am: *01 - August – 2020*
Weitere Informationen finden Sie unter:
Ausnahmebewilligungen für nicht konforme Medizinprodukte

Aktualisierte Dokumente
Veröffentlicht am:31 *- Juli– 2020*
Weitere Informationen finden Sie unter:
Juli 2020

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. *

I would like to double-check a general question concerning the use of a superseded CEP version in the manufacture of an FDF.

In the case that according to the EDQM database the current valid version of the CEP for a certain API is let's say R1 Rev 02 (e.g. since 01.10.2019) but the API manufacturer has still today API batches on stock manufactured and released before 01.10.2019 according to R1 Rev 01 – is it ok to provide the FDF manufacturer (e.g.) in June 2020 with API manufactured and released according to R1 Rev 01? (Premise: The reason for the CEP update from Rev 01 to Rev 02 was NOT a non-compliance of an intermediate manufacturing site and the retest period is stated in both CEPs versions (e.g. 36 months)).

My understanding according to the Question and Answers 2.4 https://www.ema.europa.eu/en/human-regulatory/post-authorisation/classification-changes-questions-answers is: only the versions of the CEP (i.e. updated certificates) which were used in the manufacturing process of a batch of finished product need to be included in the dossier. So the FDF manufacturer could use for the FDF manufacturing in June 2020, API manufactured and released according to R1 Rev 01, EVEN if since 01.10.2019 R1 Rev 02 is valid. Once the FDF manufacturer would receive and use API manufactured and released according to R1 Rev 02, the MA Holder should present a variation Type IA (provided the conditions are met!) within 1 year of the implementation of R1 Rev 02 at the FDF end (=use of API R1 Rev 02 in FDF manufacturing). Is my understanding correct?
But there seems to be a GREY AREA about how long the MAH is allowed to take before implementing a revised CEP.

In other words, it is clear that the MAH has a year to submit their IA type variation in case of a revised CEP. But how long do they have between validity date of a new CEP version and implementation at their end?

Sollten Sie die Antwort wissen bzw. über Erfahrungen verfügen, würden wir uns über eine Einsendung an info-as@megra.org freuen (Referenz Kalenderwoche Newsletter/Frage). Die eingesendeten Antworten werden anonym behandelt und zur Publikation im nächsten Newsletter konsolidiert.

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

16th International Paul-Ehrlich-Seminar (IPES)
Termin: *02.09.2020 - 05.09.2020*
Ort: *Maritim Hotel Bad Homburg, Germany*
Weitere Informationen finden Sie unter:
Paul-Ehrlich-Institut - Veranstaltungen - 16th International Paul-Ehrlich-Seminar (IPES)

Österreich

BASG-Gespräch: AT als RMS – Meet the Case Manager
Termin: 13.10.2020
AGES-Akademie, Spargelfeldstrasse 191, 1220 Wien
Weitere Informationen finden Sie unter:
https://www.basg.gv.at/news-center/veranstaltungen-vorschau/

BASG-Gespräch: Neues eServices Hämo- und Gewebevigilanzmeldungen
Termin: 10.11.2020
AGES-Akademie, Spargelfeldstrasse 191, 1220 Wien
Weitere Informationen finden Sie unter:
https://www.basg.gv.at/ueber-uns/veranstaltungen

BASG-Gespräch: IT-Neuigkeiten für den regulatorischen Bereich
Termin: 24.11.2020
AGES-Akademie, Spargelfeldstrasse 191, 1220 Wien
Weitere Informationen finden Sie unter:
https://www.basg.gv.at/ueber-uns/veranstaltungen

BASG-Gespräch: Illegalitätsbekämpfung am Medizinmarkt
Termin: 03.12.2020
AGES-Akademie, Spargelfeldstrasse 191, 1220 Wien
Weitere Informationen finden Sie unter:
https://www.basg.gv.at/ueber-uns/veranstaltungen

BASG-Gespräch: Aktuelles zur Guten Laborpraxis
Termin: 10.12.2020
AGES-Akademie, Spargelfeldstrasse 191, 1220 Wien
Weitere Informationen finden Sie unter:
https://www.basg.gv.at/ueber-uns/veranstaltungen

Schweiz

Veranstaltungen über Medizinprodukte mit Swissmedic Referenten
In der Liste finden sich die Veranstaltungen mit Swissmedic Referentin, die zur Zeit für dieses Jahr geplant sind.
Weitere Informationen finden Sie unter:
Veranstaltungen über Medizinprodukte

Externe Veranstaltungen mit Swissmedic Referenten
In der Liste finden sich die Veranstaltungen mit Swissmedic Referentin, die zur Zeit für dieses Jahr geplant sind.
Weitere Informationen finden Sie unter:
Kurse, Vorträge und andere Referententätigkeiten

Europa

eXtended EudraVigilance Medicinal Product Dictionary training course
onine
from 30/09/2020 to 02/10/2020
Weitere Informationen finden Sie unter:
eXtended EudraVigilance Medicinal Product Dictionary training course | European Medicines Agency

eXtended EudraVigilance Medicinal Product Dictionary training course
Ort: Munich, Germany,
from 21/10/2020 to 23/10/2020
Weitere Informationen finden Sie unter:
eXtended EudraVigilance Medicinal Product Dictionary training course | European Medicines Agency

eXtended EudraVigilance Medicinal Product Dictionary training course
Ort: Munich, Germany,
from 14/12/2020 to 16/12/2020
Weitere Informationen finden Sie unter:
eXtended EudraVigilance Medicinal Product Dictionary training course | European Medicines Agency

eXtended EudraVigilance Medicinal Product Dictionary training course
Ort: Munich, Germany,
from 26/11/2020 to 27/11/2020
Weitere Informationen finden Sie unter:
eXtended EudraVigilance Medicinal Product Dictionary training course (Munich) | European Medicines Agency

From data to evidence in medicines regulation
Update: In the context of the escalating situation with the COVID-19 outbreak, this conference is postponed to later in 2020, from 22/04/2020 to 07/09/2020.
Ort: European Medicines Agency, Amsterdam, The Netherlands,
From: 07/09/2020 to 07/09/2020
Weitere Informationen finden Sie unter:

From data to evidence in medicines regulation | European Medicines Agency

Workshop on benefit-risk of medicines used during pregnancy and breastfeeding,
Virtual meeting,
from 22/09/2020 to 22/09/2020
Weitere Informationen finden Sie unter:
Workshop on benefit-risk of medicines used during pregnancy and breastfeeding | European Medicines Agency