19. Februar – 02. März 2018

MEGRA NEWSLETTER

Humanarzneimittel - EU

Allgemeines – General

Eligible healthcare professionals' organisations (updated)

"The European Medicines Agency (EMA) engages with a network of over twenty-five eligible organisations ensuring that the needs and concerns of a wide range of healthcare professionals across Europe are represented via direct contact with the EMA. These organisations are not-for-profit, in most cases have a European Union-wide mandate, and include:" […]

Published on: 19 - February – 2018

For more information, please refer to:

http://www.ema.europa.eu/ema/index.jsp?curl=pages/partners_and_networks/q_and_a/q_and_a_detail_000130.jsp&mid=WC0b01ac05805c0cad

Letter of support for intermediate age related macular degeneration (AMD) biomarker and novel clinical endpoint development - EMA/72511/2018

"The Agency supported exploration of markers that address both how the patient functions and how the patient feels and that the correlation between structural and functional markers/PROs will be evaluated. Overall, it is agreed with the Consortium that it is important to create a dataset of functional, structural and PRO assessments also in patients with impaired central vision (BCVA 20/40-20/200)." […]

Published on:20 - February – 2018

For more information, please refer to:

http://www.ema.europa.eu/docs/en_GB/document_library/Minutes/2018/02/WC500243370.pdf

Medicines for older people (updated)

"According to EurostatExternal link icon, the number of people aged 65 years or over in the EU is expected to grow from around 84 million in 2008 to around 141 million by 2050. This represents an increase from 17% to 30% of the total EU population. This increase is partly due to developments in medicine over the past few decades." […]

Published on: 23 - February – 2018

For more information, please refer to:

http://www.ema.europa.eu/ema/index.jsp?curl=pages/special_topics/general/general_content_000249.jsp&mid=WC0b01ac058004cbb9

Second industry stakeholder platform on research and development support, European Medicines Agency, London, UK, From: 15-Nov-2017, To: 15-Nov-2017 (updated)

"This is the second event in a series of (semi-)annual meetings between regulators and representatives of industry stakeholder organisations. It addresses all areas of product development support, from scientific advice, over specifics for paediatric and orphan medicines and to innovation support. This platform aims to provide an opportunity for both general updates and more focused discussions on specific processes or issues to support continuous improvement, and generally to foster a constructive dialogue with industry stakeholders. Registration by invitation only." […]

All information can be found under the tab „documents".

Published on:26 - February – 2018

For more information, please refer to:

http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/events/2017/11/event_detail_001545.jsp&mid=WC0b01ac058004d5c3

and

http://www.ema.europa.eu/docs/en_GB/document_library/Report/2018/02/WC500244421.pdf

Humanarzneimittel - EU

Management Board initiates building approval process for EMA premises in Amsterdam
"The European Medicines Agency's (EMA) Management Board met today in an extraordinary session to further discuss the building approval process for EMA's future premises in Amsterdam, the Netherlands. EMA needs to be fully operational in Amsterdam on 30 March 2019, when the United Kingdom withdraws from the European Union (EU)." 8…]
Published on: 28 – February – 2018
For more information, please refer to:
http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/news/2018/02/news_detail_002914.jsp&mid=WC0b01ac058004d5c1

Pharmakovigilanz – PRAC

Report: Highlights from the twelfth industry stakeholder platform on the operation of pharmacovigilance in the European Union - EMA/790351/2017
"The following records announcements and action points from the 12th Pharmacovigilance Industry Platform meeting held on 24 November 2017."
Published on:19 – February – 2018
For more information, please refer to:
http://www.ema.europa.eu/docs/en_GB/document_library/Report/2018/02/WC500243989.pdf
and
http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/events/2018/01/event_detail_001567.jsp&mid=WC0b01ac058004d5c3

Regulatory and procedural guideline: EudraVigilance release notes v.1.8 (updated) - EMA/107038/2018 Information Management
"This document lists and briefly describes the following areas for the releases of the EudraVigilance system. This includes the EudraVigilance messaging system, the EVWEB interface and the EV post function:
- *What's New: The enhancements and other changes released (new feature).*
- *Known Issues: The issues that exist (open issue).*
- *Fixed Issues: The issues that are fixed (fixed issue).*
- *Points to Note: The important aspects to keep in mind (point to note)." […]*

Published on: 20 – February – 2018
For more information, please refer to:
http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2017/11/WC500238985.pdf

PRAC meetings in 2019, 2020, 2021
Published on: 26 – February – 2018
For more information, please refer to:
http://www.ema.europa.eu/docs/en_GB/document_library/Other/2018/02/WC500244424.pdf

List of medicines under additional monitoring
"The list of medicines under additional monitoring includes medicines authorised in the European Union (EU) that are being monitored particularly closely by regulatory authorities. Medicines under additional monitoring have a black inverted triangle displayed in their package leaflet and summary of product characteristics**,** together with a short sentence explaining what the triangle means." […]
Published on: 28 – February – 2018
For more information, please refer to:
http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/document_listing/document_listi

ng_000366.jsp&mid=WC0b01ac058067c852

Regulatory and procedural guideline: EudraVigilance release notes v.1.9 (updated) - EMA/115443/2018 Page 2/9
"The new release of EudraVigilance includes a number of improvements that increase the performance and usability of the system by all stakeholders. Some of these improvements will also enhance aspects of the functionality of the system, which are highlighted below." […]
Published on: 28 – February – 2018
For more information, please refer to:
http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2017/11/WC500238985.pdf

Zulassung – Regulatory Affairs

Plasma-master-file certifications
Published on: 28 - February – 2018
For more information, please refer to:
http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_000071.jsp&mid=WC0b01ac05800265d0

News and press releases: Meeting highlights from the Committee for Medicinal Products for Human Use (CHMP) 19-22 February 2018
"Five medicines recommended for approval, including two orphans
The European Medicines Agency's (EMA) Committee for Medicinal Products for Human Use (CHMP) recommended five medicines for approval, including two orphan medicines1, at its February 2018 meeting." […]
Published on: 23 - February – 2018
For more information, please refer to:
http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/news/2018/02/news_detail_002907.jsp&mid=WC0b01ac058004d5c1

Referral: Article 30 referrals, Scandonest and associated names, mepivacaine (updated)
"The European Medicines Agency (EMA) has started a review of the medicine Scandonest, a local anaesthetic (a medicine used to block pain in a part of the body) that contains the active substance mepivacaine." […]
Published on: 26- February – 2018
For more information, please refer to:
http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/referrals/Scandonest_and_associated_names/human_referral_000424.jsp&mid=WC0b01ac05805c516f

Submission of referentials management services (RMS) and organisations management services (OMS) change requests, European Medicines Agency, London, UK, From: 12-Feb-2018, To: 12-Feb-2018
"The European Medicines Agency's (EMA) programme for substance, product, organisation and referential (SPOR) data services held a webinar with industry stakeholders to summarise the milestones and impacts on industry of the referentials management services (RMS) and organisations management services (OMS). The webinar focused on the submission of RMS and OMS change requests relating to referential and organisation data." […]
All information can be found under the tab document.
Published on: 27- February – 2018

Humanarzneimittel - EU

For more information, please refer to:
http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/events/2018/02/event_detail_001600.jsp&mid=WC0b01ac058004d5c3

List of withdrawn medicinal products in accordance with Art. 123(4) of the Directive (28/02/2018)
"Introduction: The Agency should annually make public a list of human medicinal products which have been withdrawn from the EU market. This includes products for which marketing authorisations have been refused, revoked or suspended, and products whose supply has been prohibited or which have been withdrawn from the market (Article 123(4) of Directive 2001/83/EC). The list covers centrally authorised products as well as nationally authorised products (including products authorised via the mutual recognition and decentralised procedures), which have been withdrawn from 1 June 2017 to 31 December 2017 due to concerns relating to their safety, quality or efficacy. The infomation included herein is based on notifications received from Marketing Authorisation Holders (MAHs) and National Competent Authorities (NCAs), as well as outcomes of EU Community procedures.
The list specifies whether the action has been initiated by the MAH or if it was imposed by the NCA (e.g. following a review procedure at European level).
Disclaimer: The actions described in this list and the rationale behind them pertain only to the specific products mentioned below and should not be read as applicable to all products containing the same active substance." […]
Published on: 28- February – 2018
For more information, please refer to:
http://www.ema.europa.eu/docs/en_GB/document_library/Other/2018/02/WC500244608.xls

Report: List of products granted eligibility to PRIME (updated)
"This document includes information on products that have been granted eligibility to PRIME and that are active in the scheme.
PRIME is a development support scheme for medicines addressing an unmet medical need. Further information on the criteria for eligibility and features of the scheme are available on the EMA website.
Products are removed from this list when a marketing authorisation application is submitted or if a product is withdrawn from the scheme if emerging data show that the eligibility criteria are no longer met." […]
Published on:28- February – 2018
For more information, please refer to:
http://www.ema.europa.eu/docs/en_GB/document_library/Report/2016/10/WC500214862.xlsx

Report: Recommendations on eligibility to PRIME scheme - Adopted at the CHMP meeting of 19-22 February 2018 - EMA/777146/2017
"During its February 2018 meeting, the CHMP reviewed 6 recommendations for eligibility to PRIME: 1 was granted and 5 were denied "[…]
Published on:28- February – 2018
For more information, please refer to:
http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/referrals/Esmya/human_referral_prac_000070.jsp&mid=WC0b01ac05805c516f
and
http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/news/2018/02/news_detail_002902.jsp&mid=WC0b01ac058004d5c1

Humanarzneimittel - EU

List of European Union reference dates and frequency of submission of periodic safety update reports (updated) - EMA/630645/2012 Rev. 65

"PRAC recommends updating measures for pregnancy prevention during retinoid use. Warning on possible risk of neuropsychiatric disorders also to be included for all oral retinoids." […]

Published on: 28- February – 2018

For more information, please refer to:

http://www.ema.europa.eu/docs/en_GB/document_library/Other/2012/10/WC500133159.xls

Referral: Article 31 referrals, Paracetamol modified-release, paracetamol (updated)

"On 13 December 2017 the CMDh1 endorsed by majority a European Medicines Agency recommendation to suspend marketing of modified- or prolonged-release products containing paracetamol (designed to release paracetamol slowly over a longer period than the usual immediaterelease products). The recommendation was made by the Agency's experts in medicines safety, the Pharmacovigilance Risk Assessment Committee (PRAC)." […]

Published on: 01- March – 2018

For more information, please refer to:

http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/referrals/Paracetamol-modified_release/human_referral_prac_000062.jsp&mid=WC0b01ac05805c516f

Excipients labelling (updated)

"The European Commission's Notice to Applicants Group has adopted a revised guideline on excipients labelling, following a targeted stakeholder consultationExternal link icon carried out by the European Commission. The revised guideline includes a timeline for the implementation of its annex and updated explanatory notes. The Commission published the revised guideline in March 2018." […]

Published on: 01 - March – 2018

For more information, please refer to:

http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_001683.jsp&mid=WC0b01ac05808c01f6

Mutual recognition agreements (updated)

"USA: In November 2017, the FDA confirmed the capability of eight EU Member States (Austria, Croatia, France, Italy, Malta, Spain, Sweden, and United Kingdom) and in March 2018, a further four more EU Member States (Czech Republic, Greece, Hungary, and Romania). This means that the FDA can now rely on a total of 12 Member States to replace their own inspections. Imported products still need to be batch tested until the FDA recognises all EU Member States' authorities for human pharmaceuticals." […]

Published on: 01 - March – 2018

For more information, please refer to:

http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_001843.jsp&mid=WC0b01ac058005f8ac#chapter6

Report: Outcome of the European Medicines Agency (EMA) survey on centralised initial marketing authorisation procedure 2016/2017 - EMA/338870/2017

Published on: 01 - March – 2018

For more information, please refer to:

http://www.ema.europa.eu/docs/en_GB/document_library/Report/2018/03/WC500244874.pdf

Referral: Article 20 procedures, Zinbryta, Daclizumab

"*Medicine to be voluntarily withdrawn from the market by the company*

Humanarzneimittel - EU

The European Medicines Agency (EMA) has started an urgent review of the multiple sclerosis medicine Zinbryta (daclizumab) following 7 cases of serious inflammatory brain disorders in Germany, including encephalitis and meningoencephalitis, and one case in Spain." […]
Published on: 01 - March – 2018
For more information, please refer to:
http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/referrals/Zinbryta/human_referral_prac_000074.jsp&mid=WC0b01ac05805c516f

Orphan Drugs und neuartige Therapierichtungen (ATMP)

Orphan medicines figures 2000-2017 (updated)
Published on: 23- February– 2018
For more information, please refer to:
http://www.ema.europa.eu/docs/en_GB/document_library/Other/2015/04/WC500185766.pdf

Orphan designation
"In February 2108, EMA published a question-and-answer document addressing common misunderstandings about the meaning of orphan designation and other aspects pertaining to orphan medicines." [..]
Published on: 28- February– 2018
For more information, please refer to: http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_000029.jsp&mid=WC0b01ac0580b18a41

Qualität – Quality

No news available.

(Prä-) Klinische Forschung – Research and Development

Physical frailty: instruments for baseline characterisation of older populations in clinical trials - EMA/CHMP/778709/2015
"The reflection paper describes how to characterise the baseline frailty status of older patients enrolled in clinical trials other than by their age. The aim is to ensure that clinical trial populations are representative of the users of the medicine, as the benefit-risk balance in older patients may depend on their physical frailty status. These supplements the requirements of ICH E7 note for guidance and questions and answers." […]
Effective from: 24/01/2018
Published on: 22 - February – 2018
For more information, please refer to:
http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2018/02/WC500244285.pdf
and
http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/clinical_general/general_content_001232.jsp&mid=WC0b01ac0580032ec4 (website)

Report: Biennial report of the joint CVMP/CHMP working group on the application of the 3Rs in regulatory testing of medical products (2016/2017)
Published on: 26 - February – 2018
For more information, please refer to:
http://www.ema.europa.eu/docs/en_GB/document_library/Report/2018/02/WC500244422.pdf

and
http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/news/2018/02/news_detail_002911.jsp&mid=WC0b01ac058004d5c1

Clinical investigation of medicines for the treatment of Alzheimer's disease (updated) - CPMP/EWP/553/1995 Rev. 2
"This guideline provides guidance for the development of medicines across all stages of Alzheimer's disease. It covers the impact of new diagnostic criteria for Alzheimer's, including early and even asymptomatic disease stages, factors to be considered when selecting parameters to measure clinical trial outcomes at the different disease stages in Alzheimer's, the potential use of biomarkers in the various stages of medicine development and the design and analysis of efficacy and safety studies." […]
Revision 2 enters into effect 01/09/2018
Published on: 28 - February – 2018
For more information, please refer to:
http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2018/02/WC500244609.pdf

Kinderarzneimittel – Paediatrics

Minutes - PDCO minutes of the 12-15 December 2017 meeting - EMA/PDCO/830920/2017
Published on: 22 - February – 2018
For more information, please refer to:
http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/events/2014/07/event_detail_001020.jsp&mid=WC0b01ac058004d5c3

Paediatric investigation plans: questions and answers (updated)
*"**T**his page provides detailed guidance for companies intending to apply for a paediatric investigation plan (PIP), waiver, deferral or product-specific waiver, as well as for companies that already have an agreed PIP. The information is available as questions and answers, which the European Medicines Agency (EMA) revises as necessary." […]*
Published on: 22 - February – 2018
For more information, please refer to:
http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/events/2014/07/event_detail_001020.jsp&mid=WC0b01ac058004d5c3

Submission deadlines for paediatric applications 2018-2021 - EMA/66028/2018
Published on: 22 - February – 2018
For more information, please refer to:
http://www.ema.europa.eu/docs/en_GB/document_library/Other/2018/02/WC500244264.pdf

Mandate of the European network of paediatric research-European Medicines Agency working groups (updated) - EMA/493016/2013 Rev. 6
"At the open meeting of Enpr-EMA in June 2013 it was agreed to set up ad hoc working groups (WG) tasked with addressing some of the most important needs identified. The needs relate to making the best use of paediatric research networks to develop medicines for children. […] The focus is on stating what networks can do, or what networks need to do, rather than developing comprehensive guidance. […] Each WG is responsible for defining its role and working practices, including identifying a spokesperson, preparing meeting minutes and drafting outcomes/deliverables.
Members of the WGs, who represent a network, are required to lodge a declaration of interests with

the EMA." […]
Published on: 01 – March - 2018
For more information, please refer to:
http://www.ema.europa.eu/docs/en_GB/document_library/Other/2014/03/WC500163382.pdf

Pflanzliche Arzneimittel – Herbal medicines

HMPC meeting report on European Union herbal monographs, guidelines and other activities - 29-30 January 2018 - - EMA/HMPC/74171/2018
"The 80th HMPC meeting, held on 29-30 January 2018: The Chair of the Committee on Herbal Medicinal Products (HMPC) welcomed all delegates and experts to the 80th meeting of the Committee. The committee welcomed Erika Svedlund as new member from Sweden and Katarzyna Tomaszewska as new Polish member". […]
Published on: 19 - February – 2018
For more information, please refer to:
http://www.ema.europa.eu/docs/en_GB/document_library/Committee_meeting_report/2018/02/WC500243991.pdf

Herbal medicinal products: Hamamelis, Hamamelidis folium et cortex aut ramunculus destillatum, Hamamelis virginiana L. (updated)
"The European Union herbal monograph adopted by the HMPC and supporting documents can be found under the 'All documents' tab." […]
Published on: 01 – March - 2018
For more information, please refer to:
http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/herbal/medicines/herbal_med_000112.jsp&mid=WC0b01ac058001fa1d

Herbal medicinal products: Hamamelis, Hamamelidis cortex, Hamamelis virginiana L. (updated)
"The European Union herbal monograph adopted by the HMPC and supporting documents can be found under the 'All documents' tab." […]
Published on: 01 – March - 2018
For more information, please refer to:
http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/herbal/medicines/herbal_med_000107.jsp&mid=WC0b01ac058001fa1d

Herbal medicinal products: Phaseolus, Phaseoli fructus (sine semine), Phaseolus vulgaris L. (updated)
"The European Union herbal monograph adopted by the HMPC and supporting documents can be found under the 'All documents' tab."[…]
Published on: 01 – March - 2018
For more information, please refer to:
http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/herbal/medicines/herbal_med_000191.jsp&mid=WC0b01ac058001fa1d

Herbal medicinal products: Leonurus, Leonuri cardiacae herba, Leonurus cardiaca L. (updated)
"The European Union herbal monograph adopted by the HMPC and supporting documents can be found under the 'All documents' tab."[…]
Published on: 01 – March - 2018
For more information, please refer to:
http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/herbal/medicines/herbal_med_0

00124.jsp&mid=WC0b01ac058001fa1d

Herbal medicinal products: Ilex, Mate folium, Ilex paraguariensis St. Hilaire (updated)
"The European Union herbal monograph adopted by the HMPC and supporting documents can be found under the 'All documents' tab."[…]
Published on: 01 – March - 2018
For more information, please refer to:
http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/herbal/medicines/herbal_med_000137.jsp&mid=WC0b01ac058001fa1d

Herbal medicinal products: Hamamelis, Hamamelidis folium, Hamamelis virginiana L. (updated)
"The European Union herbal monograph adopted by the HMPC and supporting documents can be found under the 'All documents' tab."[…]
Published on: 01 – March - 2018
For more information, please refer to:
http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/herbal/medicines/herbal_med_000111.jsp&mid=WC0b01ac058001fa1d

Herbal medicinal products: Echinacea, Echinaceae angustifoliae radix, Echinacea angustifolia DC. (updated)
"The European Union herbal monograph adopted by the HMPC and supporting documents can be found under the 'All documents' tab."[…]
Published on: 01 – March - 2018
For more information, please refer to:
http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/herbal/medicines/herbal_med_000068.jsp&mid=WC0b01ac058001fa1d

EDQM

New standards for haemophilia patients care in Council of Europe Resolution
"The Council of Europe's decision-making body, the Committee of Ministers, adopted Resolution CM/Res(2017)43 on principles concerning haemophilia therapies at the end of 2017. Elaborated by the European Committee on Blood Transfusion (CD-P-TS) on the basis of the recommendations from the Wildbad Kreuth Initiative IV meeting « Optimal use of clotting factors and platelets » of 2016*, the new Resolution replaces Resolution CM/Res (2015)3 on the same subject and calls on governments to take into account specific principles for the treatment of haemophilia and care for haemophilia patients." […]
Published on: 22 - February – 2018
For more information, please refer to:
https://www.edqm.eu/en/news/new-standards-haemophilia-patients-care-council-europe-resolution

Rapid implementation of the monograph Products of fermentation (1468)
"Due to the public health risk associated with histamine contamination, further requirements related to the quality of raw materials have been added to the Raw materials section of the monograph on Products of fermentation (1468). The revised monograph will be implemented on 1 April 2018." […]
Published on: 01 – March - 2018
For more information, please refer to:
https://www.edqm.eu/en/news/rapid-implementation-monograph-products-fermentation-1468

European Commission

Synopsis report of the Consultation - Transformation Health and Care in the Digital Single Market
Published on: 19 - February – 2018
For more information, please refer to:
https://ec.europa.eu/health/sites/health/files/ehealth/docs/2018_consultation_dsm_en.pdf

Presentations and project's outputs - Final conference: VulnerABLE: Improving the health of those in isolated and vulnerable situations (7 November 2017)
Published on: 23 - February – 2018
For more information, please refer to:
https://ec.europa.eu/health/social_determinants/events/ev_20171107_en

EU Agencies Network on Scientific Advice (EU-ANSA): web page; explanatory leaflet and Exposure science research cluster paper now available
Published on: 23 - February – 2018
For more information, please refer to:
http://www.emcdda.europa.eu/about/partners/euansa

European Commission revised guideline on 'Excipients in the labelling and package leaflet of medicinal products for human use'
Published on: 01 – March - 2018
For more information, please refer to:
https://ec.europa.eu/health/sites/health/files/files/eudralex/vol-2/c/guidelines_excipients_march2018_en.pdf

EU-US FDA mutual recognition of inspections of medicines manufacturers enters operational phase
Published on: 01 – March - 2018
For more information, please refer to:
http://ec.europa.eu/newsroom/sante/newsletter-specific-archive-issue.cfm?newsletter_service_id=327&newsletter_issue_id=7516&page=1&fullDate=Wed%2003%20Jan%202018&lang=default

Health Systems in the EU: Commission publishes report on Primary Care
Published on: 02 – March - 2018
For more information, please refer to:
http://ec.europa.eu/newsroom/sante/newsletter-specific-archive-issue.cfm?newsletter_service_id=327&newsletter_issue_id=7571&page=1&fullDate=Sat%2003%20Feb%202018&lang=default

CMDh

UPDATE - List of safety concerns per approved Risk Management Plan (RMP) of active substances per product
Published on: 22 - February – 2018
Weitere Informationen finden Sie unter:
http://www.hma.eu/fileadmin/dateien/Human_Medicines/CMD_h_/Pharmacovigilance_Legislation/RMPs/CMDh_330_2015_Rev08_2018_02.xlsx

NEW - November 2017 CMDh meeting with Interested Parties Minutes
Published on: 22 - February – 2018
Weitere Informationen finden Sie unter:
http://www.hma.eu/fileadmin/dateien/Human_Medicines/CMD_h_/About_CMDh/Contact_with_Representatives_Organisations/Meeting_w._IPs_Nov_2015/Minutes_CMDh_Meeting_with_IPs_November_2015.pdf
and
http://www.hma.eu/208.html

NEW - Report from the meeting held on 19-22 February 2018
Published on: 28 - February – 2018
Weitere Informationen finden Sie unter:
http://www.hma.eu/fileadmin/dateien/Human_Medicines/CMD_h_/cmdh_pressreleases/2018/02_2018_CMDh_Press_release.pdf

UPDATE - CMDh Best Practice Guide on the processing of renewals in the MRP/DCP
Published on: 02 – March - 2018
Weitere Informationen finden Sie unter:
http://www.hma.eu/fileadmin/dateien/Human_Medicines/CMD_h_/procedural_guidance/Renewal/CMDh_004_2005_Rev16_02_2018_clean.pdf

UPDATE - Procedural advice: Validation of MR/Repeat-use/DC Procedures
Published on: 02 – March - 2018
Weitere Informationen finden Sie unter:
http://www.hma.eu/fileadmin/dateien/Human_Medicines/CMD_h_/procedural_guidance/Application_for_MA/CMDh_040_2001_Rev6_02_2018_clean.pdf

UPDATE - Flow chart of the Decentralised Procedure
Published on: 02 – March - 2018
Weitere Informationen finden Sie unter:
http://www.hma.eu/fileadmin/dateien/Human_Medicines/CMD_h_/procedural_guidance/Application_for_MA/DCP/CMDh_080_2005_Rev3_02_2018_clean.pdf

UPDATE - CMDh Standard Operating Procedure - Disagreement in procedures -Referral to CMDh
Published on: 02 – March - 2018
Weitere Informationen finden Sie unter:
http://www.hma.eu/fileadmin/dateien/Human_Medicines/CMD_h_/CMDhReferrals_Art29/CMDh_103_2005_Rev12_02_2018_clean.pdf

CMDh

UPDATE - 'Blue-box' requirements
Published on: 02 – March - 2018
Weitere Informationen finden Sie unter:
http://www.hma.eu/fileadmin/dateien/Human_Medicines/CMD_h_/procedural_guidance/Application_for_MA/CMDh_258_2012_Rev14_03_2018_clean.pdf

UPDATE - CMDh procedural advice on changing the RMS
Published on: 02 – March - 2018
Weitere Informationen finden Sie unter:
http://www.hma.eu/fileadmin/dateien/Human_Medicines/CMD_h_/procedural_guidance/01_General_Info/CMDh_039_2002_Rev.6_02_2018_clean.pdf

UPDATE - List of active substances for which data has been submitted in accordance with Article 45 of the Paediatric Regulation
Published on: 02 – March - 2018
Weitere Informationen finden Sie unter:
http://www.hma.eu/fileadmin/dateien/Human_Medicines/CMD_h_/Paediatric_Regulation/Article_45_and_previous_Worksharing/CMDh_151_2009_Rev65_2018_02.xls

NEW - Art. 46 Assessment report for Certican (everolimus), TOBI (tobramycin nebuliser solution) and Asmanex Twisthaler (mometasone furoate)
Published on: 02 – March - 2018
Weitere Informationen finden Sie unter:
http://www.hma.eu/fileadmin/dateien/Human_Medicines/CMD_h_/Paediatric_Regulation/Assessment_Reports/Article_46_work-sharing/Certican_02_2018_Art._46_PdAR.pdf (Certican)
and
http://www.hma.eu/fileadmin/dateien/Human_Medicines/CMD_h_/Paediatric_Regulation/Assessment_Reports/Article_46_work-sharing/TOBI_02_2018_Art.46_PAR.pdf (TOBI)
and
http://www.hma.eu/fileadmin/dateien/Human_Medicines/CMD_h_/Paediatric_Regulation/Assessment_Reports/Article_46_work-sharing/Asmanex_Twisthaler_02_2018_Art._46_PAR.pdf (Asmanex Twisthaler)

NEW - Art. 45 Assessment report for doxycycline
Published on: 02 – March - 2018
Weitere Informationen finden Sie unter:
http://www.hma.eu/fileadmin/dateien/Human_Medicines/CMD_h_/Paediatric_Regulation/Assessment_Reports/Article_45_work-sharing/Doxycycline_02_2018_Art._45_PAR_.pdf

NEW - 2017 - Statistics for New Applications (MRP/DCP), Variations, Referrals and Paediatric Worksharing procedurese
Published on: 02 – March - 2018
Weitere Informationen finden Sie unter:
http://www.hma.eu/fileadmin/dateien/Human_Medicines/CMD_h_/Statistics/2017_Annual_CMDh_statistics.pdf

CMDh

NEW - Summary of CMDh activities 2017
Published on: 02 – March - 2018
Weitere Informationen finden Sie unter:
http://www.hma.eu/fileadmin/dateien/Human_Medicines/CMD_h_/About_CMDh/Reports/CMDh_370_2018_02_2018.pdf

NEW - Template for RMS change
Published on: 02 – March - 2018
Weitere Informationen finden Sie unter:
http://www.hma.eu/fileadmin/dateien/Human_Medicines/CMD_h_/procedural_guidance/01_General_Info/CMDh_371_2018_Rev0_02_2018.xlsx

NEW - Advise from CMDh - Concomitant use of benzodiazepines/benzodiazepine like products and opioids
Published on: 02 – March - 2018
Weitere Informationen finden Sie unter:
http://www.hma.eu/fileadmin/dateien/Human_Medicines/CMD_h_/Advice_from_CMDh/CMDh_372_2018_Rev0_02_2018.pdf

Humanarzneimittel - Deutschland

Aktuelle Bearbeitungsstatistik des Bundesinstituts für Arzneimittel und Medizinprodukte
„Die Arzneimittelzahlen und Statistiken wurden aktualisiert." [...]»
Veröffentlicht am: *20 – Februar – 2018*
Weitere Informationen finden Sie unter:
https://www.bfarm.de/DE/Service/Statistik/AM_statistik/Statistik_Bearbeitung_aktuell/statistik-bearbeitung-aktuell_Jan18.html

Aktuelle Informationen zur Meldung nach § 21 Transfusionsgesetz (TFG)
Veröffentlicht am: 20 - Februar – 2018
Weitere Informationen finden Sie unter:
https://www.pei.de/DE/infos/meldepflichtige/meldung-blutprodukte-21-transfusionsgesetz/mitteilungen/mitteilungen-21tfg-inhalt.html;jsessionid=BF44E87D1C7D1EA72F20EF0E941BE0FA.2_cid329

Auflistungen der Lieferengpässe von Human-Impfstoffen
Veröffentlicht am: 22 - Februar – 2018
Weitere Informationen finden Sie unter:
https://www.pei.de/DE/arzneimittel/impfstoff-impfstoffe-fuer-den-menschen/lieferengpaesse/listen-lieferengpaesse-humanimpfstoffe/listen-lieferengpaesse-impfstoffe-inhalt.html

Auswirkungen des Brexit: Vorbereitungen des Paul-Ehrlich-Instituts
Veröffentlicht am: 23 - Februar – 2018
Weitere Informationen finden Sie unter:
https://www.pei.de/DE/infos/pu/auswirkungen-brexit-vorbereitungen-paul-ehrlich-institut.html

PEI-C Rebuild- elektronische Einreichung von Anträgen zur Chargenfreigabe
Veröffentlicht am: 26 - Februar – 2018
Weitere Informationen finden Sie unter:
https://www.pei.de/DE/infos/pu/elektronische-einreichung/einreichungswege/chargenfreigabeportal/pei-c-rebuild-antraege-chargenfreigabe-inhalt.html

Tagesordnung (Entwurf Stand 24.01.2018) für die 77. Beratung des Ausschusses Herstellungsregeln der Deutschen Homöopathischen Arzneibuch-Kommission
„Das BfArM gibt die Tagesordnung (Entwurf Stand 24.01.2018) für die 77. Beratung des Ausschusses Herstellungsregeln der Deutschen Homöopathischen Arzneibuch-Kommission bekannt. „ […]
Veröffentlicht am: 28 - Februar – 2018
Weitere Informationen finden Sie unter:
https://www.pei.de/DE/infos/pu/auswirkungen-brexit-vorbereitungen-paul-ehrlich-institut.html

Beauflagtes Schulungsmaterial (Educational material)
Veröffentlicht am: 01 – March - 2018
Weitere Informationen finden Sie unter:
https://www.pei.de/DE/arzneimittelsicherheit-vigilanz/schulungsmaterial/schulungsmaterial-inhalt.html;jsessionid=FC37A05576382710E7EC89E1E2C2B480.1_cid319

Auflistungen der Lieferengpässe von Human-Impfstoffen
Veröffentlicht am: 02 – March - 2018
Weitere Informationen finden Sie unter:
https://www.pei.de/DE/arzneimittel/impfstoff-impfstoffe-fuer-den-menschen/lieferengpaesse/listen-lieferengpaesse-humanimpfstoffe/listen-lieferengpaesse-impfstoffe-inhalt.html

Humanarzneimittel - Österreich

Aktuelle Geschäftsordnung und Anlage
L M72 Anlage Geschäftsordnung aktualisiert
Veröffentlicht am: *14 – Februar – 2018*
Weitere Informationen finden Sie unter:
https://www.basg.gv.at/ueber-uns/geschaeftsordnung/

Chemische Referenzstandards – aktualisiert
«Etablierung chemischer Referenzstandards durch das österreichische Arzneimittelkontrolllabor: [...]»
Veröffentlicht am: *19 – Februar – 2018*
Weitere Informationen finden Sie unter:
https://www.basg.gv.at/labor/europaeisches-arzneibuch/chemische-referenzstandards/

AGES Monographieentwicklungen – aktualisiert
«Monographierevisionen und Neuentwicklungen durch die Expertengruppenmitglieder der AGES Medizinmarktaufsicht: [...]»
Veröffentlicht am: *19 – Februar – 2018*
Weitere Informationen finden Sie unter:
https://www.basg.gv.at/labor/oesterreichisches-arzneibuch/ages-monographieentwicklungen/

eCTD/VNeeS – aktualisiert
Verpflichtende Verwendung von eCTD und VNeeS auch für rein nationale Einreichungen
Veröffentlicht am: *20 – Februar – 2018*
Weitere Informationen finden Sie unter:
https://www.basg.gv.at/eservices/ectdvnees/

Amtliche Nachrichten 2018 – Februar 2018
Seretide Diskus Standard
Veröffentlicht am: *22 – Februar – 2018*
Weitere Informationen finden Sie unter:
https://www.basg.gv.at/arzneimittel/amtliche-nachrichten/2018/

GMP/GDP
Betriebsbewilligungen nach AMG – Good Manufacturing Practice (GMP) and Good Distribution Practice (GDP)
F I01 Antrag Bewilligung AMG BSG akutalisiert
Veröffentlicht am: *26 – Februar – 2018*
Weitere Informationen finden Sie unter:
https://www.basg.gv.at/inspektionen/formulare/gmpgdp/

Kontakt
Erreichbarkeit aller AGES/MEA Mitarbeiterinnen und Mitarbeiter - aktualisiert
Liste Ansprechpartner März 2018
Veröffentlicht am: *28 – Februar – 2018*
Weitere Informationen finden Sie unter:
https://www.basg.gv.at/ueber-uns/kontakt/

Humanarzneimittel - Österreich

Amtliche Nachrichten 2018

Eligard (Leuprorelinacetat), Nulojix (Belatacept), Esmya (Ulipristalacetat)

Veröffentlicht am: *01 – März – 2018*

Weitere Informationen finden Sie unter:

https://www.basg.gv.at/pharmakovigilanz/amtliche-nachrichten/2018/

Humanarzneimittel - Schweiz

Betäubungsmittelverzeichnis um 19 neue psychoaktive Substanzen ergänzt
«Die Risiken neuer synthetischer Drogen sind für Konsumentinnen und Konsumenten nicht kalkulierbar. Das Eidgenössische Departement des Inneren (EDI) hat deshalb das Betäubungsmittelverzeichnis per 1. März um 19 Einzelsubstanzen erweitert. [...]»
***Veröffentlicht am:** 01 – März – 2018*
Weitere Informationen finden Sie unter:
https://www.swissmedic.ch/swissmedic/de/home/news/mitteilungen/betaeubungsmittelverzeichnis-um-19-neue-psychoaktive-substanzen-ergaenzt.html

Aktualisierte Dokumente – März 2018
- Formular Klinische Versuche mit Forschungssequenzen auf CE-markierten MRI-Systemen
- Formular Meldung nach Art. 6 MepV für klassische oder aktiv implantierbare Medizinprodukte mit DEVITALISIERTM MENSCHLICHEM GEWEBE
***Veröffentlicht am:** 01 – März – 2018*
Weitere Informationen finden Sie unter:
https://www.swissmedic.ch/swissmedic/de/home/news/updated_documents/maerz-2018.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

Deutsche Biotechnologietage 2018 Tagung-Symposium
Beginn: 18.04.2018
Ende: 19.04.2018
Ort: bcc Berlin Congress Center GmbH, Alexanderstraße 11, 10178 Berlin
Weitere Informationen finden Sie unter:
https://www.pei.de/SharedDocs/veranstaltungen-events/2018/2018-04-18-deutsche-biotechnologietage-2018.html;jsessionid=288088390AA3F06F0E4E9B1DCB60FEE4.2_cid354

PDA Europe Virus Forum 2018 Tagung-Symposium
Advanced Technologies for Virus Detection & Clearance in Biological Products
Beginn: 08.05.2018
Ende: 09.05.2018
Ort: Hilton Florence Metropole, Via del Callavaccio 36, Florence, Italy
Weitere Informationen finden Sie unter:
https://www.pei.de/SharedDocs/veranstaltungen-events/2018/2018-05-08-pda-virus-forum.html

IPFA & PEI 25nd International Workshop on 'Surveillance and Screening of Blood-borne Pathogens'
Begin: Wednesday, 16.05.2018
End: Thursday, 17.05.2018
Location: Royal Olympic Hotel, Athens, Greece
Weitere Informationen finden Sie unter:
http://www.pei.de/SharedDocs/veranstaltungen-events/2018/2018-05-16-ipfa-pei-workshop.html;jsessionid=458FEFA9AA8B383314464F06D924F2B2.2_cid354

Österreich

EU-Verordnungen über Medizinprodukte und In-vitro-Diagnostika
20. März 2018, 13:30 – 17:00,
Achtung geänderter Veranstaltungsort! Aufgrund der großen Nachfrage findet die Veranstaltung „Implementierung der Medizinprodukteverordnung am 20.3.2018“ jetzt nicht wie geplant in der Traisengasse (zweiter Bezirk) sondern im ersten Bezirk im:
Reitersaal (OeKB-Gebäude), Strauchgasse 3, 1010 Wien statt.
Weitere Informationen finden Sie unter:
https://www.ages.at/service/ages-akademie/programm-detail/kalender/detail/event/eu-verordnungen-ueber-medizinprodukte-und-in-vitro-diagnostika/

Pharmacovigilanz Update
12.06.2018, AGES, Spargelfeldstrasse 191, 1220 Wien
Weitere Informationen finden Sie unter:
https://www.ages.at/service/ages-akademie/programm-detail/kalender/detail/event/pharmakovigilanz-update/

Schweiz

Zur Zeit keine Veranstaltungen gemeldet.

Europa

Multi-stakeholder workshop to further improve the implementation of the Paediatric Regulation, European Medicines Agency, London, UK,
From: 20-Mar-2018, To: 20-Mar-2018
Weitere Informationen finden Sie unter:
http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/events/2018/01/event_detail_001570.jsp&mid=WC0b01ac058004d5c3

The new EudraVigilance system and the electronic reporting of ICSRs in the ISO/ICH E2B(R3) format: hands-on training course, Amsterdam ,
BCN Amsterdam Arena, Amsterdam, The Netherlands,
From: 19-Mar-2018, To: 21-Mar-2018
Weitere Informationen finden Sie unter:
http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/events/2017/11/event_detail_001544.jsp&mid=WC0b01ac058004d5c3

The new EudraVigilance system and the electronic reporting of ICSRs in the ISO/ICH E2B(R3) format: hands-on training course,
Paris, Châteauform' College, Paris, France,
From: 13-Jun-2018, To: 15-Jun-2018
Weitere Informationen finden Sie unter:
http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/events/2017/11/event_detail_001543.jsp&mid=WC0b01ac058004d5c3