22. Januar - 02. Februar 2018

MEGRA NEWSLETTER

Humanarzneimittel - EU

Allgemeines – General

Report: Human medicines highlights 2017
Published on: 23 – January – 2018
For more information, please refer to:
http://www.ema.europa.eu/docs/en_GB/document_library/Report/2018/01/WC500242079.pdf

Authorisation of medicines
Published on:23 – January – 2018
For more information, please refer to:
http://www.ema.europa.eu/ema/index.jsp?curl=pages/about_us/general/general_content_000109.jsp&mid=WC0b01ac0580028a47

EMA surveys pharma companies on their preparedness for Brexit
Published on:23 – January – 2018
For more information, please refer to:
http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/news/2018/01/news_detail_002890.jsp&mid=WC0b01ac058004d5c1

Brexit-related guidance for companies (updated)
Published on: 23 – January – 2018
For more information, please refer to:
http://www.ema.europa.eu/ema/index.jsp?curl=pages/about_us/general/general_content_001891.jsp&mid=WC0b01ac0580cb2e5b

Human Medicines Research and Development Support
Published on: 01 – February – 2018
For more information, please refer to:
http://www.ema.europa.eu/ema/index.jsp?curl=pages/about_us/q_and_a/q_and_a_detail_000120.jsp&mid=WC0b01ac05805040fd

Human Medicines Research and Development Support
Published on: 01 – February – 2018
For more information, please refer to:
http://www.ema.europa.eu/ema/index.jsp?curl=pages/about_us/q_and_a/q_and_a_detail_000120.jsp&mid=WC0b01ac05805040fd

Pharmakovigilanz – PRAC

Regulatory and procedural guideline: EudraVigilance user manual for marketing authorisation holders (updated)
Published on: 22 – January – 2018
For more information, please refer to:
http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2017/11/WC500238986.pdf

Regulatory and procedural guideline: EudraVigilance user manual - Individual case safety report form - Version 1.1 (updated)
Published on: 22 – January – 2018
For more information, please refer to:

http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2017/06/WC500229803.pdf

Regulatory and procedural guideline: EudraVigilance web application (EVWEB) v.1.4 release notes (updated)
Published on: 24 – January – 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

List of medicines under additional monitoring
"Summary of changes in January 2018 - The following centrally-authorised products have been added to the list:
Adynovi (rurioctocog alfa pegol): New active substance, PASS.
Fasenra (benralizumab): New biological.
Mvasi (bevacizumab): New biological.
Ocrevus (ocrelizumab): New active substance.
Prevymis (letermovir): New active substance.
The following centrally-authorised products have been deleted from the list:
Daliresp (roflumilast): At the marketing authorisation holder's request, the marketing authorisation granted by Decision C(2011)1467(final) for "Daliresp - roflumilast", has been withdrawn on 11 January 2018.
Jetrea (ocriplasmin): Five years following its authorisation, Jetrea is no longer considered a new active substance. It is therefore removed from this list.
Libertek (roflumilast): At the marketing authorisation holder's request, the marketing authorisation granted by Decision C(2011)1471(final) for "Libertek - roflumilast", has been withdrawn on 11 January 2018.
Perjeta (pertuzumab): Five years following its authorisation and after completion of the imposed BERENICE PASS, Perjeta is no longer under additional monitoring, therefore it is removed from this list.
The following nationally-authorised product has been deleted from the list:
Albumeon (human albumin): Five years following its authorisation, Albumeon is no longer considered a new active substance. It is therefore removed from this list.
Additionally, Annex VII - List of Targocid and associated names (teicoplanin-containing medicinal products in the European Union), has been updated." […]
Published on: 31 – January – 2018
For more information, please refer to:
http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/document_listing/document_listing_000366.jsp&mid=WC0b01ac058067c852

List of European Union reference dates and frequency of submission of periodic safety update reports (updated)
Published on: 31 – January – 2018
For more information, please refer to:
http://www.ema.europa.eu/docs/en_GB/document_library/Other/2012/10/WC500133159.xls

Minutes of the PRAC meeting 27-30 November 2017
Published on: 31 – January – 2018
For more information, please refer to:
http://www.ema.europa.eu/docs/en_GB/document_library/Minutes/2018/01/WC500242926.pdf

Regulatory and procedural guideline: EudraVigilance web application (EVWEB) v.1.5 release notes (updated)
Published on: 31 – January – 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

Mutual recognition agreements (updated)
Published on: 23 – January – 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

Report: Medicinal products for human use: monthly figures - December 2017
Published on: 24 – January – 2018
For more information, please refer to:
http://www.ema.europa.eu/docs/en_GB/document_library/Report/2018/01/WC500242140.pdf

Scientific guideline: Draft guideline on core summary of products characteristics (SmPC) and package leaflet for technetium (99mTc) macrosalb, draft: consultation open
Published on: 24 – January – 2018
For more information, please refer to:
http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2018/01/WC500242227.pdf

Regulatory and procedural guideline: List of centrally authorised products requiring a notification of a change for update of annexes (updated)
Published on: 25 – January – 2018
For more information, please refer to:
http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2010/08/WC500095767.pdf

Regulatory and procedural guideline: Member states contact points for translation review (v.6.9) (updated)
Published on: 25 – January – 2018
For more information, please refer to:
http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2009/10/WC500004437.pdf

Substance and product data management services
Published on: 25 – January – 2018
For more information, please refer to:
http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_001850.jsp&mid=WC0b01ac0580bf732a

Scientific advice and protocol assistance adopted during the CHMP meeting 22 – 25 January 2018
Published on: 26 – January – 2018

For more information, please refer to:
http://www.ema.europa.eu/docs/en_GB/document_library/Annex_to_CHMP_highlights/2018/01/WC500242422.pdf

Referral: Article 107i procedures, Hydroxyethyl starch (HES) containing medicinal products, hydroxyethyl starch (HES) (updated)
Published on: 26 – January – 2018
For more information, please refer to:
http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/referrals/Hydroxyethyl_starch_(HES)_containing_medicinal_products/human_referral_prac_000068.jsp&mid=WC0b01ac05805c516f

News and press releases: New enzyme replacement therapy to treat rare genetic disorder alpha-mannosidosis in children and adults
Published on: 26 – January – 2018
For more information, please refer to:
http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/news/2018/01/news_detail_002891.jsp&mid=WC0b01ac058004d5c1

News and press releases: First-in-class medicine to prevent bleeding in haemophilia A patients with inhibitors
Published on: 26 – January – 2018
For more information, please refer to:
http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/news/2018/01/news_detail_002893.jsp&mid=WC0b01ac058004d5c1

News and press releases: Meeting highlights from the Committee for Medicinal Products for Human Use (CHMP) 22-25 January 2018
Published on: 26 – January – 2018
For more information, please refer to:
http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/news/2018/01/news_detail_002888.jsp&mid=WC0b01ac058004d5c1

News and press releases: First-in-class medicine to prevent bleeding in haemophilia A patients with inhibitors
Published on: 26 – January – 2018
For more information, please refer to:
http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/news/2018/01/news_detail_002893.jsp&mid=WC0b01ac058004d5c1

Notice to marketing authorisation holders of centrally authorised medicinal products for human and veterinary use (updated)
Published on: 29 – January – 2018
For more information, please refer to:
http://www.ema.europa.eu/docs/en_GB/document_library/Other/2017/05/WC500226603.pdf

Report: List of products granted eligibility to PRIME (updated)
Published on:01 – February – 2018
For more information, please refer to:
http://www.ema.europa.eu/docs/en_GB/document_library/Report/2016/10/WC500214862.xlsx

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Report: Recommendations on eligibility to PRIME scheme - Adopted at the CHMP meeting of 22-25 January 2018
Published on: 01 – February – 2018
For more information, please refer to:
http://www.ema.europa.eu/docs/en_GB/document_library/Report/2018/02/WC500242955.pdf

Notice to marketing authorisation holders of centrally authorised medicinal products for human Plasma-master-file certifications (updated)
Published on: 01 – 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

Orphan Drugs und neuartige Therapierichtungen (ATMP)

CAT monthly report of application procedures, guidelines and related documents on advanced Orphan medicines figures 2000-2017 (updated)
Published on: 24- January – 2018
For more information, please refer to:
http://www.ema.europa.eu/docs/en_GB/document_library/Other/2015/04/WC500185766.pdf

Minutes of the CAT meeting 10-12 April 2017 (updated)
Published on: 26- January – 2018
For more information, please refer to:
http://www.ema.europa.eu/docs/en_GB/document_library/Minutes/2017/06/WC500229703.pdf

Minutes of the CAT meeting 30-31 October 2017
Published on: 26- January – 2018
For more information, please refer to:
http://www.ema.europa.eu/docs/en_GB/document_library/Minutes/2018/01/WC500242433.pdf

Minutes of the COMP meeting of 30-31 October 2017
Published on: 29- January– 2018
For more information, please refer to:
http://www.ema.europa.eu/docs/en_GB/document_library/Minutes/2018/01/WC500242719.pdf

Regulatory and procedural guideline: Procedural advice on the evaluation of advanced therapy medicinal product in accordance with Article 8 of Regulation (EC) No 1394/2007, adopted
Published on: 01- February – 2018
For more information, please refer to:
http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2018/02/WC500242957.pdf

Marketing-authorisation procedures for advanced-therapy medicinal products (updated)
Published on: 01- February – 2018
For more information, please refer to:
http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/document_listing/document_listing_000388.jsp&mid=WC0b01ac05800862bc

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News and press releases: Evaluation of advanced therapy medicines
Published on: 01- February – 2018
For more information, please refer to:
http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/news/2018/01/news_detail_002895.jsp&mid=WC0b01ac058004d5c1

Advanced therapy medicinal products (updated)
Published on: 01- February – 2018
For more information, please refer to:
http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_000294.jsp&mid=WC0b01ac05800241e0

Pharmacovigilance for advanced therapies (updated)
Published on: 01- February – 2018
For more information, please refer to:
http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_000297.jsp&mid=WC0b01ac05800862be

Scientific guideline: Draft guideline on safety and efficacy follow-up and risk management of advanced therapy medicinal products - Rev. 1, draft: consultation open
Published on: 01- February – 2018
For more information, please refer to:
http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2018/02/WC500242959.pdf

Guideline on safety and efficacy follow-up and risk management of advanced therapy medicinal products
Published on: 01- February – 2018
For more information, please refer to:
http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/md_gene_therapy/general_content_001909.jsp&mid=WC0b01ac058002958d

Qualität – Quality

Questions and answers on the Haemagglutination Inhibition (HI) test for qualification of influenza vaccine (inactivated) seed preparations
"Based on the experience from recent evaluations of Annual Update applications for influenza vaccines (inactivated), both regulators and industry have requested further guidance about the regulatory requirements of HI testing as applied for the qualification of influenza seed virus preparations. Whilst some of the principles outlined below may be applicable to live attenuated influenza vaccines (LAIV), there are additional considerations towards the qualification of seed virus preparations using HI testing and hence LAIVs are outside the scope of this Q&A document." […]
Published on: 01- February – 2018
For more information, please refer to:
http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/bio_drug_substance/general_content_001911.jsp&mid=WC0b01ac058002956b

Dronedarone film-coated tablets 400 mg product-specific bioequivalence guidance (updated)
Published on: 01- February – 2018
For more information, please refer to:

http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/product_specific_bioequivalence/general_content_001870.jsp&mid=WC0b01ac0580848f74

Dolutegravir, film-coated tablet, 10mg, 25mg, 50mg, product-specific bioequivalence guidance (updated)
Published on: 01- February – 2018
For more information, please refer to:
http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/product_specific_bioequivalence/general_content_001869.jsp&mid=WC0b01ac0580848f74

Tadalafil product-specific bioequivalence guidance (updated)
Published on: 01- February – 2018
For more information, please refer to:
http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/product_specific_bioequivalence/general_content_001428.jsp&mid=WC0b01ac0580848f74

Rilpivirine film-coated tablets 25 mg product-specific bioequivalence guidance (updated)
Published on: 01- February – 2018
For more information, please refer to:
http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/product_specific_bioequivalence/general_content_001872.jsp&mid=WC0b01ac0580848f74

Paracetamol oral use, immediate release formulations product-specific bioequivalence guidance (updated)
Published on: 01- February – 2018
For more information, please refer to:
http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/product_specific_bioequivalence/general_content_001871.jsp&mid=WC0b01ac0580848f74

Questions and answers on bovine spongiform encephalopathies (BSE) and vaccines
Published on: 01- February – 2018
For more information, please refer to:
http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_000945.jsp&mid=WC0b01ac058002956c

Quality aspects included in the product information for vaccines for human use (updated)
Published on: 01- February – 2018
For more information, please refer to:
http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_000928.jsp&mid=WC0b01ac058002956c

(Prä-) Klinische Forschung – Research and Development

Regulatory and procedural guideline: Draft qualification opinion on molecular neuroimaging of the dopamine transporter as biomarker for to identify patients with early manifest Parkinsonism in Parkinson's disease, draft: consultation open
Published on: 24- January – 2018
For more information, please refer to:
http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2018/01/WC500242219.pdf

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Cholic acid capsules 50 mg and 250 mg product-specific bioequivalence guidance
Deadline for comments: 30/04/2018
Published on: 31- January – 2018
For more information, please refer to:
http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/product_specific_bioequivalence/general_content_001905.jsp&mid=WC0b01ac0580848f74

Vismodegib hard capsule 150 mg product-specific bioequivalence guidance
Deadline for comments: 30/04/2018
Published on: 31- January – 2018
For more information, please refer to:
http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/product_specific_bioequivalence/general_content_001908.jsp&mid=WC0b01ac0580848f74

Agomelatine oral tablet 25 mg product-specific bioequivalence guidance
Deadline for comments: 30/04/2018
Published on: 31- January – 2018
For more information, please refer to:
http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/product_specific_bioequivalence/general_content_001904.jsp&mid=WC0b01ac0580848f74

Posaconazole gastro-resistant tablet 100 mg product-specific bioequivalence guidance
Deadline for comments: 30/04/2018
Published on: 31- January – 2018
For more information, please refer to:
http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/product_specific_bioequivalence/general_content_001906.jsp&mid=WC0b01ac0580848f74

Ledipasvir/sofosbuvir film-coated tablet 90 mg/400 mg product-specific bioequivalence guidance
Deadline for comments: 30/04/2018
Published on: 31- January – 2018
For more information, please refer to:
http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/product_specific_bioequivalence/general_content_001907.jsp&mid=WC0b01ac0580848f74

Clinical pharmacology and pharmacokinetics: questions and answers
Published on: 31- January – 2018
For more information, please refer to:
http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/q_and_a/q_and_a_detail_000179.jsp&mid=WC0b01ac0580aff2ec

Questions and answers on bovine spongiform encephalopathies (BSE) and vaccines
"This is an update of the information in the Public Statement on the Evaluation of Bovine Spongiform Encephalopathies (BSE) - risk via the use of materials of bovine origin in or during the manufacture of vaccines and the Questions and Answers on Bovine Spongiform Encephalopathies (BSE) and Vaccines. " […]
Published on: 01- February – 2018
For more information, please refer to:
http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_00094

5.jsp&mid=WC0b01ac058002956c

Quality aspects included in the product information for vaccines for human use
"The current version is under revision." […]
Published on: 01- February – 2018
For more information, please refer to:
http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_000928.jsp&mid=WC0b01ac058002956c

Strategies to identify and mitigate risks for first-in-human and early clinical trials with investigational medicinal products
"Revision 1 current version published: 25/07/2017 - In operation: 01/02/2018-present " […]
Published on: 01- February – 2018
For more information, please refer to:
http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_001001.jsp&mid=WC0b01ac0580029570

Influenza vaccines - quality module
"Revision 1 - Adopted guideline - Published: 28/07/2017 - In operation: 01/02/2018-present " […]
Published on: 01- February – 2018
For more information, please refer to:
http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_000902.jsp&mid=WC0b01ac058002956b

Addendum to the note for guidance on evaluation of medicinal products indicated for treatment of bacterial infections to specifically address the clinical development of new agents to treat disease due to Mycobacterium Tuberculosis (updated)
"Revision 1 – adopted guideline - Published: 03/08/2017 - In operation: 01/02/2018-present " […]
Published on: 01- February – 2018
For more information, please refer to:
http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_001121.jsp&mid=WC0b01ac0580034cf2

Reflection paper on investigation of pharmacokinetics and pharmacodynamics in the obese population
"Obesity affects a large sub-set of the general population covering all ages and will continue to increase based on observed trends. The alteration of body composition and physiology as well as steatosis and a chronic state of inflammation (1) can potentially lead to important changes in the disposition of a given drug in obese as compared to non-obese subjects." […]
Consultation end date: 31/07/2018
Published on: 01- February – 2018
For more information, please refer to:
http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2018/02/WC500242971.pdf

Reflection paper on investigation of pharmacokinetics and pharmacodynamics in the obese population
"Obesity affects a large sub-set of the general population covering all ages and will continue to increase based on observed trends. The alteration of body composition and physiology as well as steatosis and a chronic state of inflammation (1) can potentially lead to important changes in the

disposition of a given drug in obese as compared to non-obese subjects.“ […]
Consultation end date: 31/07/2018
Published on: 01- February – 2018
For more information, please refer to:
http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2018/02/WC500242971.pdf

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Consultation end date: 31/07/2018
Published on: 01- February – 2018
For more information, please refer to:
http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2018/02/WC500242971.pdf

Kinderarzneimittel – Paediatrics

News and press releases: How to better apply the paediatric legislation to boost development of medicines for children
Published on: 31– January – 2018
For more information, please refer to:
http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/news/2018/01/news_detail_002896.jsp&mid=WC0b01ac058004d5c1

Pflanzliche Arzneimittel – Herbal medicines

No news available this time period

EDQM

The EDQM "Guidance for electronic submissions for CEPs applications" has been revised and application forms have been updated accordingly
Published on: 29 - January – 2018
For more information, please refer to:
https://www.edqm.eu/en/news/edqm-guidance-electronic-submissions-ceps-applications-has-been-revised-and-application-forms

Armenia signs Convention against Trafficking in Human Organs
Published on: 31 - January – 2018
For more information, please refer to:
https://www.edqm.eu/en/news/armenia-signs-convention-against-trafficking-human-organs

EDQM rolls out reference standards for elemental impurities: lead, cadmium, mercury and arsenic
Published on: 01 - February – 2018
For more information, please refer to:
https://www.edqm.eu/en/news/edqm-rolls-out-reference-standards-elemental-impurities-lead-cadmium-mercury-and-arsenic

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European Commission

Summary report - Meeting of Competent authorities for blood and blood components (22-23 June 2017)
Published on: 22 - January – 2018
For more information, please refer to:
https://ec.europa.eu/health/sites/health/files/blood_tissues_organs/docs/ev_20170622_sr_en.pdf

Updated - Notice to business operators in the field of regulation (EU) no 528/2012 of the European Parliament and of the Council concerning the making available on the market and use of biocidal products
Published on: 23 - January – 2018
For more information, please refer to:
https://ec.europa.eu/health/sites/health/files/biocides/docs/brexit_note_en.pdf

Updated - Notice to organisations subject to the Union legislation on substances of human origin (blood, tissues and cells, and organs) concerning the United Kingdom's withdrawal from the European Union
Published on: 23 - January – 2018
For more information, please refer to:
https://ec.europa.eu/health/sites/health/files/blood_tissues_organs/docs/2017_btc_brexit_en.pdf

Updated - Questions and Answers related to the United Kingdom's withdrawal from the European Union with regard to the medicinal products for human and veterinary use within the framework of the Centralised Procedure
Published on: 23 - January – 2018
For more information, please refer to:
https://ec.europa.eu/health/sites/health/files/files/documents/qa_on_brexit.pdf

Updated - Notice to marketing authorisation holders of centrally authorised medicinal products concerning the United Kingdom's notification pursuant to Article 50 of the Treaty on European Union
Published on: 23 - January – 2018
For more information, please refer to:
https://ec.europa.eu/health/sites/health/files/files/documents/ec_ema_notice_communication_brexit.pdf

Commission Report on Member State penalties for the falsification of medicines
Published on: 26 - January – 2018
For more information, please refer to:
https://ec.europa.eu/health/sites/health/files/files/falsified_medicines/com2018_49_final_en.pdf

Questions & Answers - Commission proposal on Health Technology Assessment
Published on: 29 - January – 2018
For more information, please refer to:
http://europa.eu/rapid/press-release_MEMO-18-487_en.htm

CMDh

UPDATE - List of safety concerns per approved Risk Management Plan (RMP) of active substances per product
Published on: 23 - January – 2018
Weitere Informationen finden Sie unter:
http://www.hma.eu/fileadmin/dateien/Human_Medicines/CMD_h_/Pharmacovigilance_Legislation/RMPs/CMDh_330_2015_Rev07_2018_01_1.xlsx

NEW - December 2017 CMDh Minutes
Published on: 30 - January – 2018
Weitere Informationen finden Sie unter:
http://www.hma.eu/fileadmin/dateien/Human_Medicines/CMD_h_/Agendas_and_Minutes/Minutes/2017_12_Plenary_Minutes_December.pdf

UPDATE - List of active substances for which data has been submitted in accordance with Article 45 of the Paediatric Regulation
Published on: 31 - January – 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_Rev64_2018_01.xls

UPDATE - Member States Recommendations on the Cover Letter for New Applications submitted through MRP/DCP
Published on: 31 - January – 2018
Weitere Informationen finden Sie unter:
http://www.hma.eu/fileadmin/dateien/Human_Medicines/CMD_h_/procedural_guidance/Application_for_MA/CMDh_076_2007_Rev4_01_2018_clean.pdf

UPDATE - Template for Cover letter for new applications submitted through MRP/DCP
Published on: 31 - January – 2018
Weitere Informationen finden Sie unter:
http://www.hma.eu/fileadmin/dateien/Human_Medicines/CMD_h_/Templates/MA_Application/CMDh_226_2007_Rev05_2018_01.doc

UPDATE - Extension of pilot for splitting of MRP/DCPs
Published on: 31 - January – 2018
Weitere Informationen finden Sie unter:
http://www.hma.eu/fileadmin/dateien/Human_Medicines/CMD_h_/Advice_from_CMDh/CMDh_354_2017_Rev2_01_2018_clean.pdf

•NEW - Art. 46 Assessment report for Lidocain Kreussler/Dynexan Mundgel (lidocaine hydrochloride)
End of procedure: 07/08/2017
Date of publication: 31/01/2018
Published on: 31 - January – 2018
Weitere Informationen finden Sie unter:
http://www.hma.eu/fileadmin/dateien/Human_Medicines/CMD_h_/Paediatric_Regulation/Assessment_Reports/Article_46_work-sharing/Lidocaine_Hydrochloride_Art._46_PAR_01_2018_.pdf

CMDh

NEW - Art. 45 Assessment report for lymecycline
End of procedure: 06/12/2017
Date of publication: 31/01/2018
Published on: 31 - January – 2018
Weitere Informationen finden Sie unter:
http://www.hma.eu/fileadmin/dateien/Human_Medicines/CMD_h_/Paediatric_Regulation/Assessment_Reports/Article_45_work-sharing/Lymecycline_Art_45_PAR_01_2018.pdf

NEW - PSUR Assessment report for ezetimibe/simvastatin
Date of publication: 31/01/2018
Published on: 31 - January – 2018
Weitere Informationen finden Sie unter:
http://www.hma.eu/fileadmin/dateien/Human_Medicines/CMD_h_/Pharmacovigilance_Legislation/PSUR/Summary_AR/Ezetimibe__simvastatin_SAR_01_2018.pdf

NEW - Report from the meeting held on 22-24 January 2018
Published on: 31 - January – 2018
Weitere Informationen finden Sie unter:
http://www.hma.eu/fileadmin/dateien/Human_Medicines/CMD_h_/Agendas_and_Minutes/Minutes/2017_12_Plenary_Minutes_December.pdf

NEW - December 2017 CMDh Minutes
Published on: 30 - January – 2018
Weitere Informationen finden Sie unter:
http://www.hma.eu/fileadmin/dateien/Human_Medicines/CMD_h_/cmdh_pressreleases/2018/01_2018_CMDh_press_release.pdf

UPDATE - Additional Data requested for New Applications in the Mutual Recognition and Decentralised Procedures
Published on: 01 - February – 2018
Weitere Informationen finden Sie unter:
http://www.hma.eu/fileadmin/dateien/Human_Medicines/CMD_h_/procedural_guidance/Application_for_MA/CMDh_043_2007_Rev14_2018_01_clean.pdf

Humanarzneimittel - Deutschland

Anordnung des Ausschlusses von Blutspendern zur Verhinderung einer möglichen Übertragung des West-Nil-Virus durch nicht Pathogen-inaktivierte Blutkomponenten

„Wirkstoff Hydroxyethylstärke

Der Ausschuss für Risikobewertung im Bereich der Pharmakovigilanz (PRAC) hat im Rahmen des im Oktober 2017 gestarteten Risikobewertungsverfahrens nach Artikel 107i der Richtlinie 2001/83 das Ruhen von Zulassungen HES-haltiger Arzneimittel zur Infusion in Europa empfohlen..“ […]

Veröffentlicht am: 23 – Januar – 2018

Weitere Informationen finden Sie unter:

https://www.pei.de/DE/infos/pu/zulassung-humanarzneimittel/verfahren/blut-blutkomponenten/wnv-spenderrueckstellung/wnv-spenderrueckstellung-inhalt.html

CMDh bestätigt die PRAC-Empfehlung zum Ruhen der Zulassungen von Hydroxyethylstärke (HES)-haltigen Arzneimitteln

Wirkstoff Hydroxyethylstärke

Die Koordinierungsgruppe für Verfahren der gegenseitigen Anerkennung und dezentrale Verfahren (CMDh) bestätigt die Empfehlung des Ausschusses für Risikobewertung im Bereich der Pharmakovigilanz (PRAC) der Europäischen Arzneimittelagentur (EMA), die Zulassungen HES-haltiger Arzneimittel zur Infusion in Europa ruhen zu lassen.“ […]

Veröffentlicht am: 26 – Januar - 2018

Weitere Informationen finden Sie unter:

https://www.bfarm.de/SharedDocs/Risikoinformationen/Pharmakovigilanz/DE/RV_STP/g-l/hes-neu2017.html

Pressemitteilungen des Paul-Ehrlich-Instituts

Veröffentlicht am:26 – Januar – 2018

Weitere Informationen finden Sie unter:

https://www.pei.de/DE/infos/presse/pressemitteilungen/pressemitteilungen-inhalt.html

Zulassungen und andere Amtshandlungen im Bundesanzeiger seit 2005

Veröffentlicht am:31 – Januar – 2018

Weitere Informationen finden Sie unter:

https://www.pei.de/DE/service/bekanntmachungen/zulassungen-alle-chronologisch-inhalt.html

Europäische Datenbank zu Verdachtsfällen von Nebenwirkungen löst nationale Datenbanken ab – Ausnahme Impfstoffe

Veröffentlicht am:01 – Februar – 2018

Weitere Informationen finden Sie unter:

https://www.pei.de/DE/arzneimittelsicherheit-vigilanz/pharmakovigilanz/uaw-datenbank/europaeische-datenbank-verdachtsfaelle-nebenwirkungen-loest-nationale-datenbanken-ab.html

Auflistungen der Lieferengpässe von Human-Impfstoffen

Veröffentlicht am: 02 – 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

Humanarzneimittel - Österreich

Good Manufacturing/Distribution Practice
FAQ Good Manufacturing/Distribution Practice Nr. 14 neu
Veröffentlicht am: *22 – Januar – 2018*
Weitere Informationen finden Sie unter:
https://www.basg.gv.at/inspektionen/faq-inspektionen/good-manufacturingdistribution-practice/

Amtliche Nachrichten – Gewebe
ECDC RRA UPDATE 2 – Yellow fever-Brazil 22.01.2018
Veröffentlicht am: *22 – Januar – 2018*
Weitere Informationen finden Sie unter:
https://www.basg.gv.at/arzneimittel/gewebe/amtliche-nachrichten/

Compassionate Use – Verfahren in Österreich
Liste laufender Compassionate Use Programme in Österreich (FI453) aktualisiert
Veröffentlicht am: *24 – Januar – 2018*
Weitere Informationen finden Sie unter:
https://www.basg.gv.at/arzneimittel/vor-der-zulassung/compassionate-use/

Pharmakovigilanz in Europa – Interne Audits des Pharmakovigilanzsystems
Summary of pharmacovigilance system audit report results AT 2017
Veröffentlicht am: *24 – Januar – 2018*
Weitere Informationen finden Sie unter:
https://www.basg.gv.at/pharmakovigilanz/pharmakovigilanz-in-europa/

Dopingwarnhinweis
Verbotsliste BGBl. III Nr. 1-2018
Veröffentlicht am: *24 – Januar – 2018*
Weitere Informationen finden Sie unter:
https://www.basg.gv.at/arzneimittel/faq/dopingwarnhinweis/

Übersicht Erledigungen BASG / AGES Medizinmarktaufsicht
Klinische Prüfungen 2006 bis 2017 sowie Medizinprodukte 2008 bis 2017 aktualisiert
Veröffentlicht am: *25 – Januar – 2018*
Weitere Informationen finden Sie unter:
https://www.basg.gv.at/news-center/statistiken/basg/

Nationale Zulassung und lifecycle – PSUR Einreichformulare
Formular B24 PSUR Einreichformular Human aktualisiert
Veröffentlicht am: *25 – Januar – 2018*
Weitere Informationen finden Sie unter:
https://www.basg.gv.at/arzneimittel/formulare/nationale-zulassung-und-lifecycle/

Amtliche Nachrichten 2018
Jänner 2018 – Saroten
Veröffentlicht am: *25 – Januar – 2018*
Weitere Informationen finden Sie unter:
https://www.basg.gv.at/arzneimittel/amtliche-nachrichten/2018/

Humanarzneimittel - Österreich

Betriebsbewilligungen nach AMG – Good Manufacturing Practice (GMP) and Good Distribution Practice (GDP)
Formular I146 Checkliste FAMBO aktualisiert
Veröffentlicht am: *25 – Januar – 2018*
Weitere Informationen finden Sie unter:
https://www.basg.gv.at/inspektionen/formulare/gmpgdp/

Meldung einer vermuteten ernsten unerwünschten Reaktion im Rahmen der Transfusion
Liste I125 Krankenanstalten und Betriebsidentifikationsnummern für die Absetzung einer Hämovigilanz-Meldung aktualisiert
Veröffentlicht am: *29 – Januar – 2018*
Weitere Informationen finden Sie unter:
https://www.basg.gv.at/arzneimittel/blut/formulare/

Sonstige Mustertexte 2018
Vitamin K Antagonisten & Simvastatin/Ezetimib – neu
Veröffentlicht am: *30 – Januar – 2018*
Weitere Informationen finden Sie unter:
https://www.basg.gv.at/pharmakovigilanz/pv-wordings-mustertexte/sonstige-mustertexte-2018/

Leitfäden für eServices
LI21 Leitfaden für Vertriebseinschränkungen
Veröffentlicht am: *31 – Januar - 2018*
Weitere Informationen finden Sie unter:
https://www.basg.gv.at/eservices/leitfaeden/

Übersichtsliste Vertriebseinschränkungen aktualisiert
Stand 26.01.2018
Veröffentlicht am: *01 – Februar - 2018*
Weitere Informationen finden Sie unter:
https://www.basg.gv.at/news-center/news/news-detail/article/uebersichtsliste-vertriebseinschraenkungen-986/

Vertriebseinschränkungen Register neu
„Ab 1. Februar 2018 besteht für Zulassungsinhaber bzw. befugte Vertreterinnen und Vertreter des Zulassungsinhabers die Möglichkeit, Vertriebseinschränkungen über das eService zu melden.“ [.....]
Veröffentlicht am: *01 – Februar - 2018*
Weitere Informationen finden Sie unter:
https://www.basg.gv.at/news-center/news/news-detail/article/vertriebseinschraenkungen-register-neu-1213/

Nutzungshinweise für öffentliche Datenregister aktualisiert
Veröffentlicht am: *01 – Februar - 2018*
Weitere Informationen finden Sie unter:
https://www.basg.gv.at/eservices/nutzungshinweise/

Humanarzneimittel - Österreich

PSUR outcome 2018
Simvastatin/Ezetimib, Simvastatin, Glucosamin, Epoprostenol, Cefuroxim-Natrium, Lanthan, Ivermectin
Veröffentlicht am: *02 – Februar – 2018*
Weitere Informationen finden Sie unter:
https://www.basg.gv.at/pharmakovigilanz/pv-wordings-mustertexte/psur-outcome-2018/

Humanarzneimittel - Schweiz

Aktualisierte Dokumente – Januar 2018
Formular Melden der Materiovigilance-Kontaktperson
Veröffentlicht am: *19 – Januar – 2018*
Weitere Informationen finden Sie unter:
https://www.swissmedic.ch/swissmedic/de/home/news/updated_documents/januar-2018.html

Medizinprodukte – Neue Informationen zu den EU-Verordnungen (MDR/IVDR)
Aktuelles zur Umsetzung
Veröffentlicht am: *23 – Januar – 2018*
Weitere Informationen finden Sie unter:
https://www.swissmedic.ch/swissmedic/de/home/medizinprodukte/neue-eu-verordnungen--mdr--ivdr-/aktuelles-zur-umsetzung.html

Anpassung des Formulars Gesuch Verlängerung der Zulassung per sofort
«Gemäss SMJ 10/2010 dürfen Gesuchsverlängerung nicht zu früh eingereicht werden. Diese Präzisierung wurde im oben erwähnten Formular angeführt.
Veröffentlicht am: *31 – Januar – 2018*
Weitere Informationen finden Sie unter:
https://www.swissmedic.ch/swissmedic/de/home/humanarzneimittel/authorisations/informationen/anpassung-des-formulars-gesuch-verlaengerung-der-zulassung-per-sofort.html

Anpassung des Formulars Gesuch Verlängerung der Zulassung von Homöopathischen und antroposophischen Arzneimitteln im Meldeverfahren (HOMANT) per sofort
«Gemäss SMJ 10/2010 dürfen Gesuchsverlängerung nicht zu früh eingereicht werden. Diese Präzisierung wurde im oben erwähnten Formular angeführt.
Veröffentlicht am: *01 – Februar – 2018*
Weitere Informationen finden Sie unter:
https://www.swissmedic.ch/swissmedic/de/home/kpa/aktuell/anpassung-des-formulars-gesuch-verlaengerung-der-zulassung_homant_per-sofort1.html

Aktualisierte Dokumente – Februar 2018
- HD-Verzeichnis Anerkannte KBS für MEP
- Formular Änderungsmeldung nach Art. 6 MepV für klass. oder aktiv implantierbare Med. prod. mit DEVITALISIERTEM MENSCHLICHEM GEWEBE
Veröffentlicht am: *01 – Februar – 2018*
Weitere Informationen finden Sie unter:
https://www.swissmedic.ch/swissmedic/de/home/news/updated_documents/februar-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, AGES, Traisengasse 5, 1200 Wien
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/

Lieferengpässe: Vorstellung des neuen elektronischen Meldewesens
11. April 2018, AGES, Spargelfeldstrasse 191, Wien
Weitere Informationen finden Sie unter:
https://www.ages.at/service/ages-akademie/programm-detail/kalender/detail/event/lieferengpaesse-vorstellung-des-neuen-elektronischen-meldewesens/

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