02. – 14. März 2020

MEGRA

NEWSLETTER

Humanarzneimittel - EU

Allgemeines – General

Regulatory information – adjusted fees for applications to EMA from 1 April 2020
Published on: *06 - March - 2020*
For more information, please refer to:
Regulatory information – adjusted fees for applications to EMA from 1 April 2020 | European Medicines Agency

Human medicines highlights - March 2020 (new)
Published on: *11 - March - 2020*
For more information, please refer to:
https://www.ema.europa.eu/en/documents/newsletter/human-medicines-highlights-march-2020_en.pdf

Human medicines highlights - March 2020 (new)
Published on: *11 - March - 2020*
For more information, please refer to:
COVID-19: EMA meetings with delegates and experts will be held virtually until end April 2020 | European Medicines Agency

Coronavirus disease (COVID-19) (updated)
Published on: *13 - March - 2020*
For more information, please refer to:
Coronavirus disease (COVID-19) | European Medicines Agency

Pharmakovigilanz – PRAC

EudraVigilance registration manual (updated) 2019 - EMA/536361/2019, Rev. 4
Published on: *04 - March - 2020*
For more information, please refer to:
https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/eudravigilance-registration-manual_en.pdf

PRAC recommendations on signals adopted at the 10-13 February 2020 PRAC meeting (new) - EMA/PRAC/64581/2020
Published on: *10 - March – 2020*
For more information, please refer to:
https://www.ema.europa.eu/en/documents/prac-recommendation/prac-recommendations-signals-adopted-10-13-february-2020-prac-meeting_en.pdf

Meeting highlights from the Pharmacovigilance Risk Assessment Committee (PRAC) 9-12 March 2020
Published on: *13 - March – 2020*
For more information, please refer to:
Meeting highlights from the Pharmacovigilance Risk Assessment Committee (PRAC) 9-12 March 2020 | European Medicines Agency

Zulassung – Regulatory Affairs

Nitrosamine impurities (updated)

"[…] Update: The European medicines regulatory network is conducting an exercise to determine what lessons can be learnt from the presence of nitrosamines in sartans. It plans to publish recommendations for the prevention and management of presence of impurities in the future.
Update: EMA and the national competent authorities are assessing the impact of tests which showed NDMA in some EU batches of metformin-containing medicines, used for the treatment of diabetes. This follows confirmation of NDMA in some batches outside the EU in late 2019.
EMA and the national competent authorities are awaiting further test results of EU medicines. They are working closely with companies and the official medicines control laboratories (OMCLs). EMA will provide further updates as soon as possible.
EMA advises patients in the EU to continue to take metformin medication as the risks from not treating diabetes far outweigh any possible effects of the low levels of NDMA seen in tests.
As metformin is considered a critical medicine, EMA and national authorities are cooperating closely to avoid possible shortages so patients can continue to get the treatments they need." […]
Published on: *03 - March - 2020*
For more information, please refer to:
Nitrosamine impurities | European Medicines Agency

Referral: Panexcel , Article 31 referrals, Procedure started, 27/02/2020, 05/03/2020 (updated) *"The European Medicines Agency (EMA) has started a review of medicines for which studies have been conducted by Panexcell Clinical Laboratories Priv. Ltd at its site in Mumbai, India. This follows a good clinical practice (GCP) inspection which raised concerns about the study data used to support marketing authorisation applications of some medicines in the EU. The inspection was carried out jointly by Austrian and German authorities in October 2019 in the context of the evaluation of an application for marketing authorisation of a medicine." […]*
Published on: *04 - March - 2020*
For more information, please refer to:
Panexcell | European Medicines Agency

Referral: Xeljanz , tofacitinib , Article 20 procedures, European Commission final decision, 14/11/2019, 31/01/2020, 06/03/2020 (updated)
Published on: *06 - March - 2020*
For more information, please refer to:
Xeljanz | European Medicines Agency

Regulatory and procedural guideline: Guidance for applicants on a pilot for Simultaneous National Scientific Advice (SNSA) (updated)
Published on: *09 – March - 2020*
For more information, please refer to:
https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/guidance-applicants-pilot-simultaneous-national-scientific-advice-snsa_en.pdf

Referral: Ranitidine-containing medicinal products, ranitidine, Article 31 referrals, Under evaluation, 19/09/2019, 11/03/2020 (updated)
"At the request of the European Commission, EMA is to start a review of ranitidine medicines after tests showed that some of these products contained an impurity called N-nitrosodimethylamine (NDMA).
NDMA is classified as a probable human carcinogen (a substance that could cause cancer) on the basis of animal studies. It is present in some foods and in water supplies but is not expected to cause harm when ingested in very low levels." […]
Published on: *11 - March - 2020*

Humanarzneimittel - EU

For more information, please refer to
Ranitidine-containing medicinal products | European Medicines Agency

Referral: Fluorouracil and fluorouracil related substances (capecitabine, tegafur and flucytosine) containing medicinal products -PRAC recommendations
"[…] The PRAC assessed the available data and recommended the following measures to ensure the safe use of fluorouracil and fluorouracil-related medicines:
Fluorouracil, capecitabine and tegafur
Testing of patients for DPD deficiency is recommended before starting treatment with fluorouracil injection or infusion, capecitabine and tegafur. This can be done by measuring the level of uracil (a substance broken down by DPD) in the blood, or by checking for the presence of certain mutations (changes) in the gene for DPD which are associated with an increased risk of severe side effects. Relevant clinical guidelines should be taken into consideration.
Patients with a known complete DPD deficiency must not be given fluorouracil injection or infusion, capecitabine or tegafur, as a complete lack of working DPD puts them at higher risk of severe and life-threatening side effects." […]
***Published on:** 13 - March - 2020*
For more information, please refer to
Fluorouracil and fluorouracil related substances (capecitabine, tegafur and flucytosine) containing medicinal products | European Medicines Agency

Orphan Drugs und neuartige Therapierichtungen (ATMP)

Qualification of novel methodologies for medicine development (updated)
Published on: *02 - March - 2020*
For more information, please refer to:
Qualification of novel methodologies for medicine development | European Medicines Agency

COMP meeting report on the review of applications for orphan designation: February 2020 (new) - EMA/COMP/87794/2020
Published on: *09 - March - 2020*
For more information, please refer to:
https://www.ema.europa.eu/en/documents/committee-report/comp-meeting-report-review-applications-orphan-designation-february-2020_en.pdf

Committee for Advanced Therapies (CAT): 6-8 November 2019, European Medicines Agency, Amsterdam, The Netherlands, from 06/11/2019 to 08/11/2019 (updated)
Published on: *09 - March - 2020*
For more information, please refer to:
Committee for Advanced Therapies (CAT): 6-8 November 2019 | European Medicines Agency

Minutes of the CAT meeting 4-6 December 2019 (new) - EMA/CAT/127341/2020
Published on: *09 - March - 2020*
For more information, please refer to:
https://www.ema.europa.eu/en/documents/minutes/minutes-cat-meeting-4-6-december-2019_en.pdf

Minutes of the CAT meeting 22-24 January 2020 (new) - EMA/CAT/127419/2020
Published on: *09 - March - 2020*
For more information, please refer to:

https://www.ema.europa.eu/en/documents/minutes/minutes-cat-meeting-22-24-january-2020_en.pdf

CAT monthly report of application procedures, guidelines and related documents on advanced therapies: February 2020 (new) - EMA/CAT/107194/2020
Published on: *12 - March - 2020*
For more information, please refer to:
https://www.ema.europa.eu/en/documents/committee-report/cat-monthly-report-application-procedures-guidelines-related-documents-advanced-therapies-february_en-6.pdf

Qualität – Quality

ICH Q12 Technical and regulatory considerations for pharmaceutical product lifecycle management (updated)
Published on: *03 - March - 2020*
For more information, please refer to:
ICH Q12 Technical and regulatory considerations for pharmaceutical product lifecycle management | European Medicines Agency

Medizinprodukte - Medical Device / Health technology assessment

Multi-stakeholder workshop to support implementation of the Medical Devices Regulation on drug-device combinations
"The European Medicines Agency (EMA) is holding this multi-stakeholder workshop in preparation of the changes introduced by Article 117 of Regulation (EU) 2017/745 on Medical Devices (MDR) for integral drug-device combinations (products falling under the second sub-paragraph of Article 1(8) and Article 1(9) of the Regulation.) These require notified bodies to be involved in the assessment of certain drug-device combinations from 26 May 2020.
***Update**: In the context of the escalating situation with the COVID-19 outbreak, this workshop will not take place as planned on 31 March 2020. EMA is currently exploring options for the workshop to be held at a later date or remotely (via webinar). EMA will publish further information in due course." […]*
***Published on:** 02 - March - 2020*
For more information, please refer to:
Multi-stakeholder workshop to support implementation of the Medical Devices Regulation on drug-device combinations | European Medicines Agency

(Prä-) Klinische Forschung – Research and Development

Joint European Medicines Agency (EMA) / European Organisation for Research and Treatment of Cancer (EORTC) workshop on novel patient-reported outcomes (PRO) and quality of life (QoL) approaches in cancer clinical research, European Medicines Agency, Amsterdam, the Netherlands, from 12/03/2020 to 13/03/2020 (updated)
"Update: Due to a number of cancellations of participants, this workshop is postponed to later in 2020. EMA will contact registered participants as soon as the new date is available." […]
Published on: *04 – March - 2020*
For more information, please refer to:
Joint European Medicines Agency (EMA) / European Organisation for Research and Treatment of Cancer (EORTC) workshop on novel patient-reported outcomes (PRO) and quality of life (QoL) approaches in cancer clinical research | European Medicines Agency

Clinical pharmacology and pharmacokinetics: questions and answers (updated)

Humanarzneimittel - EU

***Pu*blished on**: 12 – *March - 2020*
For more information, please refer to:
Clinical pharmacology and pharmacokinetics: questions and answers | European Medicines Agency

Kinderarzneimittel – Paediatrics

No news available this week.

Pflanzliche Arzneimittel – Herbal medicines

Herbal - Call for data: Call for scientific data for use in HMPC assessment work on Taraxacum officinale F.H. Wigg., radix (new) - EMA/HMPC/47428/
Submission Period: 01 – 31 May 2020
Published on: *02 - March - 2020*
For more information, please refer to:
https://www.ema.europa.eu/en/documents/herbal-call-data/call-scientific-data-use-hmpc-assessment-work-taraxacum-officinale-fh-wigg-radix_en.pdf

Herbal - Call for data: Call for scientific data for the periodic review of the monograph on Lavandula angustifolia Miller, flos (new) - EMA/HMPC/103640/2020
Submission Period: 01 – 31 May 2020
Published on: *02 - March - 2020*
For more information, please refer to:
https://www.ema.europa.eu/en/documents/herbal-call-data/call-scientific-data-periodic-review-monograph-lavandula-angustifolia-miller-flos_en.pdf

Herbal - Call for data: Call for scientific data for the periodic review of the monograph on Lavandula angustifolia Miller, aetheroleum (new) - EMA/HMPC/103634/2020
Submission Period: 01 – 31 May 2020
Published on: *02 - March - 2020*
For more information, please refer to:
https://www.ema.europa.eu/en/documents/herbal-call-data/call-scientific-data-periodic-review-monograph-lavandula-angustifolia-miller-aetheroleum_en.pdf

Herbal - Call for data: Call for scientific data for the periodic review of the monograph on Fumaria officinalis L., herba (new) - EMA/HMPC/103631/2020
Submission Period: 01 – 31 March 2020
Published on: *02 - March - 2020*
For more information, please refer to:
https://www.ema.europa.eu/en/documents/herbal-call-data/call-scientific-data-periodic-review-monograph-fumaria-officinalis-l-herba_en.pdf

Herbal - Call for data: Call for scientific data for the periodic review of the monograph on Fucus vesiculosus L., thallus (new) - EMA/HMPC/103567/2020
Submission Period: 01 – 31 May 2020
Published on: *02 - March - 2020*
For more information, please refer to:
https://www.ema.europa.eu/en/documents/herbal-call-data/call-scientific-data-periodic-review-monograph-fucus-vesiculosus-l-thallus_en.pdf

Humanarzneimittel - EU

Herbal - Call for data: Call for scientific data for the periodic review of the monograph on Cinnamomum verum J.S. Presl, corticis aetheroleum (new) - EMA/HMPC/103542/2020
Submission Period: 01 – 31 May 2020
Published on: *02 - March - 2020*
For more information, please refer to:
https://www.ema.europa.eu/en/documents/herbal-call-data/call-scientific-data-periodic-review-monograph-cinnamomum-verum-js-presl-corticis-aetheroleum_en.pdf

Herbal - Call for data: Call for scientific data for the periodic review of the monograph on Cinnamomum verum J.S. Presl, cortex (new) - EMA/HMPC/103543/2020
Submission Period: 01 – 31 May 2020
Published on: *02 - March - 2020*
For more information, please refer to:
https://www.ema.europa.eu/en/documents/herbal-call-data/call-scientific-data-periodic-review-monograph-cinnamomum-verum-js-presl-cortex_en.pdf

Committee for Herbal Medicinal Products (HMPC): 02-04 March 2020, European Medicines Agency, Amsterdam, the Netherlands, from 02/03/2020 to 04/03/2020 (updated)
Published on: *02 - March - 2020*
For more information, please refer to:
Committee for Herbal Medicinal Products (HMPC): 02-04 March 2020 | European Medicines Agency

EDQM

4 new reference standards and 19 replacement batches released in February 2020
Published on: *04 - March - 2020*
For more information, please refer to:
4 new reference standards and 19 replacement batches released in February 2020 | EDQM - European Directorate for the Quality of Medicines

Shutdown of European Pharmacopoeia 9th Edition
"The European Pharmacopoeia (Ph. Eur.) 9th Edition has been obsolete since 1 January 2020. Consequently, the 9th Edition online and all previous versions, including the Ph. Eur. archives for 9th Edition clients, have no longer been accessible since ***1 March 2020****." […]*
Published on: *06 - March - 2020*
For more information, please refer to:
Shutdown of European Pharmacopoeia 9th Edition | EDQM - European Directorate for the Quality of Medicines

New European Pharmacopoeia general chapter on Balances – Last opportunity to comment
"In January 2020, the European Pharmacopoeia (Ph. Eur.) launched a public consultation on a new general chapter on Balances (2.1.7).
This important general chapter is limited to balances used for analytical purposes and as such is the basis of every analytical procedure described in the European Pharmacopoeia. The new text details requirements for checking instruments between calibrations, during routine use. The performance checks have been limited to verifying repeatability and sensitivity, which are considered to be the two most significant parameters for the performance of balances. This general chapter completes existing guidelines and requirements for the use and qualification of balances established elsewhere." […]
Published on: *09 - March - 2020*

Humanarzneimittel - EU

For more information, please refer to:
New European Pharmacopoeia general chapter on Balances – Last opportunity to comment | EDQM - European Directorate for the Quality of Medicines

Certification Monthly Report of Activities: February 2020
Published on: *11 - March - 2020*
For more information, please refer to:
Certification Monthly Report of Activities: February 2020 | EDQM - European Directorate for the Quality of Medicines

Impact of Covid-19 outbreak on the EDQM Certificate of Suitability (CEP) procedure
"The EDQM would like to inform CEP holders of the impact of the Covid-19 outbreak on activities related to the CEP procedure.
With regards to sending CEPs, due to issues experienced in shipping/delivering CEPs in some zones considered at risk, the EDQM is contacting the relevant CEP holders in advance to confirm that delivery is possible or to propose alternatives when companies are closed.
EDQM is aware that companies may have issues regarding submissions of information linked to CEP dossiers under assessment (e.g. preparing and sending responses to deficiency letters), inspections (e.g. preparing and sending CAPA) and risk assessments related to nitrosamines. However, EDQM expects to be informed as soon as possible by CEP holders/substance manufacturers if they cannot meet the deadline for submitting the requested information." […]
Published on: *13 - March - 2020*
For more information, please refer to:
Impact of Covid-19 outbreak on the EDQM Certificate of Suitability (CEP) procedure | EDQM - European Directorate for the Quality of Medicines

EDQM laboratory obtains ISO 17025:2017 accreditation
Published on: *13 - March - 2020*
For more information, please refer to:
EDQM laboratory obtains ISO 17025:2017 accreditation | EDQM - European Directorate for the Quality of Medicines

European Commission

Health Security Committee Summary - Outbreak of coronavirus disease (COVID-19)
Published on: *02 – March - 2020*
For more information, please refer to:
https://ec.europa.eu/health/sites/health/files/preparedness_response/docs/ev_20200302_sr_en.pdf

COVID-19: Commission steps up research funding and selects 17 projects in vaccine development, treatment and diagnostics
Published on: *06 – March - 2020*
For more information, please refer to:
Heads of Medicines Agencies: Recently Published history

Summary report of the 11th Health Security Committee (13 March 2020)
Published on: *13 – March - 2020*
For more information, please refer to:
https://ec.europa.eu/health/sites/health/files/preparedness_response/docs/ev_20200313_sr_en.pdf

CMDh

NEW - Report from the meeting held on 25-27 February 2020
Published on: *04 – March - 2020*
For more information, please refer to:
https://www.hma.eu/fileadmin/dateien/Human_Medicines/CMD_h_/cmdh_pressreleases/2020/02_2020_CMDh_Press_Release.pdf

NEW - 2019 - Statistics for New Applications (MRP/DCP), Variations, Referrals and Paediatric Worksharing procedures
Published on: *05 – March - 2020*
For more information, please refer to:
https://www.hma.eu/fileadmin/dateien/Human_Medicines/CMD_h_/Statistics/2019_Annual_CMDh_Statistics.pdf

NEW - January 2020 CMDh Minutes
Published on: *05 – March - 2020*
For more information, please refer to:
https://www.hma.eu/fileadmin/dateien/Human_Medicines/CMD_h_/Agendas_and_Minutes/Minutes/2020_01_CMDh_Minutes.pdf

UPDATE - CMDh practical guidance for Marketing Authorisation Holders of nationally authorised products (incl. MRP/DCP) in relation to the Art. 5(3) Referral on Nitrosamines
Published on: *06 – March - 2020*
For more information, please refer to:
https://www.hma.eu/fileadmin/dateien/Human_Medicines/CMD_h_/Advice_from_CMDh/Nitrosamins/CMDh_412_2019_Rev.3_clean_2020_02_PG_to_MAHs_on_nitrosamines.pdf

UPDATE - CMDh Standard Operating Procedure - Disagreement in procedures -Referral to CMDh;
Published on: *09 – March - 2020*
For more information, please refer to:
https://www.hma.eu/fileadmin/dateien/Human_Medicines/CMD_h_/procedural_guidance/Application_for_MA/DCP/CMDh_078_2005_Rev8_2020_02_clean_DCP_SOP.pdf

UPDATE - Decentralised Procedure Members States' Standard Operating Procedure;
Published on: *09 – March - 2020*
For more information, please refer to:
https://www.hma.eu/fileadmin/dateien/Human_Medicines/CMD_h_/CMDhReferrals_Art29/CMDh_103_2005_Rev13_02_2020_clean_Referral_to_CMDh.pdf

NEW - Art. 46 assessment reports for Ismigen/PMBL tablet (polyvalent mechanical bacterial lysate), Valtrex (valaciclovir), Palexia, Yantil, Tapentadol Grünenthal (tapentadol (as hydrochloride) (DE/W/123+124/pdWS/01);
Published on: *09 – March - 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/ISMIGEN_Art._46_PAR_2020_02.pdf

CMDh

NEW - Art. 45 assessment reports for econazole nitrate & triamcinolone acetonide and oxcarbazepine;
Published on: *09 – March - 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/Econazole_triamcinolone_Art._45_PAR_2020_02.pdf

UPDATE - National recommendations for requests to act as RMS in DCPs;
Published on: *10 – March - 2020*
For more information, please refer to:
https://www.hma.eu/fileadmin/dateien/Human_Medicines/CMD_h_/procedural_guidance/Application_for_MA/DCP/CMDh_020_2009_Rev28_02_2020_DCP_Requests_to_act_as_RMS.pdf

Humanarzneimittel - Deutschland

Sartane: Verunreinigungen der Wirkstoffe
„Das BfArM hat nach Anhörung das Ruhen der Zulassungen bis zur vollständigen Umsetzung angeordnet.“ […]
***Veröffentlicht am**:02 – März - 2020*
Weitere Informationen finden Sie unter:
BfArM - Risikobewertungsverfahren - Sartane: Verunreinigungen der Wirkstoffe

Lieferengpässe
***Veröffentlicht am:** 03 – März - 2020*
Weitere Informationen finden Sie unter:
BfArM - Lieferengpässe

Bearbeitungsstatistiken
„An dieser Stelle veröffentlicht das BfArM monatlich die aktuelle Bearbeitungsstatistik der Zulassungen und Registrierungen sowie der Verlängerungen.“ [….]
***Veröffentlicht am**: 03 – März - 2020*
Weitere Informationen finden Sie unter:
BfArM - Statistiken - Arzneimittel - Bearbeitungsstatistiken

Aktuelle Informationen zu Nitrosaminen in Humanarzneimitteln
„Aktuelle Informationen zu Nitrosaminen in metforminhaltigen und weiteren Humanarzneimitteln.“ […]
***Veröffentlicht am**: 04 – März - 2020*
Weitere Informationen finden Sie unter:
BfArM - Weitere Arzneimittelrisiken - Aktuelle Informationen zu Nitrosaminen in Humanarzneimitteln

Wissenschaftliche und verfahrenstechnische Beratung durch das BfArM
***Veröffentlicht am**: 06 – März - 2020*
Weitere Informationen finden Sie unter:
BfArM - Wissenschaftliche und verfahrenstechnische Beratung

Einreichung finaler Produktinformationstexte nach Verfahrensabschluss
***Veröffentlicht am**: 06 – März - 2020*
Weitere Informationen finden Sie unter:
BfArM - eSubmission - Einreichung finaler Produktinformationstexte nach Verfahrensabschluss

Informationen zur AMIS-Gesamtablösung
***Veröffentlicht am**: 11 – März - 2020*
Weitere Informationen finden Sie unter:
BfArM - eSubmission - Informationen zur AMIS-Gesamtablösung

PEI Lieferengpässe von Human-Impfstoffen:
***Veröffentlicht am**: 12 – März - 2020*
Weitere Informationen finden Sie unter:
https://www.pei.de/SiteGlobals/Functions/RSSFeed/RSSGenerator_Lieferengpaesse.xml;jsessionid=0339FDDA55D40E1EE4EEED05D9CDEA28.1_cid319?nn=11245824

Humanarzneimittel - Österreich

Hinweis zu möglichen Auswirkungen der Coronaviruserkrankung (COVID-19) auf die Versorgungslage von Arzneimitteln
Veröffentlicht am: *10 – März – 2020*
Weitere Informationen finden Sie unter:
Hinweis zu möglichen Auswirkungen der Coronaviruserkrankung (COVID-19) auf die Versorgungslage von Arzneimitteln - BASG

Register Arzneimittelvermittler - aktualisiert
Veröffentlicht am: *10 – März – 2020*
Weitere Informationen finden Sie unter:
Arzneimittelvermittler - BASG

Register bewilligter Arzneimittelbetriebe in Österreich- aktualisiert
Veröffentlicht am: *10 – März – 2020*
Weitere Informationen finden Sie unter:
Arzneimittelbetriebe - BASG

Blutsicherheit, Spendekriterien und Blutversorgung bei CoV-2-Pandemie
Veröffentlicht am: *11 – März – 2020*
Weitere Informationen finden Sie unter:
https://www.basg.gv.at/marktbeobachtung/amtliche-nachrichten/detail/blutsicherheit-spendekriterien-und-blutversorgung-bei-cov-2-pandemie

Aktualisierung: Blue Box Guideline
Veröffentlicht am: *12 – März – 2020*
Weitere Informationen finden Sie unter:
Aktualisierung: Blue Box Guideline - BASG

Humanarzneimittel - Schweiz

Illegale Importe von Arzneimitteln: Vereinfachtes Verfahren hat sich bewährt

„Im Jahr 2019 stellte Swissmedic zusammen mit der Eidgenössischen Zollverwaltung (EZV) 7'781 illegale Arzneimittelimporte sicher. Das definitiv eingeführte verkürzte Verwaltungsmassnahmeverfahren («vereinfachtes Verfahren») ermöglichte bei gleichbleibender Menge der Importe mehr als doppelt so viele Beschlagnahmungen wie im Vorjahr. Gefälschte und illegal importierte Medikamente sind ein grosses Gesundheitsrisiko." […]

Veröffentlicht am: *05 - März – 2020*

Weitere Informationen finden Sie unter:

Illegale Importe von Arzneimitteln: Vereinfachtes Verfahren hat sich bewährt

Swissmedic Journal

„Auszug aus dem Inhaltsverzeichnis:

- *Zulassung eines Arzneimittels mit neuem Wirkstoff: Xofluza®, Filmtabletten (Baloxavirum marboxilum)*
- *Zulassung eines Arzneimittels mit neuem Wirkstoff: Luxturna®, Konzentrat und Lösungsmittel zur Herstellung einer Injektionslösung*
- *Zulassung eines Arzneimittels mit neuem Wirkstoff: Cerdelga®, Hartkapseln (Eliglustatum)*
- *Zulassung eines Arzneimittels mit neuem Wirkstoff: Lorviqua®, Filmtabletten (Lorlatinibum)*
- *Zulassung eines Arzneimittels mit neuem Wirkstoff: Spravato®, Nasenspray (Esketaminum)*
- *Informationen aus der Rubrik "Arzneimittel Statistik" […]*

Veröffentlicht am: *06 - März – 2020*

Weitere Informationen finden Sie unter:

Swissmedic Journal

Swissmedic und die Bill & Melinda Gates Foundation (BMGF) setzen ihre Zusammenarbeit fort

„Am 3. Februar 2020 haben Swissmedic und die Bill & Melinda Gates Foundation (BMGF) eine weitere Finanzierungsvereinbarung unterzeichnet. Somit verpflichten sich die beiden Parteien für weitere 3 Jahre, die Aufsichtsbehörden in ressourcenarmen Ländern zu fördern und so den beteiligten Ländern einen besseren Zugang zu medizinischer Versorgung zu ermöglichen. Dieses Engagement erfolgt im Einklang mit der Schweizerischen Gesundheitsaussenpolitik."[…]

Veröffentlicht am: *06 - März – 2020*

Weitere Informationen finden Sie unter:

Swissmedic und die Bill & Melinda Gates Foundation (BMGF) setzen ihre Zusammenarbeit fort

Swissmedic beteiligt sich am FDA-Projekt «Orbis»

„Swissmedic hat an einem Treffen mit dem Oncology Center of Excellence (OCE) der amerikanischen Heilmittelbehörde FDA die Möglichkeit einer Zusammenarbeit im Bereich der parallelen Begutachtung von Onkologika diskutiert. Swissmedic beteiligt sich wie auch die australischen Therapeutic Goods Agency (TGA), Health Canada (HC) und der Health Sciences Authority (HSA) des ACSS Consortium im Rahmen eines Pilotversuchs am Projekt «Orbis», um Patientinnen und Patienten länderübergreifend möglichst rasch Zugang zu innovativen Krebstherapien zu ermöglichen.."[…]

Veröffentlicht am: *14 - März – 2020*

Weitere Informationen finden Sie unter:

Swissmedic beteiligt sich am FDA-Projekt «Orbis»

Aktualisierte Dokumente
Veröffentlicht am: *14 - März - 2020*
Weitere Informationen finden Sie unter:
März 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.*

*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)

Digitalisierung und Telemedizin in klinischen Prüfungen – Chancen und Herausforderungen?
Termin*: 05.05.2020*
Ort: *Stifterverband für die Deutsche Wissenschaft, Wissenschaftszentrum, Ahrstr. 45, 53175 BonnWeitere Informationen finden Sie unter:*
BfArM - Dialog-Veranstaltungen - Digitalisierung und Telemedizin in klinischen Prüfungen – Chancen und Herausforderungen?

Österreich

BASG-Gespräch: Das neue europäische Medizinprodukterecht
Termin: 02.04.2020
AGES-Akademie, Spargelfeldstrasse 191, 1220 Wien
Weitere Informationen finden Sie unter:
https://www.basg.gv.at/news-center/veranstaltungen-vorschau/

BASG-Gespräch: Qualitätsmängel bei Arzneimitteln
Termin: 06.05.2020
AGES-Akademie, Spargelfeldstrasse 191, 1220 Wien
Weitere Informationen finden Sie unter:
https://www.basg.gv.at/news-center/veranstaltungen-vorschau/

BASG-Gespräch: Pharmakovigilanz
Termin: 15.06.2020
AGES-Akademie, Spargelfeldstrasse 191, 1220 Wien
Weitere Informationen finden Sie unter:
https://www.basg.gv.at/news-center/veranstaltungen-vorschau/

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/

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,
Ort:Lisbon, Portugal,
from 14/05/2020 to 15/05/2020
Weitere Informationen finden Sie unter:
eXtended EudraVigilance Medicinal Product Dictionary training course (Lisbon) | European Medicines Agency

eXtended EudraVigilance Medicinal Product Dictionary training course,
European Medicines Agency, Amsterdam, the Netherlands,
from 18/06/2020 to 19/06/2020
Weitere Informationen finden Sie unter:
eXtended EudraVigilance Medicinal Product Dictionary training course (Amsterdam) | European Medicines Agency

eXtended EudraVigilance Medicinal Product Dictionary training course
Ort: Munich, Germany,
from 02/07/2020 to 03/07/2020
Weitere Informationen finden Sie unter:
eXtended EudraVigilance Medicinal Product Dictionary training course (Munich) | European Medicines Agency