09. Dezember 2019 - 03. Januar 2020

MEGRA §

NEWSLETTER

Humanarzneimittel - EU

Allgemeines – General

Human medicines highlights - December 2019
Published on: *10 - December - 2019*
For more information, please refer to:
https://www.ema.europa.eu/en/documents/newsletter/human-medicines-highlights-december-2019_en.pdf

Guide on access to unpublished documents (updated)
"Second revision: Further clarification of the queuing system including measures in place to prevent the possible circumvention of the access to documents queuing system (revised Q14)." […]
Published on: *10 - December - 2019*
For more information, please refer to:
https://www.ema.europa.eu/en/documents/other/guide-access-unpublished-documents_en.pdf

EMA Management Board: highlights of December 2019 meeting
Published on: *20 - December - 2019*
For more information, please refer to:
EMA Management Board: highlights of December 2019 meeting | European Medicines Agency

Brexit: the United Kingdom's withdrawal from the European Union (updated)
Published on: *20 - December - 2019*
For more information, please refer to:
Brexit: the United Kingdom's withdrawal from the European Union | European Medicines Agency

Financial Regulation applicable to the budget of the European Medicines Agency from 1 July 2019 (updated) - EMA/MB/911312/2019 Corrigendum of 18 December 2019
Published on: *20 - December - 2019*
For more information, please refer to:
https://www.ema.europa.eu/en/documents/other/financial-regulation-applicable-budget-european-medicines-agency-1-july-2019_en.pdf

Pharmakovigilanz – PRAC

How will pharmacovigilance look in 2030?
Published on: *10 - December - 2019*
For more information, please refer to:
How will pharmacovigilance look in 2030? | European Medicines Agency

Good pharmacovigilance practices (updated)
"Guidelines on good pharmacovigilance practices (GVP)
Introductory cover note, last updated with chapter P.III on pharmacovigilance for the use of medicines by pregnant and breastfeeding women"[…]
Published on: *11 - December - 2019*
For more information, please refer to:
Good pharmacovigilance practices | European Medicines Agency
And
https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/guidelines-good-pharmacovigilance-practices-gvp-introductory-cover-note-last-updated-chapter-piii_en.pdf

Humanarzneimittel - EU

Six-year review shows success of the EU signal management system in improving safe use of medicines
Published on: *11 - December - 2019*
For more information, please refer to:
Six-year review shows success of the EU signal management system in improving safe use of medicines | European Medicines Agency

List of medicines under additional monitoring (updated)
"Update - Summary of changes in December 2019:
The following CAP has been added to the list up to 5 December 2019:
•Rhokiinsa (netarsudil) – New active substance
In addition, Annex IV (List of thiocolchicoside-containing medicinal products in the EU) has been updated." […]
***Pu*blished on**: *12 - December - 2019*
For more information, please refer to:
List of medicines under additional monitoring | European Medicines Agency

EMA issues alert on the risk of dosing errors with the cancer medicine Trisenox - EMA/189409/2019
***Pu*blished on**: *13 - December - 2019*
For more information, please refer to:
https://www.ema.europa.eu/en/documents/medication-error/ema-issues-alert-risk-dosing-errors-cancer-medicine-trisenox_en.pdf

Implementation of the pharmacovigilance legislation
"Update: In December 2019, EMA and the Heads of Medicines Agencies (HMA) have published a joint report measuring the longer-term impact of the pharmacovigilance legislation, based on a four-year overview of the pharmacovigilance activities carried out by the European medicines regulatory network:
•Report on pharmacovigilance tasks from EU Member States and the European Medicines Agency (EMA), 2015-2018 - It highlights key outcomes in the simplification of pharmacovigilance processes, improved transparency and stakeholder engagement and the protection of public health.
This follows a three-year report in 2016 and a one-year report in 2014 on the pharmacovigilance activities of the network:
- Three-year report on implementation of pharmacovigilance legislation
- One-year report on the pharmacovigilance tasks of the European Medicines Agency" […]
***Pu*blished on**: 17 - *December - 2019*
For more information, please refer to:
Implementation of the pharmacovigilance legislation | European Medicines Agency

Signal management
"Update: In December 2019 EMA and the European Commission agreed to extend the pilot until the end of 2021 to generate more robust data after reviewing the experience gained in the first year of the pilot. MAHs with active substances included in the list should continue to monitor them in EudraVigilance for the duration of the pilot." […]
***Pu*blished on**: 18 - *December - 2019*
For more information, please refer to:
Signal management | European Medicines Agency

Humanarzneimittel - EU

Zulassung – Regulatory Affairs

Plasma master file certificates (updated)
Published on: *10 - December - 2019*
For more information, please refer to:
Plasma master file certificates | European Medicines Agency

Referral: Fluorouracil and fluorouracil related substances (capecitabine, tegafur and flucytosine) containing medicinal products , capecitabine, fluorouracil, tegafur, flucytosine , Article 31 referrals, Under evaluation, 11/12/2019 (updated)
"Fluorouracil (given by injection), capecitabine and tegafur are cancer medicines, whereas topical (applied to the skin) fluorouracil is used for various skin conditions and flucytosine is a medicine used in severe fungal infections.
It is known that some patients lack a working enzyme called dihydropyrimidine dehydrogenase (DPD) which is needed to break down fluorouracil[1]. Prescribers may be unaware that their patients lack working DPD, and if these patients are given fluorouracil or related substances, their bodies cannot break fluorouracil down, resulting in its build-up in the blood." […]
Published on: *11 - December - 2019*
For more information, please refer to:
Fluorouracil and fluorouracil related substances (capecitabine, tegafur and flucytosine) containing medicinal products | European Medicines Agency

Medicinal products for human use: monthly figures - November 2019
Published on: *13 - December - 2019*
For more information, please refer to:
https://www.ema.europa.eu/en/documents/report/medicinal-products-human-use-monthly-figures-november-2019_en.pdf

Meeting highlights from the Committee for Medicinal Products for Human Use (CHMP) 9-12 December 2019
Published on: *13 - December - 2019*
For more information, please refer to:
Meeting highlights from the Committee for Medicinal Products for Human Use (CHMP) 9-12 December 2019 | European Medicines Agency

Referral: Fosfomycin-containing medicinal products , fosfomycin calcium, fosfomycin disodium, fosfomycin sodium, fosfomycin trometamol , Article 31 referrals, Under evaluation, 13/12/2018, 16/12/2019 (updated)
"Fosfomycin, an antibiotic that has been in use for many decades, works in a unique way and bacteria resistant to other antibiotics are less likely to be resistant to fosfomycin. There are significant differences between Member States in the authorised uses and doses of fosfomycin medicines. The German medicines authority has requested reappraisal of the role of fosfomycin in the context of increasing resistance to antibiotics. In particular, the indications and dosage of fosfomycin and the adequacy of information on its safety and pharmacological properties will be re-evaluated in the light of up-to-date knowledge on antibacterial therapy."[…]
Published on: *16 - December - 2019*
For more information, please refer to:
Fosfomycin-containing medicinal products | European Medicines Agency

Renewal and annual re-assessment of marketing authorisation (updated)

Humanarzneimittel - EU

***Pu*blished on**: *17 - December - 2019*
For more information, please refer to:
Renewal and annual re-assessment of marketing authorisation | European Medicines Agency

Classification of changes: questions and answers (updated)
***Pu*blished on**: *17 -December - 2019*
For more information, please refer to:
Classification of changes: questions and answers | European Medicines Agency

Type-II variations: questions and answers (updated)
***Pu*blished on**: *17 - December - 2019*
For more information, please refer to:
Type-II variations: questions and answers | European Medicines Agency

Grouping of variations: questions and answers (updated)
***Pu*blished on**: *17 - December - 2019*
For more information, please refer to:
Grouping of variations: questions and answers | European Medicines Agency

International collaboration on GMP inspections (updated)
"Update: In December 2019, EMA and its European and international partners launched a pilot programme to share information on GMP inspections of manufacturers of sterile medicines located outside the participating countries and to organise joint inspections of manufacturing sites of common interest.
The products in scope include sterile medicines for human use of chemical origin and certain therapeutic biotechnology-derived products, such as monoclonal antibodies and recombinant proteins.
Vaccines, cell and gene therapies and plasma-derived pharmaceuticals are currently out of the scope of this pilot." […]
***Pu*blished on**: *17 - December - 2019*
For more information, please refer to:
International collaboration on GMP inspections | European Medicines Agency

Referral: Methocarbamol / paracetamol-containing medicinal products , methocarbamol/paracetamol , Robaxisal compuesto, Article 31 referrals, Under evaluation, 29/05/2019, 17/12/2019 (updated)
"EMA has started a review of the effectiveness of medicines containing a combination of methocarbamol and paracetamol for the treatment of painful muscle spasms. The review is being carried out at the request of the German medicines agency, BfArM, which has been asked to evaluate a marketing application for a generic medicine based on Robaxisal compuesto, a medicine authorised in Spain for painful muscle spasms associated with various short-term muscle disorders, such as low back pain." […]
***Pu*blished on**: *17 - December - 2019*
For more information, please refer to:
Methocarbamol / paracetamol-containing medicinal products | European Medicines Agency

Referral: Estradiol-containing (0.01% w/w) medicinal products for topical use , estradiol , Linoladiol,Linoladiol N,Linoladiol Estradiol,Estradiol Wolff,Montadiol, Article 31 referrals, Recommendation provided by Pharmacovigilance Risk Assessment Committee, 18/12/2019 (updated)

"Update of 31 October 2019:
Following the PRAC's recommendation of 3 October 2019, one of the marketing authorisation holders involved with this review has requested a re-examination. Upon receipt of the grounds for the request, the PRAC will start a re-examination, which is expected to conclude at the PRAC meeting of 13-16 January 2020." […]
Published on: *18 - December - 2019*
For more information, please refer to:
Estradiol-containing (0.01% w/w) medicinal products for topical use | European Medicines Agency

Referral: Ranitidine-containing medicinal products , ranitidine , Article 31 referrals, Procedure started, 19/09/2019, 18/12/2019 (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. EMA is evaluating the data to assess whether patients using ranitidine are at any risk from NDMA and will provide information about this as soon as it is available.t." […]
Published on: *18 - December - 2019*
For more information, please refer to:
Ranitidine-containing medicinal products | European Medicines Agency

Periodic safety update reports (PSURs) (updated)
Published on: *18 - December - 2019*
For more information, please refer to:
Periodic safety update reports (PSURs) | European Medicines Agency

Availability of medicines (updated)
"Update: Since April 2019, the task force has been running a pilot programme on establishing a single point of contact (SPOC) network to improve information sharing between Member States, EMA and the European Commission on important medicine shortages of human and veterinary medicines and to coordinate actions to help prevent and manage shortages. This includes information sharing on alternative medicines that are available in other Member States.

The first phase of the pilot ran from April to August 2019 to test the functioning and usefulness of the information exchange via the SPOCs. During this phase, 24 Member States used the SPOC system and circulated 52 notifications of shortages. The task force plans to run a second phase of the pilot in 2020, to test the criteria for identifying cases deserving EU-wide coordinated action and for network alerts of upcoming public communications that could have a high impact on patients. The task force will publish more information after completion of the second phase of the pilot." […]
Published on: *20 - December - 2019*
For more information, please refer to:
Availability of medicines | European Medicines Agency

Nitrosamines EMEA-H-A5(3)-1490 - Questions and answers on 'Information on nitrosamines for marketing authorisation holders' (updated) - EMA/CHMP/428592/2019 Rev. 2
"updated and new Q&A published"
Published on: *20 - December - 2019*
For more information, please refer to:
https://www.ema.europa.eu/en/documents/referral/nitrosamines-emea-h-a53-1490-questions-

answers-information-nitrosamines-marketing-authorisation_en.pdf

Orphan Drugs und neuartige Therapierichtungen (ATMP)

Advanced therapy classification (updated)
Published on:*09 - December - 2019*
For more information, please refer to:
Advanced therapy classification | European Medicines Agency

Questions and answers on comparability considerations for advanced therapy medicinal products (ATMP)
*"*This document addresses questions on how to demonstrate comparability for gene and cell-based medicinal products following change to the manufacturing process or due to introduction of additional manufacturing sites."[…]
Published on:*13 - December - 2019*
For more information, please refer to:
Questions and answers on comparability considerations for advanced therapy medicinal products (ATMP) | European Medicines Agency

COMP meeting report on the review of applications for orphan designation: December 2019 - EMA/COMP/666924/2019
Published on:*13 - December - 2019*
For more information, please refer to:
https://www.ema.europa.eu/en/documents/committee-report/comp-meeting-report-review-applications-orphan-designation-december-2019_en.pdf

Qualität – Quality

No news available this week.

Medizinprodukte - Medical Device / Health technology assessment

No news available this week.

(Prä-) Klinische Forschung – Research and Development

Clinical Trial Regulation (updated)
Update: In December 2019, EMA's Management Board endorsed to commence the audit of the system in December 2020, following an audit readiness assessment carried out by the nominated product owners, EMA and the IT supplier. The aim of this assessment was to identify critical business blockers and resulted in an updated plan outlining items that still need to be developed or fixed for audit. The product owners will work with EMA and the IT supplier to analyse and design these items in the first few months of 2020, in a way that ensures efficient delivery.
The latest release of the system, which was validated by the nominated product owners in December 2019, enhances CTIS functionalities for processing the evaluation of clinical trial applications, data submission and view of data, management of user access, users' oversight of activities and data transparency. These enhancements relate mainly to the authority and sponsor workspaces in the system." […]
Published on:*20 - December - 2019*
For more information, please refer to:
Clinical Trial Regulation | European Medicines Agency

Humanarzneimittel - EU

Kinderarzneimittel – Paediatrics

No news available this week.

Pflanzliche Arzneimittel – Herbal medicines

Tormentillae rhizoma, Tormentillae rhizoma, C: ongoing call for scientific data (updated).
Published on: *09 - December - 2019*
For more information, please refer to:
Tormentillae rhizoma | European Medicines Agency

Hamamelidis folium, Hamamelidis folium, F: Assessment finalised (updated)
Published on: *09 - December - 2019*
For more information, please refer to:
Hamamelidis folium | European Medicines Agency

Herniariae herba, Herniariae herba, D: Draft under discussion (updated)
Published on: *19 - December - 2019*
For more information, please refer to:
Herniariae herba | European Medicines Agency

HMPC meeting report on European Union herbal monographs, guidelines and other activities - 18-20 November 2019 - EMA/HMPC/639497/2019
Published on: *19 - December - 2019*
For more information, please refer to:
https://www.ema.europa.eu/en/documents/committee-report/hmpc-meeting-report-european-union-herbal-monographs-guidelines-other-activities-18-20-november-2019_en.pdf

EDQM

Consultation deadline for revised dosage form monographs and general chapters drawing near
"The European Pharmacopoeia (Ph. Eur.) Commission is undertaking a review of the dosage form monographs and related general chapters. Five different texts finalised by Ph. Eur. Group of Experts 12 have been launched for public consultation in Pharmeuropa 31.4 until 31 December 2019.
The general monograph Eye preparations (1163) has been revised to include the additional requirements and mandatory test for sub-visible particle contamination described in the proposed new general chapter 2.9.53. This test will need to be performed for all eye drops and lotions intended for use in surgical procedures or for application to injured eyes. The section on ophthalmic inserts has also been revised to include a test ensuring that the release of the active substance is suitable." […]
Published on: *10 - December - 2019*
For more information, please refer to:
Consultation deadline for revised dosage form monographs and general chapters drawing near | EDQM - European Directorate for the Quality of Medicines

Outcome of the 165th European Pharmacopoeia Commission
"During its 165th session, held in Strasbourg on 26 and 27 November 2019, the European Pharmacopoeia (Ph. Eur.) Commission (re)appointed more than 850 experts to its current 21 groups of experts and 39 active working parties for a new term running from November 2019 to November 2022." […]
Published on: *11 - December - 2019*

For more information, please refer to:
Outcome of the 165th European Pharmacopoeia Commission | EDQM - European Directorate for the Quality of Medicines
https://www.edqm.eu/en/news/9-new-reference-standards-and-20-replacement-batches-released-november-2019

Detection of N-nitrosamine impurities: the Ph. Eur. launches a public consultation on the revised general monograph Substances for pharmaceutical use (2034)
"The Ph. Eur. Commission proposes to revise the general monograph on Substances for pharmaceutical use (2034). This proposal has been made further to the European Commission referral C(2019)2698 of 2 April 2019 and the review initiated by the European Medicines Agency (EMA) in September 2019 under Article 5(3) of Regulation (EC) No. 726/2004 to provide guidance to marketing authorisation holders on how to avoid the presence of N -nitrosamine impurities in human medicines." […]
Published on: *13 - December - 2019*
For more information, please refer to:
Detection of N-nitrosamine impurities: the Ph. Eur. launches a public consultation on the revised general monograph Substances for pharmaceutical use (2034) | EDQM - European Directorate for the Quality of Medicines

Certification Monthly Report of Activities: November 2019
Published on: *16 - December - 2019*
For more information, please refer to:
Certification Monthly Report of Activities: November 2019 | EDQM - European Directorate for the Quality of Medicines

European Paediatric Formulary online
"The EDQM is pleased to announce that the European Paediatric Formulary is now available free of charge on a dedicated online platform. This is a major achievement for the PaedForm Working Party and all the stakeholders involved, since it not only embodies several years' work and dedication to the project, but feeds into the fundamental human right of equal access to quality healthcare. " […]
Published on: *18 - December - 2019*
For more information, please refer to:
European Paediatric Formulary online | EDQM - European Directorate for the Quality of Medicines

Ph. Eur. seeks feedback on new general chapter on pyrrolizidine alkaloids
"The European Pharmacopoeia (Ph. Eur.) has launched a public consultation on its new general chapter 2.8.26 on contaminant pyrrolizidine alkaloids. Users and concerned parties can submit their comments in Pharmeuropa 32.1 until 31 March 2020." […]
Published on: *19 - December - 2019*
For more information, please refer to:
Ph. Eur. seeks feedback on new general chapter on pyrrolizidine alkaloids | EDQM - European Directorate for the Quality of Medicines

Information on texts harmonised by the PDG
"The European Pharmacopoeia (Ph. Eur.) general chapter on Pharmacopoeial harmonisation (5.8) provides users with general guidance on the work of the EDQM in this field and details of the information included in harmonised Ph. Eur. general chapters and monographs. This information enables users to understand and correctly apply Ph. Eur. texts (monographs on excipients and general chapters) harmonised by the Pharmacopoeial Discussion Group (PDG), which brings together three of the world's major pharmacopoeias (Ph. Eur., the Japanese Pharmacopoeia and the United

States Pharmacopeia, with the World Health Organization as an observer).” […]
***Published on:** 20 - December - 2019*
For more information, please refer to:
Information on texts harmonised by the PDG | EDQM - European Directorate for the Quality of Medicines

European Commission

Report on pharmacovigilance related activities - Pharmacovigilance tasks from EU Member States and the European Medicines Agency - 2015-2018)

Published on:*18 - December- 2019*

For more information, please refer to:

https://ec.europa.eu/health/sites/health/files/files/pharmacovigilance/pharmacovigilance-report-2015-2018_en.pdf

CMDh

NEW - November 2019 CMDh Minutes
Published on:*13 - December - 2019*
For more information, please refer to:
https://www.hma.eu/fileadmin/dateien/Human_Medicines/CMD_h_/Agendas_and_Minutes/Minutes/2019_11_CMDh_Minutes.pdf

NEW - PSUR WS AR for Gaviscon Advance (sodium alginate, potassium hydrogen carbonate) and ciclopirox olamine (all formulations except shampoo);
Published on: *20 - December - 2019*
For more information, please refer to:
https://www.hma.eu/fileadmin/dateien/Human_Medicines/CMD_h_/Pharmacovigilance_Legislation/PSUR/Summary_AR/Gaviscon_Advance_SmAR_2019_12.pdf

UPDATE - Questions and answers on "Information on nitrosamines for marketing authorisation holders"
Published on: *20 - December - 2019*
For more information, please refer to:
https://www.ema.europa.eu/en/documents/referral/nitrosamines-emea-h-a53-1490-questions-answers-information-nitrosamines-marketing-authorisation_en.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: *20 - December - 2019*
For more information, please refer to:
https://www.hma.eu/fileadmin/dateien/Human_Medicines/CMD_h_/Advice_from_CMDh/Nitrosamins/CMDh_412_2019_Rev.2_2019_12_clean_-_PG_to_MAHs_on_nitrosamines.pdf

NEW - Report from the meeting held on 9-11 December 2019
Published on: *20 - December - 2019*
For more information, please refer to:
https://www.hma.eu/fileadmin/dateien/Human_Medicines/CMD_h_/cmdh_pressreleases/2019/12_2019_Press_release.pdf

Humanarzneimittel - Deutschland

Bulletin zur Arzneimittelsicherheit - Informationen aus BfArM und PEI
„Die neue Ausgabe des Bulletin zur Arzneimittelsicherheit ist erschienen“ […]
***Veröffentlicht am**:19 - Dezember - 2019*
Weitere Informationen finden Sie unter:
BfArM - Bulletin zur Arzneimittelsicherheit

Nichtinterventionelle Prüfungen von Arzneimitteln (Anwendungsbeobachtungen)
„Gemeinsame Empfehlungen des Bundesinstituts für Arzneimittel und Medizinprodukte und des Paul-Ehrlich-Instituts zu Anwendungsbeobachtungen nach § 67 Absatz 6 Arzneimittelgesetz und zur Anzeige von nichtinterventionellen Unbedenklichkeitsprüfungen nach § 63f Arzneimittelgesetz vom 20. Dezember 2019.“ […]
***Veröffentlicht am:** 20 - December - 2019*
Weitere Informationen finden Sie unter:
BfArM - Nicht-interventionelle Prüfungen

***Informationen für Zulassungsinhaber: Bewertung des Risikos möglicher Nitrosaminverunreinigungen in Humanarzneimitteln mit chemisch synthetisierten Wirkstoffen** „Im Dezember 2019 wurde das auf der CMDh- und EMA-Homepage veröffentlichte Q&A-Dokument, welches sich mit dem Risiko einer möglichen Nitrosaminverunreinigung beschäftigt erneut aktualisiert und ergänzt. Das Dokument richtet sich an die Zulassungsinhaber aller Humanarzneimittel, die chemisch synthetisierte pharmazeutische Wirkstoffe enthalten. Es soll die pharmazeutischen Unternehmen bei der Risikobewertung in Bezug auf das Vorhandensein von Nitrosaminen in ihren Arzneimitteln unterstützen, damit die Firmen geeignete Risikominimierungsmaßnahmen ergreifen können. Wichtigste Ergänzung im Dokument sind die Grenzwerte für Nitrosamine bei lebenslanger und kürzer als lebenslanger Anwendung der Arzneimittel.“ […]*
***Veröffentlicht am**: 20 - Dezember - 2019*
Weitere Informationen finden Sie unter:
BfArM - Risikobewertungsverfahren - Informationen für Zulassungsinhaber: Bewertung des Risikos möglicher Nitrosaminverunreinigungen in Humanarzneimitteln mit chemisch synthetisierten Wirkstoffen

PSUR Single Assessment (PSUSA)
***Veröffentlicht am**: 20 - Dezember - 2019*
Weitere Informationen finden Sie unter:
BfArM - PSUR Single Assessment (PSUSA)

Digitale-Versorgung-Gesetz (DVG)
***Veröffentlicht am**: 23 - Dezember - 2019*
Weitere Informationen finden Sie unter:
BfArM - Digitale-Versorgung-Gesetz (DVG)

Information und FAQ - Digitale-Versorgung-Gesetz (DVG)
***Veröffentlicht am**: 23 - Dezember - 2019*
Weitere Informationen finden Sie unter:
BfArM - Information und FAQ

Gemeinsames Schreiben der Europäischen Kommission, der EMA und der HMA an die Verantwortlichen von klinischen Prüfungen zu den Erfordernissen, die Ergebnisse ihrer genehmigten klinischen Studien in EudraCT bereitzustellen (Juni 2019)
***Veröffentlicht am**: 02 - Januar - 2020*
Weitere Informationen finden Sie unter:
Paul-Ehrlich-Institut - Positionen des Paul-Ehrlich-Instituts - Gemeinsames Schreiben der Europäischen Kommission, der EMA und der HMA an die Verantwortlichen von klinischen Prüfungen zu den Erfordernissen, die Ergebnisse ihrer genehmigten klinischen Studien

Humanarzneimittel - Österreich

Raubverlage und ihre Auswirkungen
„Wer wünscht sich das nicht: eine neue Arznei gegen das Leiden, das einen schon jahrelang quält, vielleicht sogar lebensbedrohlich ist. Das neue Mittel beseitigt Schmerzen, verjüngt die Zellen und beugt Krebs vor und das ohne jegliche Nebenwirkung. Leider klingt das zu gut um wahr zu sein – außer es wäre wissenschaftlich bestätigt, durch Publikationen oder Fachvorträge. Aber kann man sich darauf noch verlassen?“ […]
Veröffentlicht am: *15 - November – 2019*
Weitere Informationen finden Sie unter:
Raubverlage und ihre Auswirkungen - BASG

Bearbeitungsstand
Veröffentlicht am: *10 - Dezember– 2019*
Weitere Informationen finden Sie unter:
Gute Herstellungs- / Vertriebspraxis (GMP/GDP) - BASG

Arzneimittelvermittler
Veröffentlicht am: *10 - Dezember – 2019*
Weitere Informationen finden Sie unter:
Arzneimittelvermittler - BASG

Amtliche Nachrichten
Veröffentlicht am: *12 - Dezember – 2019*
Weitere Informationen finden Sie unter:
Cryos International – 8632 - BASG

PSUR outcome - 2019
Veröffentlicht am: *13 - Dezember – 2019*
Weitere Informationen finden Sie unter:
Mustertexte - BASG

Kommissionsentscheidungen - Referrals nach Artikel 107i der Richtlinie 2001/83/EG (Dringlichkeitsverfahren)
Veröffentlicht am: *13 - Dezember – 2019*
Weitere Informationen finden Sie unter:
Kommissionsentscheidungen - BASG

PSUR-Vorlage für homöopathische Humanarzneispezialitäten
Veröffentlicht am: *16 - Dezember – 2019*
Weitere Informationen finden Sie unter:
PSUR-Vorlage für homöopathische Humanarzneispezialitäten - BASG

BASG-Tarif Gültig ab dem 01.01.2020
Veröffentlicht am: *17 - Dezember – 2019*
Weitere Informationen finden Sie unter:
Gebührentarif - BASG

Humanarzneimittel - Österreich

Zuteilungsschemata
Veröffentlicht am: *18 - Dezember – 2019*
Weitere Informationen finden Sie unter:
Kontakt - BASG

FAQ Suchtmittel
Veröffentlicht am: *30 - Dezember - 2019*
Weitere Informationen finden Sie unter:
FAQ Suchtmittel - BASG

Suchtmittel - Formulare Stammdaten
Veröffentlicht am: *30 - Dezember - 2019*
Weitere Informationen finden Sie unter:
Formulare - Stammdaten - BASG

Zur Stellungnahme
„Monographieentwürfe vom 03.01.2020; Stellungnahmen sind bis 29.02.2020 erbeten (basg.oeab@basg.gv.at)“
Veröffentlicht am: *03 - Januar - 2020*
Weitere Informationen finden Sie unter:
Zur Stellungnahme - BASG

Humanarzneimittel - Schweiz

ICH-Treffen in Singapur im November 2019
„Expertentreffen verabschiedet neue Leitlinien (Guidelines) zur Qualität und Sicherheit von Arzneimitteln.“ […]
Veröffentlicht am: *17 - Dezember– 2019*
Weitere Informationen finden Sie unter:
ICH-Treffen in Singapur im November 2019

Swissmedic und die koreanische Heilmittelregulierungsbehörde erweitern ihre Zusammenarbeit im Heilmittelbereich
Veröffentlicht am: *18 - Dezember - 2019*
Weitere Informationen finden Sie unter:
Swissmedic und die koreanische Heilmittelregulierungsbehörde erweitern ihre Zusammenarbeit im Heilmittelbereich

Signale bei Humanarzneimitteln
„Anpassung des Signalprozesses bei Änderung der Arzneimittelinformation als risikominimierende Massnahme per 1.01.2020.“ […]
Veröffentlicht am: *19 - Dezember- 2019*
Weitere Informationen finden Sie unter:
Risk Management (Signalmanagement, PSURs, RMPs/RMP summaries)

Public Review der neuen eCTD M1 Specification v1.5
„Swissmedic wird die eCTD M1 Specification anpassen und führt dazu ein Public Review der neuen Dokumente durch.“ […]
Veröffentlicht am: *23 - Dezember- 2019*
Weitere Informationen finden Sie unter:
Public Review der neuen eCTD M1 Specification v1.5

Aktualisierte Dokumente
Veröffentlicht am: *03 - Januar - 2020*
Weitere Informationen finden Sie unter:
Dezember 2019
Und
Januar 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)

36. Jahreskongress der DGPharMed
Termin*: 12.03.2020 - 13.03.2020*
Ort: *Ellington Hotel Berlin, Nürnberger Strasse 50-55*
Weitere Informationen finden Sie unter:
Paul-Ehrlich-Institut - Veranstaltungen - 36. Jahreskongress der DGPharMed

Österreich

BASG-Gespräch: Neues eService Inspektion und Überwachung
Termin: 04.03.2020
AGES-Akademie, Spargelfeldstrasse 191, 1220 Wien
Weitere Informationen finden Sie unter:
https://www.basg.gv.at/news-center/veranstaltungen-vorschau/

BASG-Gespräch: Serialisierung von Arzneimitteln – Ende der Stabilisierungsphase
Termin: 10.03.2020
AGES-Akademie, Spargelfeldstrasse 191, 1220 Wien
Weitere Informationen finden Sie unter:
https://www.basg.gv.at/news-center/veranstaltungen-vorschau/

BASG-Gespräch: Versorgungssituation - Lieferengpässe
Termin: 26.03.2020
AGES-Akademie, Spargelfeldstrasse 191, 1220 Wien
Weitere Informationen finden Sie unter:
https://www.basg.gv.at/news-center/veranstaltungen-vorschau/

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

Informationsveranstaltung für Fachanwender und Spitäler zur revidierten Medizinprodukte-Regulierung
4. Mai 2020, im Kursaal Bern
Im Februar 2020 wird das Programm sowie das Anmeldeformular auf der Swissmedic Internetseite www.swissmedic.ch/md publiziert.
Weitere Informationen finden Sie unter:
https://www.swissmedic.ch/swissmedic/de/home/services/veranstaltungen/fruehere_veranstaltungen/info-mep.html

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

NEW: European Pharmacopoeia training session on biologicals
Where: *Straßbourg, France*
Date: *04 February 2020 to 05 February 2020*
Weitere Informationen finden Sie unter:

NEW: European Pharmacopoeia training session on biologicals | EDQM - European Directorate for the Quality of Medicines