12. – 23. Oktober 2020

MEGRA NEWSLETTER

Humanarzneimittel - EU

Allgemeines – General

European Medicines Agency's privacy statement concerning requests for information or access to documents (updated) - EMA/415481/2019 Rev. 2
Published on: *12 - October - 2020*
For more information, please refer to:
COVID-19 vaccines: key facts | European Medicines Agency

Human medicines highlights - October 2020 (new)
Published on: *12 - October - 2020*
For more information, please refer to:
https://www.ema.europa.eu/en/documents/newsletter/human-medicines-highlights-october-2020_en.pdf

COVID-19: latest updates (updated)
Published on: *23 - October- 2020*
For more information, please refer to:
COVID-19: latest updates | European Medicines Agency

Pharmakovigilanz – PRAC

EudraVigilance training and support (updated)
"The following F2F Meetings dates are cancelled:
•9 - 11 November 2020, Madrid, Spain cancelled
•23 - 25 November 2020, Munich, Germany cancelled
•30 November - 2 December 2020, Paris, France cancelled
The following Virtual Meeting dates are held:
•16-20 November 2020
•23-27 November 2020
•07-11 December 2020
Published on: *12 -October - 2020*
For more information, please refer to:
EudraVigilance training and support | European Medicines Agency

Article 57 product data (updated)
Published on: *20 - October – 2020*
For more information, please refer to:
https://www.ema.europa.eu/en/documents/other/article-57-product-data_en.xlsx

PRAC: Agendas, minutes and highlights
Published on: *23 - October - 2020*
For more information, please refer to:
PRAC: Agendas, minutes and highlights | European Medicines Agency

Zulassung – Regulatory Affairs

Core summary of product characteristics for human normal immunoglobulin for intravenous administration (IVIg)
"This guideline describes the information to be included in the summary of product characteristics (SmPC) for human normal immunoglobulins for intravenous administration." […]
Published on: *13 - October - 2020*

For more information, please refer to:
Core summary of product characteristics for human normal immunoglobulin for intravenous administration (IVIg) | European Medicines Agency

Post-authorisation measures: questions and answers
"This guidance document addresses a number of questions which marketing authorisation holders (MAHs) may have on post-authorisation procedures. It provides an overview of the Agency's position on issues, which are typically addressed in discussions or meetings with MAHs in the post-authorisation phase. It will be updated regularly to reflect new developments, to include guidance on further postauthorisation procedures and to reflect the implementation of the new European legislation. Revised topics will be marked by "New" or "Rev" upon publication." [..]
***Published on**: 14 - October- 2020*
For more information, please refer to:
Post-authorisation measures: questions and answers | European Medicines Agency

Pre-authorisation guidance
"The document was updated"
***Published on**: 14 - October- 2020*
For more information, please refer to:
Pre-authorisation guidance | European Medicines Agency

Worksharing: questions and answers
"The document was updated"
***Published on:** 14 - October- 2020*
For more information, please refer to:
Worksharing: questions and answers | European Medicines Agency

Type-IA variations: questions and answers
"The document was updated"
***Published on:** 14 - October- 2020*
For more information, please refer to:
Worksharing: questions and answers | European Medicines Agency

Grouping of variations: questions and answers
"The document was updated"
***Published on:** 14 - October- 2020*
For more information, please refer to:
Grouping of variations: questions and answers | European Medicines Agency

Type-IB variations: questions and answers (updated)
"The document was updated"
***Published on:** 14 - October- 2020*
For more information, please refer to:
Type-IB variations: questions and answers | European Medicines Agency

Obtaining and maintaining a scientific opinion on a medicine for use outside the European Union (updated)
"[…] Update: In parallel, applicants should send the form via EMA service desk, selecting the type of question 'pre-submission phase request', followed by 'eligibility request'." […]
***Published on:** 14 - October- 2020*

Humanarzneimittel - EU

For more information, please refer to:
Obtaining and maintaining a scientific opinion on a medicine for use outside the European Union | European Medicines Agency

Frequently asked questions about parallel distribution
Published on: *14 - October- 2020*
For more information, please refer to:
Frequently asked questions about parallel distribution | European Medicines Agency

Assessment templates and guidance (updated)
"Update: Assessors should always submit assessment reports and comments for initial marketing authorisation applications to:
•the EMA product lead and product assistant (whose names are listed on the dashboard for national competent authorities);
•the product shared mailbox (whose format is always 'product name-product number' in one word, followed by '@ema.europa.eu');
•the product's dedicated initial MAA mailbox (whose format is always 'MAA product name' in one word, followed by '@ema.europa.eu')." […]
Published on: *15 - October- 2020*
For more information, please refer to:
Assessment templates and guidance | European Medicines Agency

IRIS guide for applicants (updated) - EMA/444925/2018
"This guide has been produced to show applicants how to use the IRIS platform to prepare and submit an application for a scientific procedure (e.g. orphan designation application, scientific advice, or ITF briefing meeting request) and related activities.
For Parallel Distribution procedures separate user access roles are needed and separate guidance is available on the IRIS home page." […]
Published on: *15 - October- 2020*
For more information, please refer to:
https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/iris-guide-applicants_en.pdf

Nitrosamine impurities
"Rifampicin medicines (new)
Authorities in the EU are investigating the presence of a nitrosamine impurity, 1-nitroso-4-methyl piperazine (MeNP), in some batches of active substances used in rifampicin medicines.
The Coordination Group for Mutual Recognition and Decentralised Procedures - Human (CMDh), which represents EU Member States, is working to ensure adequate testing of active substances and is liaising with the companies concerned. Rifampicin is a first-line treatment for tuberculosis. It is also used for treating several other serious infections, including blood infections and leprosy. The risk to patients from not taking their rifampicin medicines far outweighs any potential risk from MeNP. Healthcare professionals should therefore continue to prescribe rifampicin medicines as normal in accordance with the product information. Authorities will provide updates as necessary.
Metformin-containing medicines:
Update: As of October 2020, EMA and the national competent authorities are asking marketing authorisation holders for metformin-containing medicines to test their medicines before releasing them onto the market. This is a precautionary step to ensure patient safety while the investigation is ongoing. It is in line with the measures introduced by EMA's Article 5(3) review to limit the presence of

nitrosamines in human medicines. EMA and the national competent authorities will carefully monitor responses to this request and take action if necessary. " […]
***Published on:** 16 - October- 2020*
For more information, please refer to:
Nitrosamine impurities | European Medicines Agency

Scientific advice and protocol assistance
"Update: Applicants from the academic sector are eligible to receive free protocol assistance for developing orphan medicines as of 19 June 2020. For more information see Academia and Fees payable to the European Medicines Agency." […]
***Published on:** 19 October - 2020*
For more information, please refer to
Scientific advice and protocol assistance | European Medicines Agency

Medicinal products for human use: monthly figures - September 2020 (new) - EMA/549770/2020
***Published on:** 20 October - 2020*
For more information, please refer to
https://www.ema.europa.eu/en/documents/report/medicinal-products-human-use-monthly-figures-september-2020_en.pdf

Angiotensin-II-receptor antagonists (sartans) containing a tetrazole group, valsartan, candesartan, irbesartan, losartan and olmesartan , Article 31 referrals, European Commission final decision, 31/01/2019, 02/04/2019, 20/10/2020 (updated)
"On 31 January 2019, EMA recommended that companies making sartan blood pressure medicines (also known as angiotensin II receptor blockers) review their manufacturing processes so that they do not produce nitrosamine impurities. Companies will have a transition period to make any necessary changes, during which strict temporary limits on levels of these impurities will apply. After this period, companies will have to demonstrate that their sartan products have no quantifiable levels of these impurities before they can be used in the EU. These recommendations follow EMA's review of N-nitrosodimethylamine (NDMA) and N-nitrosodiethylamine (NDEA), which are classified as probable human carcinogens (substances that could cause cancer) and have been detected in some sartan medicines. For the vast majority of sartan medicines, impurities were either not found or were present at very low levels." […]
***Published on:** 20 October - 2020*
For more information, please refer to
Angiotensin-II-receptor antagonists (sartans) containing a tetrazole group | European Medicines Agency

Periodic safety update reports (PSURs)
***Published on:** 21 October - 2020*
For more information, please refer to
Periodic safety update reports (PSURs) | European Medicines Agency

Panexcell, Article 31 referrals, European Commission final decision, 27/02/2020, 24/09/2020, 22/10/2020 (updated)
"On 24 July 2020, EMA's human medicines committee (CHMP) recommended the suspension of the marketing authorisations of generic medicines tested by Panexcell Clinical Laboratories Priv. Ltd at its site in Mumbai, India. The recommendation came after Austrian and German inspectors found irregularities in how the company carried out bioequivalence studies. These are studies used to show that a generic medicine produces the same amount of active substance in the body as the reference

medicine. […] The CHMP's recommendation was sent to the European Commission for a legally binding decision." […]
***Published on:** 22 October - 2020*
For more information, please refer to
Panexcell | European Medicines Agency

PRIME: priority medicines (updated)
"List of products granted eligibility. " […]
***Published on:** 22 October - 2020*
For more information, please refer to
PRIME: priority medicines | European Medicines Agency

CHMP: Agendas, minutes and highlights
***Published on:** 23 October - 2020*
For more information, please refer to
CHMP: Agendas, minutes and highlights | European Medicines Agency

Orphan Drugs und neuartige Therapierichtungen (ATMP)

Qualification of novel methodologies for medicine development (updated)
New: Applicants should use EMA's secure online IRIS platform to apply for qualification from EMA: The IRIS platform provides a single space for applicants and EMA to submit requests, communicate, share information and deliver documents concerning a qualification procedure. Applicants first need to complete the registration steps set out in the Quick interactive guide to IRIS registration process before using IRIS to apply for qualification.
The IRIS platform homepage also provides guidance on registering and using IRIS to make regulatory submissions. Applicants need to upload a complete draft dossier in IRIS at the time of application.
For regulatory guidance on applying for qualification, including the dossier contents, see Guidance for applicants seeking qualification of novel methodologies. For information on submission deadlines, see Scientific advice and protocol assistance: Regulatory and procedural guidance.
***Published on:** 1 -October- 2020*
For more information, please refer to:
Qualification of novel methodologies for medicine development | European Medicines Agency

CAT: Agendas, minutes and reports
***Published on: 23** - October- 2020*
For more information, please refer to:
CAT: Agendas, minutes and reports | European Medicines Agency

COMP: Agendas, minutes and meeting reports
***Published on:** 23 - October- 2020*
For more information, please refer to:
COMP: Agendas, minutes and meeting reports | European Medicines Agency

Qualität – Quality

ICH M7 Assessment and control of DNA reactive (mutagenic) impurities in pharmaceuticals to limit potential carcinogenic risk (updated)
"This guideline emphasizes considerations of both safety and quality risk management in establishing levels of mutagenic impurities that are expected to pose negligible carcinogenic risk. It outlines

recommendations for assessment and control of mutagenic impurities that reside or are reasonably expected to reside in final drug substance or product, taking into consideration the intended conditions of human use." […]
***Published on:** 16 -October - 2020*
For more information, please refer to:
ICH M7 Assessment and control of DNA reactive (mutagenic) impurities in pharmaceuticals to limit potential carcinogenic risk | European Medicines Agency

Medizinprodukte - Medical Device / Health technology assessment

Medical Devices
***Published on:** 23 - October - 2020*
For more information, please refer to:
Medical devices | European Medicines Agency

(Prä-) Klinische Forschung – Research and Development

Clinical investigation of human normal immunoglobulin for intravenous administration (IVIg)
"This Guideline describes the information to be documented when an application is made for a market-ing authorisation for a human normal immunoglobulin for intravenous use (IVIg). The guidance covers biological data, clinical trials and patient follow-up. Quality aspects are outside the scope of this guide-line.
Guidance is also provided for authorised products where a significant change in the manufacturing process has been made.
This is the third revision of the Guideline on the clinical investigation of human normal immunoglobulin for intravenous administration (EMA/CHMP/BPWP/94033/2007 rev. 3). It replaces Version 2 and mainly encompasses the inclusion of multifocal motor neuropathy (MMN), and chronic inflammatory demye-linating polyradiculoneuropathy (CIDP) and the rewording of the secondary immunodeficiencies." […]
***Published on:** 13 - October - 2020*
For more information, please refer to:
Clinical investigation of human normal immunoglobulin for intravenous administration (IVIg) | European Medicines Agency

Pharmaceutical development of medicines for use in the older population
"The reflection paper describes aspects that medicines developers may consider when designing medicines for older people, such as selecting appropriate routes of administration and dosage forms, dosing frequency, excipients, container closure systems, devices and technologies, and user instructions in the product information. The reflection paper describes aspects that medicines developers may consider when designing medicines for older people, such as selecting appropriate routes of administration and dosage forms, dosing frequency, excipients, container closure systems, devices and technologies, and user instructions in the product information." […]
***Published on:** 22 - October- 2020*
For more information, please refer to
Pharmaceutical development of medicines for use in the older population | European Medicines Agency

Kinderarzneimittel – Paediatrics

PDCO: Agendas, minutes and meeting reports
***Published on:** 23 - October - 2020*

Humanarzneimittel - EU

For more information, please refer to:
PDCO: Agendas, minutes and meeting reports | European Medicines Agency

Pflanzliche Arzneimittel – Herbal medicines

Herniariae herba, Herniariae herba, F: Assessment finalised (updated)
Published on: *14 - October - 2020*
For more information, please refer to:
Herniariae herba | European Medicines Agency

Thymi aetheroleum, Thymi aetheroleum, F: Assessment finalised (updated)
Published on: *15 - October - 2020*
For more information, please refer to:
Thymi aetheroleum | European Medicines Agency

Tanaceti parthenii herba, Tanaceti parthenii herba, F: Assessment finalised (updated)
Published on: *20 - October - 2020*
For more information, please refer to:
Tanaceti parthenii herba | European Medicines Agency

Thymi aetheroleum, Thymi aetheroleum, F: Assessment finalised (updated)
Published on: *15 - October - 2020*
For more information, please refer to:
Thymi aetheroleum | European Medicines Agency

HMPC: Agendas, minutes and meeting reports
Published on: *23 - October – 2020*
For more information, please refer to:
HMPC: Agendas, minutes and meeting reports | European Medicines Agency

EDQM

Certification Monthly Report of Activities: September 2020
Published on: *12 October- 2020*
For more information, please refer to:
Certification Monthly Report of Activities: September 2020 | EDQM - European Directorate for the Quality of Medicines

Products and extemporaneous preparation of paediatric formulations that may be useful in the treatment of COVID-19
"During the COVID-19 pandemic caused by SARS-CoV-2, clinical trials aimed at demonstrating the safety and efficacy of established active substances in this new indication are currently ongoing and medicinal products are also being used experimentally in clinical practice. Reference is made to the WHO information on "Clinical management of severe acute respiratory infection (SARI) when COVID-19 disease is suspected."
The European Paediatric Formulary (PaedF) Working Party, in this exceptional situation, wishes to serve pharmacists by compiling existing knowledge on paediatric formulations for active substances under investigation as well as known authorised medicinal products. Information on paediatric formulations of active substances used in clinical trials but also experimentally in clinical practice

throughout the world will therefore be gathered and published in tables on the EDQM website, by the PaedF Working Party. These tables will be continuously updated and will be living documents.".[…]
***Published on:** 16 - October - 2020*
For more information, please refer to:
Products and extemporaneous preparation of paediatric formulations that may be useful in the treatment of COVID-19 | EDQM - European Directorate for the Quality of Medicines

New Council of Europe resolution to strengthen safety of food contact materials
"The Committee of Ministers of the Council of Europe1 has adopted a new resolution2 on the safety and quality of materials and articles for contact with food. This instrument is expected to improve the protection of consumers from contaminants (metals, antioxidants, stabilisers, colorants, plasticisers, etc.) potentially released by material in contact with food, such as containers, work surfaces or packaging." […]
***Published on:** 19 - October- 2020*
For more information, please refer to:
New Council of Europe resolution to strengthen safety of food contact materials | EDQM - European Directorate for the Quality of Medicines

Launch of public consultation on the CEP of the future
"The content and layout of the current Certificate of Suitability (CEP) remains very similar to the original created in 1992. The EDQM is nonetheless well aware of the far-reaching effects that globalisation, the rise of digital technology and many other major regulatory and scientific developments have had on the pharmaceutical industry and competent authorities over the last three decades and, in response, is launching a project to design the CEP of the future. The aim is to develop a "new-look" CEP that will better fit the emerging needs of stakeholders and offer both enhanced user-friendliness and greater transparency of the information conveyed without, however, increasing the administrative regulatory burden related to their revision." […]
***Published on:** 22 - October- 2020*
For more information, please refer to:
Launch of public consultation on the CEP of the future | EDQM - European Directorate for the Quality of Medicines

European Commission

New web page with the basic information on the EUDAMED Actor registration module
Published on: *20 - October - 2020*
For more information, please refer to:
Actor registration module | Public Health

Summary record and documents - 89th meeting of the Pharmaceutical Committee (18-21 September 2020)
Published on: *21 - October - 2020*
For more information, please refer to:
Human Pharmaceutical Committee - Meetings | Public Health

Updated presentation - Information on the applications for designation as a notified body under Regulations (EU) 2017/745 and 2017/746
Published on: *22 - October - 2020*
For more information, please refer to:
https://ec.europa.eu/health/sites/health/files/md_newregulations/docs/notifiedbodies_overview_en.pdf

Commission launches public consultation on Preliminary Opinion on the safety of breast implants in relation to anaplastic large cell lymphoma (BIA-ALCL
Published on: *23 - October - 2020*
For more information, please refer to:
https://ec.europa.eu/newsroom/sante/newsletter-specific-archive-issue.cfm?newsletter_service_id=327&newsletter_issue_id=26502&pdf=true&fullDate=Fri%2023%20Oct%202020&lang=default

CMDh

NEW - September 2020 CMDh Minutes
Published on: *16 - October - 2020*
For more information, please refer to:
https://www.hma.eu/fileadmin/dateien/Human_Medicines/CMD_h_/Agendas_and_Minutes/Minutes/2020_09_CMDh_Minutes.pdf

NEW - Report from the meeting held on 13-14 October 2020
Published on: 21 - *October - 2020*
For more information, please refer to:
https://www.hma.eu/fileadmin/dateien/Human_Medicines/CMD_h_/cmdh_pressreleases/2020/10_2020_CMDh_press_release.pdf

Humanarzneimittel - Deutschland

Ergebnisprotokoll der 26. Beratung des Ausschusses Mikrobiologie der Deutschen Arzneibuch-Kommission vom 10. Oktober 2019

„Das BfArM gibt das Ergebnisprotokoll der 26. Beratung des Ausschusses Mikrobiologie der Deutschen Arzneibuch-Kommission vom 10. Oktober 2019 bekannt.“ […]

***Veröffentlicht am**: 12 - Oktober- 2020*

Weitere Informationen finden Sie unter:

BfArM - Fachausschüsse der Deutschen Arzneibuch-Kommission - Ergebnisprotokoll der 26. Beratung des Ausschusses Mikrobiologie der Deutschen Arzneibuch-Kommission vom 10. Oktober 2019

Digitale-Versorgung-Gesetz / Medical Apps

***Veröffentlicht am**: 12 - Oktober - 2020*

Weitere Informationen finden Sie unter:

BfArM - Digitale Gesundheitsanwendungen (DiGA)

Fachausschüsse der Deutschen Arzneibuch-Kommission

***Veröffentlicht am**: 12 - Oktober- 2020*

Weitere Informationen finden Sie unter:

BfArM - Fachausschüsse der Deutschen Arzneibuch-Kommission

Informationen und Schulungsunterlagen

„Das BfArM hat die Webseite zum Schulungsangebot für die PharmNet.Bund-Anwendungen aktualisiert.“ […]

***Veröffentlicht am**: 13 - Oktober - 2020*

Weitere Informationen finden Sie unter:

BfArM - eSubmission - Informationen und Schulungsunterlagen

Coronavirus SARS-CoV-2

***Veröffentlicht am**: 15 - Oktober - 2020*

Weitere Informationen finden Sie unter:

BfArM - Coronavirus SARS-CoV-2

Der Risikomanagementplan: Neufokussierung durch die zweite Revision des Moduls V des EU-Leitfadens zur Guten Pharmakovigilanzpraxis

„Der Risikomanagementplan: Neufokussierung durch die zweite Revision des Moduls V des EU-Leitfadens zur Guten Pharmakovigilanzpraxis.“ […]

***Veröffentlicht am**: 15 - Oktober - 2020*

Weitere Informationen finden Sie unter:

https://www.bfarm.de/SharedDocs/Downloads/DE/Arzneimittel/Pharmakovigilanz/Bulletin2-2020_Artikel-Risikomanagementplan.pdf?__blob=publicationFile&v=2

Antigentests auf SARS-CoV-2

***Veröffentlicht am**: 15 - Oktober - 2020*

Weitere Informationen finden Sie unter:

BfArM - Antigentests auf SARS-CoV-2

Der Sachverständigen-Ausschuss für Verschreibungspflicht
***Veröffentlicht am**: 16 - Oktober- 2020*
Weitere Informationen finden Sie unter:
BfArM - Verschreibungspflicht

Die EU-Überwachungsbehörden fordern Nitrosamin-Untersuchungen von metforminhaltigen Arzneimitteln
„Die EU-Überwachungsbehörden fordern Nitrosamin-Untersuchungen von metforminhaltigen Arzneimitteln." […]
***Veröffentlicht am**: 16 - Oktober - 2020*
Weitere Informationen finden Sie unter:
BfArM - Weitere Arzneimittelrisiken - Die EU-Überwachungsbehörden fordern Nitrosamin-Untersuchungen von metforminhaltigen Arzneimitteln

DiGA-Leitfaden
„Das Fast-Track-Verfahren für digitale Gesundheitsanwendungen (DiGA) nach § 139e SGB V" […]
***Veröffentlicht am**: 23 - Oktober - 2020*
Weitere Informationen finden Sie unter:
https://www.bfarm.de/SharedDocs/Downloads/DE/Service/Beratungsverfahren/DiGA-Leitfaden.pdf?__blob=publicationFile&v=11

PSUR Single Assessment (PSUSA)
„Hier finden Sie Informationen und Hinweise zum Ergebnis einzelner Verfahren des PSUR Single Assessment (PSUSA)." […]
***Veröffentlicht am**: 23 - Oktober - 2020*
Weitere Informationen finden Sie unter:
BfArM - PSUR Single Assessment (PSUSA)

PEI IVD Maßnahmen von Herstellern:
***Veröffentlicht am**: 23 - Oktober - 2020*
Weitere Informationen finden Sie unter:
Paul-Ehrlich-Institut - IVD-Vigilanz - Maßnahmen von Herstellern

Paul-Ehrlich-Institut (PEI) - Beauflagtes Schulungsmaterial (Educational Material)
***Veröffentlicht am**: 23 - Oktober - 2020*
Weitere Informationen finden Sie unter:
Paul-Ehrlich-Institut - Auflistung von genehmigtem Schulungsmaterial

PEI Lieferengpässe von Human-Impfstoffen:
***Veröffentlicht am**: 23 - Oktober - 2020*
Weitere Informationen finden Sie unter:
Paul-Ehrlich-Institut - Lieferengpässe

Sicherheitsinformationen
***Veröffentlicht am**: 23 - Oktober - 2020*
Weitere Informationen finden Sie unter:
Paul-Ehrlich-Institut - Sicherheitsinformationen - Warnung vor dem Off-label-Einsatz von BCG-Präparaten

Humanarzneimittel - Österreich

Gute Herstellungs- / Vertriebspraxis (GMP/GDP)
Veröffentlicht am: *12 - Oktober – 2020*
Weitere Informationen finden Sie unter:
https://www.basg.gv.at/fileadmin/redakteure/Inspektionen/Transparenzlisten/1020_Bearbeitungsstand.pdf

Register Arzneimittelvermittler
„Register der Arzneimittelvermittler gemäß § 71a AMG" […]
Veröffentlicht am: *12 - Oktober – 2020*
Weitere Informationen finden Sie unter:
https://www.basg.gv.at/fileadmin/redakteure/Inspektionen/Transparenzlisten/1020_Register_Arzneimittelvermittler.pdf?sword_list%5B0%5D=Arzneimittelvermittler

COVID-19
Datum der Information*: 15 - Oktober – 2020*
Weitere Informationen finden Sie unter:
COVID-19 - BASG

Information zu Excipients in Homöopathischen Arzneispezialitäten
„Excipients, die bei der Wirkstoffherstellung verwendet werden (wie zum Beispiel Lactose, Molke, Saccharose, Honig, Ethanol, Glycerol) und in Spuren im Fertigprodukt enthalten sein können, wurden gemäß…" […]
Datum der Information: *23 – Oktober – 2020*
Weitere Informationen finden Sie unter:
Information zu Excipients in Homöopathischen Arzneispezialitäten - BASG

Humanarzneimittel - Schweiz

Produktionsunterbruch bei Schweizer Lohnhersteller kann zu vorübergehenden Versorgungsstörungen führen
„Inspektion durch Swissmedic zeigt Mängel der Guten Herstellpraxis (GMP)". […]
Veröffentlicht am: *12 – Oktober – 2020*
Weitere Informationen finden Sie unter:
Produktionsunterbruch bei Schweizer Lohnhersteller kann zu vorübergehenden Versorgungsstörungen führen

ACSS Consortium begrüsst das Vereinigte Königreich als neues Mitglied
„Die MHRA freut sich über die Aufnahme ins Consortium“ […]
Veröffentlicht am: *14 - Oktober– 2020*
Weitere Informationen finden Sie unter:
ACSS Consortium begrüsst das Vereinigte Königreich als neues Mitglied

Swissmedic erhält zweites Zulassungsgesuch für einen Corona-Impfstoff
„Die Schweizer Heilmittelbehörde prüft einen weiteren Impfstoff im rollenden Verfahren." […]
Veröffentlicht am: *19 - Oktober– 2020*
Weitere Informationen finden Sie unter:
Swissmedic erhält zweites Zulassungsgesuch für einen Corona-Impfstoff

Out-of-Stock – COVID-19 – Bewilligungen zum befristeten Import und Vertrieb von Humanarzneimitteln – Update
„Bewilligungen gemäss Art. 22 Abs. 3 der COVID-19-Verordnung 3" […]
Veröffentlicht am: *21 - Oktober– 2020*
Weitere Informationen finden Sie unter:
Out-of-Stock – COVID-19 – Bewilligungen zum befristeten Import und Vertrieb von Humanarzneimitteln – Update

Aktualisierte Dokumente
Veröffentlicht am: *23 - Oktober– 2020*
Weitere Informationen finden Sie unter:
Oktober 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. *

Es geht um eine Einreichung hinsichtlich der „Volldeklaration“ in der Schweiz. Wir haben bei unseren Produkten NaOH und HCl nicht in Modul 3.2.P.1 gelistet, auch wenn die Substanzen durchaus zur pH-Einstellung eingesetzt werden. In der EU haben wir sie daher auch nicht gemäß Excipients-Guideline in unseren Texten.

Nun möchte unsere Schweizer Kollegin, dass wir für die Schweiz NaOH und HCl auf die mock-ups für Faltschachtel und Etikett aufnehmen und analog in der PIL und SmPC ergänzen. Inklusive eines Natrium-Warnhinweises.

Wir als HQ möchten aber nicht, dass unsere deutschsprachigen Texte auseinanderlaufen; wir in der Schweiz einen Na-Warnhinweis drin haben und in AT und DE nicht.

Von der EU weiß ich, dass hinsichtlich Excipients-Guideline eine Bezugnahme auf 3.2.P.1 korrekt ist. Können Sie mir sagen, wie sich das in der Schweiz verhält? Wir finden leider keine genaue Angabe, worauf sich die Volldeklaration bezieht.

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

*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

Virtueller Workshop zur Vorbereitung der Bereitstellung von SNOMED CT
Termin: 16. November 2020
Weitere Informationen finden Sie unter:
BfArM - Sonstige Veranstaltungen - Virtueller Workshop zur Vorbereitung der Bereitstellung von SNOMED CT

Österreich

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

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

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

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

Schweiz

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

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

Europa

See also the information in the section Pharmacovigilance