



08. – 19. Juni
2020



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<u>Urheberrechtshinweis:</u>	

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Allgemeines – General

Human medicines highlights - June 2020 (new)

Published on: 08 - June - 2020

For more information, please refer to:

https://www.ema.europa.eu/en/documents/newsletter/human-medicines-highlights-june-2020_en.pdf

EMA receives application for conditional authorisation of first COVID-19 treatment in the EU

“EMA has now received an application for conditional marketing authorisation (CMA) of the antiviral medicine remdesivir for the treatment of COVID-19 and has formally started its evaluation. The assessment of the benefits and risks of remdesivir is being performed under a reduced timeline and an opinion could be issued within weeks, depending on the robustness of the data submitted and whether further information is required to support the evaluation.” [...]

Published on: 08 - June - 2020

For more information, please refer to:

[EMA receives application for conditional authorisation of first COVID-19 treatment in the EU | European Medicines Agency](#)

EU actions to support availability of medicines during COVID-19 pandemic – update #7

“The EU Executive Steering Group on Shortages of Medicines Caused by Major Events held a virtual meeting on 3 June 2020. Regular participation in the meeting of the steering group was extended to all the heads of the national competent authorities (NCAs) of the EU Member States to discuss the measures taken by EU authorities to ensure the continued availability of medicines in Europe during the ongoing COVID-19 pandemic.” [...]

Published on: 08 - June - 2020

For more information, please refer to:

[EU actions to support availability of medicines during COVID-19 pandemic – update #7 | European Medicines Agency](#)

What we publish on medicines and when

“EMA's guide describes the different types of information stakeholders can expect on this website about centrally and non-centrally authorised medicines, including the publication times and location.” [...]

Published on: 09 - June - 2020

For more information, please refer to:

[What we publish on medicines and when | European Medicines Agency](#)

Small and medium-sized enterprise (SME) Office annual report 2018 (updated)

Published on: 10 - June - 2020

For more information, please refer to:

https://www.ema.europa.eu/en/documents/report/small-medium-sized-enterprise-sme-office-annual-report-2018_en.pdf

Small and medium-sized enterprise (SME) Office annual report 2019 (new)

Published on: 10 - June - 2020

For more information, please refer to:

https://www.ema.europa.eu/en/documents/report/small-medium-sized-enterprise-sme-office-annual-report-2019_en.pdf

Humanarzneimittel - EU

Stakeholder engagement highlights

“EMA's guide describes the different types of information stakeholders can expect on this website about centrally and non-centrally authorised medicines, including the publication times and location.”
[...]

Published on: 11 - June - 2020

For more information, please refer to:

https://www.ema.europa.eu/en/documents/other/stakeholder-engagement-highlights-2016_en.pdf
and

https://www.ema.europa.eu/en/documents/other/stakeholder-engagement-highlights-2018_en.pdf
and

https://www.ema.europa.eu/en/documents/other/stakeholder-engagement-highlights-2019_en.pdf

International: Canada

“Update: EMA, the European Commission and Health Canada signed a confidentiality arrangement in 2007, which was renewed in 2013 and in 2020. Changes introduced in 2020 include references to personal data legislation and the permanent validity of the arrangement.

- Working arrangement between DG Sante, EMA and Health Canada for the exchange of non-public information on health / medicinal products. “[...]”

Published on: 12 - June - 2020

For more information, please refer to:

[Canada | European Medicines Agency](#)

Pharmakovigilanz – PRAC

Medical literature monitoring (updated)

“Update: In June 2020, EMA added nine additional active substances (chloroquine, darunavir, emtricitabine-tenofovir, filgrastim, ivermectin, nitric oxide, oseltamivir, prednisone and ritonavir) which are being investigated as potential treatments for COVID-19, and for which there are multiple marketing authorisation holders in the EEA.

It is also adding COVID-19-related search terms to its regular literature searches for six active substance groups (azithromycin, ciclosporin, dexamethasone, hydrocortisone, ribavirin and prednisolone) that were already included in the service.

COVID-19-related literature searches commenced on 1 June 2020 in EMBASE, and will commence on 1 July 2020 in EBSCO.” [...]

Published on: 10 - June - 2020

For more information, please refer to:

[Medical literature monitoring | European Medicines Agency](#)

PRAC: Agendas, minutes and highlights

Published on: 12 - June – 2020

For more information, please refer to:

[PRAC: Agendas, minutes and highlights | European Medicines Agency](#)

Zulassung – Regulatory Affairs

Treatments and vaccines for COVID-19 (updated)

“The European Medicines Agency's (EMA) is interacting with developers of potential COVID-19 treatments and vaccines to enable promising medicines to reach patients as soon as possible, initially in the clinical trial setting and eventually on the market.” [...]

Published on: 10 – June - 2020

Humanarzneimittel - EU

For more information, please refer to:

[Treatments and vaccines for COVID-19 | European Medicines Agency](#)

CHMP: Agendas, minutes and highlights

Published on: 11 – June - 2020

For more information, please refer to:

[CHMP: Agendas, minutes and highlights | European Medicines Agency](#)

Plasma master file certificates (updated)

Published on: 11 – June - 2020

For more information, please refer to:

[Plasma master file certificates | European Medicines Agency](#)

Annual reports and work programmes (updated)

“2019 annual report (new)

EMA's 2019 annual report highlights the Agency's most significant achievements in 2019, including the successful relocation to Amsterdam, the finalisation of the 'Regulatory science to 2025' strategy and the response to the discovery of nitrosamine impurities in medicines.

The report is available in two formats:

- navigate the digital version to view interviews, short videos and an interactive timeline of the Agency's main activities in 2019;*
- read the traditional PDF version to see additional figures and statistics on EMA's regulatory procedures and activities [...]*

Published on: 12 - June- 2020

For more information, please refer to

[Annual reports and work programmes | European Medicines Agency](#)

Referral: Methocarbamol / paracetamol-containing medicinal products, methocarbamol/ paracetamol , Robaxisal compuesto, Article 31 referrals, European Commission final decision, 26/03/2020, 09/06/2020, 17/06/2020 (updated)

Published on: 17 - June - 2020

For more information, please refer to

[Methocarbamol / paracetamol-containing medicinal products | European Medicines Agency](#)

Referral: Fosfomycin-containing medicinal products , fosfomycin calcium, fosfomycin disodium, fosfomycin sodium, fosfomycin trometamol , Afastural,Berny Adulti,Danifos Adulti, Fomicyt, Fosfocin,Fosfocina,Fosfocine,Fosfopharm,Fosfuro,Fosmol,Fostrofemge,Gynofostrome,Infectofos,Inf eurAdulti,Interfos,Monural,Monuril,Monurol,Rapidnorm,Solufos,Symural,Uridoz,Urifos,Urinex,Urof ast,Uromaste,Uroseptic, Article 31 referrals, European Commission final decision, 26/03/2020, 09/06/2020, 18/06/2020 (updated)

“The review aimed to determine the place of fosfomycin in the treatment of infections, taking into account the latest available evidence. It concluded that:

- fosfomycin given into a vein should now only be used for treating certain serious infections such as those affecting the heart, lungs, blood and brain or those that are difficult to treat such as complicated infections of the abdomen, urinary tract, bone, joint or of the skin and soft tissue.*
- fosfomycin, for use by mouth, can continue to be used for treating uncomplicated cystitis in women and adolescent girls. Fosfomycin granules (which contain fosfomycin trometamol) can also continue to be used in men undergoing biopsy of the prostate. EMA asked companies for further data to justify the continued use of oral medicines containing fosfomycin trometamol and fosfomycin calcium.*

Humanarzneimittel - EU

•intramuscular fosfomycin and fosfomycin granules for children (2 g) should be suspended as there is no clear evidence that they are sufficiently effective for their currently authorised uses.” [...]

Published on: 18 - June - 2020

For more information, please refer to:

[Fosfomycin-containing medicinal products | European Medicines Agency](#)

International regulators stress value of safe and effective vaccines

“EMA has endorsed two statements about the importance, safety and effectiveness of vaccines published today by the International Coalition of Medicines Regulatory Authorities (ICMRA). International regulators from around the world have come together and jointly developed these statements for healthcare professionals and the general public to give assurance that the regulatory processes for the authorisation and safety monitoring of vaccines are robust, independent and focus firmly on public health.

The COVID-19 health emergency reminds us how important vaccines are to protect ourselves and our loved ones against infectious diseases,’ said Guido Rasi, Chair of ICMRA and EMA’s Executive Director. ‘In fact, vaccines are that one medical intervention that benefits not only those who receive it directly but also those who are too young, too old or too ill to be vaccinated themselves.” [...]

Published on: 18 - June - 2020

For more information, please refer to:

[International regulators stress value of safe and effective vaccines | European Medicines Agency](#)

Orphan Drugs und neuartige Therapierichtungen (ATMP)

CAT: Agendas, minutes and reports

Published on: 08 - June - 2020

For more information, please refer to:

[CAT: Agendas, minutes and reports | European Medicines Agency](#)

COMP: Agendas, minutes and meeting reports

Published on: 09 - June - 2020

For more information, please refer to:

[COMP: Agendas, minutes and meeting reports | European Medicines Agency](#)

Regulatory and procedural guideline: Procedural advice for orphan medicinal product designation: Guidance for sponsors (updated) - EMA/420706/2018 Rev 8¹

¹Mechanism of action

In examining an application for orphan medicinal product designation, the COMP will focus on determining whether the sponsor has established that the designation criteria are met, i.e.:

- the life-threatening or debilitating nature of the condition;
- the medical plausibility of the proposed orphan indication;
- that the prevalence of the condition in the European Union is not more than five in 10,000 or that it is unlikely that marketing the medicinal product in the European Union, without incentives, would generate sufficient return to justify the necessary investment;
- that no satisfactory method of diagnosis prevention or treatment exists, or if such a method exists, that the medicinal product will be of significant benefit to those affected by the condition.

The evaluation process has a maximum duration of 90 days without clock stops and cannot be lengthened to accommodate for the lack of data or other omissions in the application submitted by the sponsor. To assist in the development of a policy on orphan medicinal products, an expert network will be built up by the Committee, with expert(s) identified as appropriate to be involved in the evaluation of applications for orphan medicinal product designation.” [...]

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Published on: 19 - June - 2020

For more information, please refer to:

https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/procedural-advice-orphan-medicinal-product-designation-guidance-sponsors_en.pdf

Qualität – Quality

COMP: Agendas, minutes and meeting reports

“Update: Guidance is available for inspectors on how to initiate and conduct remote inspections to verify compliance with GCP standards during the COVID-19 pandemic:

- Guidance on remote GCP inspections during the COVID-19 pandemic

The guidance covers all phases of remote GCP inspections, with a particular focus on the more challenging aspects, such inspection initiation, feasibility assessment and preparation.

EMA published the guidance on 10 June 2020.” [...]

Published on: 11 - June - 2020

For more information, please refer to:

[Good clinical practice \(GCP\) inspection procedures | European Medicines Agency](#)

Medizinprodukte - Medical Device / Health technology assessment

No news available this week.

(Prä-) Klinische Forschung – Research and Development

No news available this week.

Kinderarzneimittel – Paediatrics

No news available this week.

Pflanzliche Arzneimittel – Herbal medicines

Aloysiae folium, Aloysiae folium, P: Draft published (updated)

Published on: 08 – June - 2020

For more information, please refer to:

[Aloysiae folium | European Medicines Agency](#)

Tormentillae rhizoma, Tormentillae rhizoma, F: Assessment finalised (updated)

Published on: 08 – June - 2020

For more information, please refer to:

[Tormentillae rhizoma | European Medicines Agency](#)

Solidaginis virgaureae herba, Solidaginis virgaureae herba, F: Assessment finalised

Published on: 08 – June - 2020

For more information, please refer to:

[Solidaginis virgaureae herba | European Medicines Agency](#)

Combination: Species amarae, Combination: Species amarae, P: Draft published

Published on: 08 – June - 2020

For more information, please refer to:

[Combination: Species amarae | European Medicines Agency](#)

Humanarzneimittel - EU

Combination: Species sedativae, Combination: Species sedativae, P: Draft published

Published on: 08 – June - 2020

For more information, please refer to:

[Combination: Species sedativae | European Medicines Agency](#)

Quercus cortex, Quercus cortex, F: Assessment finalised (updated)

Published on: 08 – June - 2020

For more information, please refer to:

[Quercus cortex | European Medicines Agency](#)

Herniariae herba, Herniariae herba, PF: Assessment close to finalisation (pre-final)

Published on: 08 – June - 2020

For more information, please refer to:

[Herniariae herba | European Medicines Agency](#)

HMPC: Agendas, minutes and meeting reports

Published on: 10 – June - 2020

For more information, please refer to:

[HMPC: Agendas, minutes and meeting reports | European Medicines Agency](#)

Quercus cortex, Quercus cortex, F: Assessment finalised (updated)

Published on: 08 – June - 2020

For more information, please refer to:

[Quercus cortex | European Medicines Agency](#)

EDQM

EDQM provides COVID-19 vaccine developers with free access to quality standards applicable in Europe

“The EDQM is committed to supporting vaccine developers during the coronavirus disease (COVID-19) pandemic – as well as contributing to the wider global effort to combat the virus – by openly sharing knowledge and offering temporary free access to relevant guidance and standards.

The EDQM and the Ph. Eur. have therefore decided to share Ph. Eur. quality standards for vaccines in order to support vaccine developers (many of which are universities and small and medium-sized enterprises) in designing appropriate analytical strategies for their candidate vaccines and to help ensure the quality and safety of the final product. Application of such quality requirements may ultimately help to facilitate regulatory acceptance of a subsequent marketing authorisation application.” [...]

Published on: 08 - June - 2020

For more information, please refer to:

[EDQM provides COVID-19 vaccine developers with free access to quality standards applicable in Europe | EDQM - European Directorate for the Quality of Medicines](#)

EDQM continues to support COVID-19 vaccine developers by providing selected training materials

“Further to the publication of the COVID-19 vaccine developers’ package of pharmacopoeial texts (see “EDQM provides COVID-19 vaccine developers with free access to quality standards applicable in Europe”), the EDQM has compiled a companion list of training materials on the European Pharmacopoeia (Ph. Eur.) and on Ph. Eur. texts related to vaccines.

Humanarzneimittel - EU

Drawn from selected presentations given earlier this year, the aim is to fast track understanding of the Ph. Eur. for COVID-19 vaccine developers, many of which are universities and small and medium-sized enterprises, and show them how to apply the relevant texts.” [...]

Published on: 11 - June - 2020

For more information, please refer to:

[EDQM continues to support COVID-19 vaccine developers by providing selected training materials | EDQM - European Directorate for the Quality of Medicines](#)

Certification Monthly Report of Activities: May 2020

Published on: 12 - June - 2020

For more information, please refer to:

[Certification Monthly Report of Activities: May 2020 | EDQM - European Directorate for the Quality of Medicines](#)

Oxygen 98%: Ph. Eur. receives valuable feedback on new oxygen quality

“The EDQM would like to warmly thank its stakeholders for their invaluable feedback and their commitment to the work of the European Pharmacopoeia (Ph. Eur.). About 40 different interested parties, including gas producers and industry associations, National Pharmacopoeia Authorities (NPAs), hospitals, consultants, dispensing pharmacists, healthcare establishments and manufacturers of oxygen generators commented on the news item entitled “Oxygen 98%: Ph. Eur. requests feedback on new oxygen quality to boost availability”, published on 16 April 2020, and on the corresponding draft monograph. This ground-level feedback was essential and helped the NPAs decide how best to proceed with the monograph on Oxygen (98 per cent) (3098). It was clear from the comments that co-operation between the national authorities, hospitals and gas producers was excellent during the COVID-19 crisis and that no oxygen shortages had occurred. The use of oxygen generators in this context appeared to be very limited.” [...]

Published on: 15 - June - 2020

For more information, please refer to:

[Oxygen 98%: Ph. Eur. receives valuable feedback on new oxygen quality | EDQM - European Directorate for the Quality of Medicines](#)

European Commission

Pharmaceutical Strategy: European Commission launches open public consultation

"[...] The Strategy aims to create a "future proof" system, which reaps the benefits of digitalisation and promotes innovation especially in areas of unmet needs, such as antimicrobials, medicines for children and medicines for rare diseases. It also intends to reduce the EU's dependency on imports from third-countries. A part of active pharmaceutical ingredients necessary for production of some generic medicines (including "old" antibiotics, oncologic medicines and the most basic medicines, such as paracetamol) comes from China and India." [...]

Published on: 16 - June - 2020

For more information, please refer to:

[Press corner | European Commission](#)

Pharmaceutical Strategy: European Commission launches open public consultation

Published on: 17 - June - 2020

For more information, please refer to:

[Press corner | European Commission](#)

UPDATE - List of active substances for which data has been submitted in accordance with Article 45 of the Paediatric Regulation

Published on: 08 – June - 2020

For more information, please refer to:

[Heads of Medicines Agencies: Article 45 and previous Worksharing](#)

UPDATE - End of pilot for splitting of MRP/DCPs

Published on: 08 – June - 2020

For more information, please refer to:

https://www.hma.eu/fileadmin/dateien/Human_Medicines/CMD_h_/Advice_from_CMDh/CMDh_354_2017_Rev7_05_2020_clean_-_Pilot_for_splitting.pdf

UPDATE - Q&As on Variations;

Published on: 08 – June - 2020

For more information, please refer to:

https://www.hma.eu/fileadmin/dateien/Human_Medicines/CMD_h_/Questions_Answers/CMDh_132_2009_Rev56_05_2020_clean_-_QA_on_Variations.pdf

NEW - Meeting with Interested Parties Presentations

Published on: 08 – June - 2020

For more information, please refer to:

[Heads of Medicines Agencies: Contacts with Representative Organisations](#)

NEW - Art.46 assessment report for Ciclosporin, Lisdexamfetamine dimesylate, Leuprorelin acetate, Mometasone furoate;

Published on: 08 - June - 2020

For more information, please refer to:

[Heads of Medicines Agencies: Article 46 work-sharing](#)

NEW - Art.45 assessment report for Clemastine;

Published on: 08 - June - 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/Clemastine_Art._45_PAR_05_2020.pdf

Humanarzneimittel - Deutschland

Gesetze und Verordnungen zur Änderung der AMVerkRV

Veröffentlicht am: 09 - Juni - 2020

Weitere Informationen finden Sie unter:

[BfArM - Apothekenpflicht - Gesetze und Verordnungen zur Änderung der AMVerkRV](#)

Coronavirus SARS-CoV-2

Veröffentlicht am: 12 - Juni - 2020

Weitere Informationen finden Sie unter:

[BfArM - Coronavirus SARS-CoV-2](#)

Bekanntmachung des Arzneibuchs

„Auflistung der zuletzt im Bundesanzeiger erschienenen Bekanntmachungen des Europäischen, Deutschen und Homöopathischen Arzneibuchs.“ [...]

Veröffentlicht am: 15 - Juni - 2020

Weitere Informationen finden Sie unter:

[BfArM - Bekanntmachungen](#)

Arzneibücher

„Das BfArM informiert über die Arzneibücher nach § 55 AMG. Ab dem Grundwerk zur 9. Ausgabe des Europäischen Arzneibuchs, Amtliche deutsche Ausgabe stehen

3 Anwendungsmöglichkeiten zur Verfügung: die Printversion, die Installation der DVD, die Registrierung und Anmeldung in der Online-Version.“ [...]

Veröffentlicht am: 02 - Juni - 2020

Weitere Informationen finden Sie unter:

[BfArM - Arzneibücher](#)

Versagungen und Rücknahmen von Zulassungsanträgen

Veröffentlicht am: 15 - Juni - 2020

Weitere Informationen finden Sie unter:

[BfArM - Statistiken - Arzneimittel - Versagungen und Rücknahmen von Zulassungsanträgen](#)

PSUR Single Assessment (PSUSA)

Veröffentlicht am: 18 - Juni - 2020

Weitere Informationen finden Sie unter:

[BfArM - PSUR Single Assessment \(PSUSA\)](#)

Paul-Ehrlich-Institut (PEI) - Beauftragtes Schulungsmaterial (Educational Material)

Veröffentlicht am: 18 - Juni - 2020

Weitere Informationen finden Sie unter:

[Paul-Ehrlich-Institut - Auflistung von genehmigtem Schulungsmaterial](#)

PEI Lieferengpässe von Human-Impfstoffen:

Veröffentlicht am: 18 - Juni - 2020

Weitere Informationen finden Sie unter:

[Paul-Ehrlich-Institut - Lieferengpässe](#)

Sicherheitsinformationen

Veröffentlicht am: 18. Juni - 2020

Weitere Informationen finden Sie unter:

[Paul-Ehrlich-Institut - Sicherheitsinformationen - Warnung vor dem Off-label-Einsatz von BCG-Präparaten](#)

Humanarzneimittel - Österreich

Datenbereitstellung Vertriebsbeschränkungen (ist ab Mitte Dezember 2020 verfügbar)

Datum der Information: 10 – Juni – 2020

Weitere Informationen finden Sie unter:

[Datenbereitstellung Vertriebsbeschränkungen \(ist ab Mitte Dezember 2020 verfügbar\) - BASG](#)

List von Arzneyspezialitäten, die über das Verfalldatum hinaus abgegeben werden dürfen

Datum der Information: 15 – Juni – 2020

Weitere Informationen finden Sie unter:

https://www.basg.gv.at/fileadmin/redakteure/Arzneimittel/Liste_von_Arzneispezialit%C3%A4ten_die_%C3%BCber_Verfalldatum_hinaus_abgegeben_werden_d%C3%BCrfen_15-06-2020.xlsx

Häufige Fragen - Rücknahme von Maßnahmen

Veröffentlicht am: 18 – Juni – 2020

Weitere Informationen finden Sie unter:

[Häufige Fragen - BASG](#)

Zur Stellungnahme - Monographieentwürfe vom 18.06.2020; Stellungnahmen sind bis 31.08.2020 erbeten

Veröffentlicht am: 18 - Juni – 2020

Weitere Informationen finden Sie unter:

[Zur Stellungnahme - BASG](#)

Kontakt

Veröffentlicht am: 18 - Juni – 2020

Weitere Informationen finden Sie unter:

[Kontakt - BASG](#)

Humanarzneimittel - Schweiz

Swissmedic Journal

„Auszug aus dem Inhaltsverzeichnis:

- Zulassung eines Arzneimittels mit neuem Wirkstoff: Zebinix®, Tabletten
- Zulassung eines Arzneimittels mit neuem Wirkstoff: Tukysa™, Filmtabletten (Tucatinibum)
- Zulassung eines Arzneimittels mit neuem Wirkstoff: Quofenix®, Tabletten (Delafloxacinum)
- Zulassung eines Arzneimittels mit neuem Wirkstoff: Libtayo®, Konzentrat zur Herstellung einer Infusionslösung (Cemiplimabum)
- Zulassung eines Arzneimittels mit neuem Wirkstoff: Vitrakvi®, Kapseln (Larotrectinibum)
- Zulassung eines Arzneimittels mit neuem Wirkstoff: Triogen, Kapseln (Trientindihydrochloridum)
- Anpassung der Wegleitung Arzneimittelinformation für Humanarzneimittel HMV4
- Anforderungen an Kombinationsprodukte (Arzneimittel mit einer Medizinproduktkomponente) – Verlängerung der Übergangsfrist
- Informationen aus der Rubrik "Arzneimittel Statistik" [...]

Veröffentlicht am: 08 - Juni – 2020

Weitere Informationen finden Sie unter:

[Swissmedic Journal](#)

Impfstoffe gegen COVID-19

„Das European Directorate for the Quality of Medicines & HealthCare (EDQM) engagiert sich für die Unterstützung der Impfstoffentwickler während der Coronavirus-Pandemie (COVID-19) und trägt zu den umfassenderen weltweiten Bemühungen zur Bekämpfung des Virus bei, indem es offen sein Wissen weitergibt und vorübergehend freien Zugang zu den einschlägigen Normen und Leitlinien gewährt.“ [...]

Veröffentlicht am: 09 - Juni – 2020

Weitere Informationen finden Sie unter:

[Impfstoffe gegen COVID-19](#)

Out-of-Stock – COVID-19 – Bewilligungen zum befristeten Import und Vertrieb von Humanarzneimitteln – Update

„Der Bundesrat hat in der Verordnung 2 über Massnahmen zur Bekämpfung des Coronavirus (Covid-19-Verordnung 2, SR 818.101.24) Bestimmungen zur Sicherstellung der Versorgung mit wichtigen medizinischen Gütern erlassen. Gestützt auf Art. 4m Abs. 3 dieser Verordnung kann Swissmedic, zur Überbrückung einer temporären Nichtverfügbarkeit eines zugelassenen Arzneimittels, den Import von im Wesentlichen gleichen Arzneimitteln genehmigen.“ [...]

Veröffentlicht am: 17 - Juni – 2020

Weitere Informationen finden Sie unter:

[Out-of-Stock – COVID-19 – Bewilligungen zum befristeten Import und Vertrieb von Humanarzneimitteln – Update](#)

COVID-19-Pandemie: Erklärung internationaler Arzneimittelbehörden zu Impfstoffen

„Die Mitglieder der «International Coalition of Medicines Regulatory Authorities» (ICMRA, internationale Koalition von Arzneimittelbehörden) haben eine gemeinsame Erklärung zur Sicherheit und Wirksamkeit von Impfstoffen veröffentlicht.“ [...]

Veröffentlicht am: 28 - Mai – 2020

Weitere Informationen finden Sie unter:

[COVID-19-Pandemie: Erklärung internationaler Arzneimittelbehörden zu Impfstoffen](#)

Swissmedic Geschäftsbericht 2019

Veröffentlicht am: 19 - Juni – 2020

Weitere Informationen finden Sie unter:

[Swissmedic Geschäftsbericht 2019](#)

Aktualisierte Dokumente

Veröffentlicht am: 19 - Juni – 2020

Weitere Informationen finden Sie unter:

[Juni 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. *

I would like to double-check a general question concerning the use of a superseded CEP version in the manufacture of an FDF.

In the case that according to the EDQM database the current valid version of the CEP for a certain API is let's say R1 Rev 02 (e.g. since 01.10.2019) but the API manufacturer has still today API batches on stock manufactured and released before 01.10.2019 according to R1 Rev 01 – is it ok to provide the FDF manufacturer (e.g.) in June 2020 with API manufactured and released according to R1 Rev 01? (Premise: The reason for the CEP update from Rev 01 to Rev 02 was NOT a non-compliance of an intermediate manufacturing site and the retest period is stated in both CEPs versions (e.g. 36 months)).

My understanding according to the Question and Answers 2.4 <https://www.ema.europa.eu/en/human-regulatory/post-authorisation/classification-changes-questions-answers> is: only the versions of the CEP (i.e. updated certificates) which were used in the manufacturing process of a batch of finished product need to be included in the dossier. So the FDF manufacturer could use for the FDF manufacturing in June 2020, API manufactured and released according to R1 Rev 01, EVEN if since 01.10.2019 R1 Rev 02 is valid. Once the FDF manufacturer would receive and use API manufactured and released according to R1 Rev 02, the MA Holder should present a variation Type IA (provided the conditions are met!) within 1 year of the implementation of R1 Rev 02 at the FDF end (=use of API R1 Rev 02 in FDF manufacturing). Is my understanding correct?

But there seems to be a GREY AREA about how long the MAH is allowed to take before implementing a revised CEP.

In other words, it is clear that the MAH has a year to submit their IA type variation in case of a revised CEP. But how long do they have between validity date of a new CEP version and implementation at their end?

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.

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.



UMFRAGE ZUR AKTUELLEN LAGE COVID-19

Erste Rückmeldungen

Wir würden uns über weitere Zuschriften freuen, bitte senden Sie diese an info-as@megra.org.

Österreich

Es ist mir ein Bedürfnis, mich an dieser Umfrage zu beteiligen, weil ich der österreichischen Behörde ein absolut großes Lob aussprechen möchte.

Egal mit welchem Anliegen man in der Covid-19 Zeit gekommen ist – Lieferunfähigkeiten – nicht im Land zugelassene Ersatzprodukte – Ausnahmeregelungen für Nicht-zulassungskonforme Freigaben oder auch beschleunigte EU Zulassungsverfahren (2nd wave mit AT als RMS -diesbezüglich habe ich von unserer globalen Zulassungsabteilung großes Lob gehört), die Erreichbarkeit und Lösungskompetenz der Behörde war einzigartig! Jedes Problem wurde schnellstens intern besprochen und evaluiert und die Rückmeldung kam ohne Verzögerung. Ebenso war die telefonische Erreichbarkeit großartig.

Ich kann der österreichischen Behörde nur danken für die schnelle und pragmatische Unterstützung der Industrie und damit der Sicherstellung der Arzneimittelversorgung in dieser Krise.

Aber auch in „normalen“ Zeiten ist die Kommunikationsmöglichkeit mit dem BASG ausgezeichnet und ermöglicht ein reibungsloses Zusammenarbeiten zwischen Industrie und Behörde.

Deutschland

Unsere Firma als Großhändler von Arzneimittel für den Critical Care Bereich hat in diesen schwierigen Zeiten alle Hände voll zu tun. Die ganze Mannschaft in Europa, und teilweise auch die Kollegen in dem USA und Indien, geben alles, damit der deutsche Markt bestmöglich mit unseren Produkten versorgt wird. Wir erleben tagtäglich Supply Chain Herausforderungen und ich persönlich bin erstaunt, dass es trotz größten Schwierigkeiten die Ware heil ankommt und ich sie freigeben kann. Unsere Behörden, in diesem Fall die ROB, das BfArM und die BOPST, arbeiten eng und offen mit uns zusammen. Wir ziehen alle an einem Strang, im Rahmen dessen, was die Regularien erlauben, damit die Covid-19 Beatmungspatienten bestmöglich versorgt sind.

Als Verantwortlichen Person würde ich mir wünschen, dass meine Arbeit aus dem Home Office nicht nur während der Ausgangsbeschränkungen von der ROB geduldet wurde. Meiner Meinung nach sollte die Behörde, so wie mein Arbeitgeber es tut, viel mehr mich dazu ermutigen zu Hause zu bleiben. Das Ziel muss es sein, dass ich keinen unnötigen Ansteckungsgefahren ausgesetzt bin, gesund bleibe und meine Arbeit machen kann. Dabei sollten wir berücksichtigen, dass die Firma keine Lagerhaltung führt, meine Arbeit kann ich zu 100% aus dem Home Office erledigen.

Herzlichen Dank an unsere Mitglieder für die Beiträge.

Wenn Sie nicht möchten, dass Ihr Beitrag mit Namen veröffentlicht werden soll, lassen Sie dies uns wissen und wir werden Ihren Beitrag anonymisiert veröffentlichen.

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 \(IPES\)](#)

Österreich

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/>

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

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](#)

From data to evidence in medicines regulation

Update: In the context of the escalating situation with the COVID-19 outbreak, this conference is postponed to later in 2020, from 22/04/2020 to 07/09/2020.

Ort: European Medicines Agency, Amsterdam, The Netherlands,

From: 07/09/2020 to 07/09/2020

Weitere Informationen finden Sie unter:

[From data to evidence in medicines regulation | European Medicines Agency](#)