

27. April – 08.
Mai 2020



HUMANARZNEIMITTEL - EU	2
<i>Allgemeines – General</i>	2
<i>Pharmakovigilanz – PRAC</i>	2
<i>Zulassung – Regulatory Affairs</i>	3
<i>Orphan Drugs und neuartige Therapierichtungen (ATMP)</i>	6
<i>Qualität – Quality</i>	7
<i>Medizinprodukte - Medical Device / Health technology assessment</i>	7
<i>(Prä-) Klinische Forschung – Research and Development</i>	7
<i>Kinderarzneimittel – Paediatrics</i>	8
<i>Pflanzliche Arzneimittel – Herbal medicines</i>	9
<i>EDQM</i>	9
EUROPEAN COMMISSION	11
CMDH	12
HUMANARZNEIMITTEL - DEUTSCHLAND	13
HUMANARZNEIMITTEL - ÖSTERREICH	15
HUMANARZNEIMITTEL - SCHWEIZ	16
 FRAGEN AN DAS NETZWERK	19
VERANSTALTUNGEN / EVENTS – BEHÖRDEN UND ANDERE VERANSTALTER	20
DEUTSCHLAND	20
ÖSTERREICH	20
SCHWEIZ	20
EUROPA	20
<u>Urheberrechtshinweis:</u>	

Der MEGRA Newsletter und die darin enthaltenen Beiträge sind urheberrechtlich geschützt. Ohne die ausdrückliche Genehmigung der Urheber oder der Inhaber der Nutzungsrechte darf weder der MEGRA Newsletter noch Teile davon verbreitet, bearbeitet, öffentlich zugänglich, vorgetragen, in einem Abrufsystem gespeichert oder in ein solches eingeführt oder in einer beliebigen anderen Form (elektronisch, mechanisch, per Hyperlink, per Fotokopie, per Aufzeichnung oder auf anderem Wege) oder zu einem beliebigen anderen Zweck vervielfältigt oder übermittelt werden. Downloads und Kopien des Newsletters sind nur Mitgliedern der *Mittel Europäischen Gesellschaft für Regulatory Affairs e.V. (MEGRA)* und für den privaten, nicht kommerziellen Gebrauch gestattet. Durch das Herunterladen oder Kopieren von Inhalten werden keine Rechte bezüglich der Inhalte übertragen.

Allgemeines – General

COVID-19: What's new (updated)

Published on: 08 -May - 2020

For more information, please refer to:

[COVID-19: What's new | European Medicines Agency](#)

EMA-EUnetHTA work plan 2017-2021 (updated)

Published on: 05 - May - 2020

For more information, please refer to:

https://www.ema.europa.eu/en/documents/other/ema-eunethhta-work-plan-2017-2021_en.pdf

News bulletin for small and medium-sized enterprises - Issue 49 (new)

Published on: 07 - May - 2020

For more information, please refer to:

https://www.ema.europa.eu/en/documents/newsletter/news-bulletin-small-medium-sized-enterprises-issue-49_en.pdf

Pharmakovigilanz – PRAC

List of medicines under additional monitoring (updated)

“Update - Summary of changes in April 2020:

The following CAP has been added to the list:

- Liumjev (insulin lispro) - New biological.
- Nilemdo (bempedoic acid) - New active substance.
- NUBEQA (darolutamide) - New active substance.
- Nustendi (bempedoic acid / ezetimibe) - New active substance.
- Rybelsus (semaglutide) - New biological.
- Staquis (crisaborole) - New active substance.
- Ruxience (rituximab) - New biological.

The following CAPs has been removed from the list:

- Keytruda (pembrolizumab) - Five years following its authorisation (July 2015), Keytruda no longer qualifies for additional monitoring as a new active substance and therefore is removed from this list.
- Synjardy (empagliflozin/metformin) - Five years following its authorisation (June 2015), Synjardy no longer qualifies for additional monitoring as a new active substance and therefore is removed from this list.
- Evotaz (atazanavir/cobicistat) - Five years following its authorisation (July 2015), Evotaz no longer qualifies for additional monitoring as a new active substance and therefore is removed from this list.
- Repatha (evolocumab) - Five years following its authorisation (Sep 2015), Repatha no longer qualifies for additional monitoring as a new active substance and therefore is removed from this list.
- Respreeza (Human alpha1-proteinase inhibitor) - Five years following its authorisation (Sep 2015), Respreeza no longer qualifies for additional monitoring as a new active substance and therefore is removed from this list.
- Zerbaxa (Ceftolozane / tazobactam) - Five years following its authorisation (Sep 2015), Zerbaxa no longer qualifies for additional monitoring as a new active substance and therefore is removed from this list.” [...]

Published on: 29 - April - 2020

For more information, please refer to:

[List of medicines under additional monitoring | European Medicines Agency](#)

Humanarzneimittel - EU

Pharmacovigilance inspection procedures: human (updated)

Published on: 30 - April - 2020

For more information, please refer to:

[Pharmacovigilance inspection procedures: human | European Medicines Agency](#)

Guideline on good pharmacovigilance practices (GVP): Module VII – Periodic safety update report - Explanatory note (updated) - EMA/670256/2017 Rev. 2

Published on: 05 - May - 2020

For more information, please refer to:

https://www.ema.europa.eu/en/documents/scientific-guideline/guideline-good-pharmacovigilance-practices-gvp-module-vii-periodic-safety-update-report-explanatory_en.pdf

Zulassung – Regulatory Affairs

Frequently asked questions about parallel distribution (updated)

Published on: 28 - April - 2020

For more information, please refer to:

[Frequently asked questions about parallel distribution | European Medicines Agency](#)

Referrals document: Assessment report for Article-5(3) procedure: direct oral anticoagulants (DOACs) (new) - EMA/194375/2020

“On 14 January 2019 the Executive Director triggered a procedure under Article 5(3) of Regulation (EC) No 726/2004, and asked the CHMP to assess the impact of a study on direct oral anti-coagulants (DOACs) that was funded by EMA and conducted by a consortium of research centres led by University of Utrecht. More specifically the CHMP was called to assess the study results and whether those have any clinical implications and to give its scientific opinion if changes to the current conditions of use of these products and/or optimisation of the risk minimisation measures should be recommended.” [...]

Published on: 28 - April - 2020

For more information, please refer to:

[Guidance for medicine developers and companies on COVID-19 | European Medicines Agency](#)

International Coalition of Medicines Regulatory Authorities (ICMRA) (updated)

“Update: On 28 April 2020, ICMRA members committed to strengthening global collaborative efforts in order to facilitate the rapid development, approval and global roll-out of safe and effective medicines to prevent and treat COVID-19. The efforts focus in particular on increasing the efficiency of regulatory processes and decision-making:

ICMRA statement on COVID-19: International regulators pledge collective support to combat COVID-19

The ICMRA members also recommend that:

- governments and the international research community should prioritise large, well-designed, controlled clinical trials. Such trials are most likely to generate the conclusive evidence that developers and regulators need to enable the rapid development and approval of potential COVID-19 treatments;
- a global approach should be developed to achieve equitable access around the world to treatments and vaccines against COVID-19;
- pharmaceutical industry should work cooperatively in addressing medicine supply issues, shortages and decreased manufacturing capacities.” [...]

Published on: 28 – April - 2020

For more information, please refer to:

[International Coalition of Medicines Regulatory Authorities \(ICMRA\) | European Medicines Agency](#)

Humanarzneimittel - EU

Guidance for medicine developers and companies on COVID-19 (updated)

“Update: An update to this guidance on 28 April 2020 provided additional flexibility and clarification on:

- the distribution of medicines to trial participants. This takes into account social-distancing measures and possible limitations in trial site and hospital resources;
- the remote verification of source data (SDV) in the context of social distancing measures. This aims to facilitate activities that support the approval of COVID-19 and other life-saving medicines;
- notifying authorities of urgent actions taken to protect trial participants against an immediate hazard, or of other changes taken to support patient safety or data robustness.

For more information on the changes introduced by this update, see the press release published by the European Commission:

- European Commission: Coronavirus: Commission issues guidance to mitigate clinical trial disruption in the EU” [...]

Published on: 28 - April - 2020

For more information, please refer to

[Guidance for medicine developers and companies on COVID-19 | European Medicines Agency](#)

Medicinal products for human use: monthly figures - March 2020 (new) - EMA/221650/2020

Published on: 23 - April - 2020

For more information, please refer to

https://www.ema.europa.eu/en/documents/report/medicinal-products-human-use-monthly-figures-march-2020_en.pdf

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, Gynofostrom e, Infectofos, Infeur Adulti, Interfos, Monural, Monuril, Monurol, Rapidnorm, Solufos, Symural, Uridoz, Urif os, Urinex, Urofast, Uromaste, Uroseptic, Article 31 referrals, Opinion provided by Committee for Medicinal Products for Human Use, 26/03/2020, 29/04/2020 (updated)

“current status: Opinion provided by Committee for Medicinal Products for Human Use” [...]

Published on: 29 - April - 2020

For more information, please refer to:

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

Referral: Ulipristal acetate 5mg medicinal products, Ulipristal acetate, Article 31 referrals, Under evaluation, 29/04/2020 (updated)

“On 12 March 2020, EMA’s safety committee (PRAC) recommended women to stop taking 5-mg ulipristal acetate (Esmya and generic medicines) for uterine fibroids while a safety review is ongoing. No new patients should start treatment with the medicines, which will be temporarily suspended throughout the EU during the review.

EMA is starting its review at the request of the European Commission following a recent case of liver injury, which led to liver transplantation in a patient taking the medicine.” [...]

Published on: 29 - April - 2020

For more information, please refer to:

[Ulipristal acetate 5mg medicinal products | European Medicines Agency](#)

Good distribution practice (updated)

“Regulatory expectations during COVID-19 pandemic (new)

Humanarzneimittel - EU

Guidance is available for marketing authorisation holders, manufacturers and importers of human medicines on adaptations to the regulatory framework to address challenges of the COVID-19 pandemic, including with GDP certificates and inspections:

- Notice to stakeholders: questions and answers on regulatory expectations for medicinal products for human use during the COVID-19 pandemic,

In this context, GDP certificates and time-limited wholesale authorisations are automatically extended until the end of 2021.

This does not waive distributors' and wholesalers' obligations to comply with GDP standards.

National competent authorities may launch inspections (including distant assessment) at any time if required. On-site inspections will resume as soon as COVID-19 restrictions are lifted.

The guidance was agreed by the GMP/GDP Inspectors Working Group coordinated by EMA, the European Commission, the European medicines regulatory network and endorsed by the EU Executive Steering Group on Shortages of Medicines Caused by Major Events. It is updated as the pandemic develops.

For more information, see: *Guidance for medicine developers and companies on COVID-19: Regulatory expectations and flexibility [...]*

Published on: 29 - April - 2020

For more information, please refer to:

[Good distribution practice | European Medicines Agency](#)

Good manufacturing practice (updated)

“Regulatory expectations during COVID-19 pandemic (new)

Guidance is available for marketing authorisation holders, manufacturers and importers of human medicines on adaptations to the regulatory framework to address challenges of the COVID-19 pandemic, including with GMP certificates and inspections:

- Notice to stakeholders: Questions and answers on regulatory expectations for medicinal products for human use during the COVID-19 pandemic.

In this context, for sites in the European Economic Area (EEA), GMP certificates and time-limited manufacturing and import authorisations are automatically extended until the end of 2021.

This does not waive manufacturers' and importers' obligations to comply with GMP standards.

For new sites and facilities within and outside the EEA that have not been inspected or where an inspection is required, a distant assessment may be carried out. On-site inspections will resume as soon as feasible.

The guidance was agreed by the GMP/GDP Inspectors Working Group coordinated by EMA, the European Commission, the European medicines regulatory network and endorsed by the EU Executive Steering Group on Shortages of Medicines Caused by Major Events. It is updated as the pandemic develops.

For more information, see: *Guidance for medicine developers and companies on COVID-19: Regulatory expectations and flexibility.” [...]*

Published on: 29 - April - 2020

For more information, please refer to:

[Good manufacturing practice | European Medicines Agency](#)

Periodic safety update reports (PSURs) (updated)

Published on: 07 - May - 2020

For more information, please refer to:

[Periodic safety update reports \(PSURs\) | European Medicines Agency](#)

Recommendations on eligibility to PRIME scheme - Adopted at the CHMP meeting of 28-30 April 2020 (new) - EMA/65740/2020

Humanarzneimittel - EU

Published on: 08 - May - 2020

For more information, please refer to:

[Periodic safety update reports \(PSURs\) | European Medicines Agency](#)

List of products granted eligibility to PRIME (updated)

Published on: 08 - May - 2020

For more information, please refer to:

https://www.ema.europa.eu/en/documents/report/list-products-granted-eligibility-prime_en-0.xlsx

Orphan Drugs und neuartige Therapierichtungen (ATMP)

Advanced therapy medicinal products: Overview (updated)

“Update: In April 2020, EMA’s Committee for Advanced Therapies (CAT) advised patients and the general public to beware of unproven cell-based therapies.

This followed the appearance of advertisements for cell therapies as cures for serious conditions across the European Union in early 2020.

In its statement, the CAT warned against the use of unregulated cell-based therapies, which may be ineffective and increase the risk of serious adverse reactions.

- *EMA warns against using unproven cell-based therapies (28/04/2020)*

Healthcare providers should explain the benefits and risks of the cell-based therapies that they are providing to patients, as well as confirming that regulatory authorities have approved their use.

Anyone with doubts can contact EMA or their national competent authority.

The CAT’s statement replaces a statement it issued in 2010 following reports of unregulated stem-cell therapies being offered to patients.” [...]

Published on: 28 - April - 2020

For more information, please refer to:

[Advanced therapy medicinal products: Overview | European Medicines Agency](#)

Changing the name or address of a sponsor (updated)

“Update: To update only the sponsor’s telephone number or email address appearing on the public summary of orphan designation on EMA’s corporate website (under ‘Sponsor’s contact details’), sponsors should simply contact the EMA Service Desk providing the updated details.

Updating the contact person in IRIS

The IRIS platform allows an applicant (with the role of “IRIS Industry Manager” for a submission) to change the contact person assigned to an ongoing case. This is the person who will receive all EMA communications, and needs to have an “IRIS Industry Manager” role for that submission. As an alternative, applicants may wish to set up an auto-forwarding rule on the email account of the contact person, so that IRIS emails are redirected to another recipient(s).

If an IRIS contact person, manager or contributor for any submission leaves their function or the organisation, an “IRIS Industry Admin” user should consider removing his/her affiliation to the OMS organisation in EMA’s Account Management portal, otherwise the EMA account of that user will still be usable to modify applications on behalf of the affiliated organisation.

For more information about EMA accounts and affiliation, see the IRIS Quick Guide to Registration or contact EMA Service de” [...]

Published on: 29 - April - 2020

For more information, please refer to:

[Changing the name or address of a sponsor | European Medicines Agency](#)

Qualität – Quality

ICH Q3C (R6) Residual solvents (updated)

Published on: 04 - May - 2020

For more information, please refer to:

[ICH Q3C \(R6\) Residual solvents | European Medicines Agency](#)

Dasatinib product-specific bioequivalence guidance (updated)

Published on: 05 - May - 2020

For more information, please refer to:

[Dasatinib product-specific bioequivalence guidance | European Medicines Agency](#)

Clinical pharmacology and pharmacokinetics: questions and answers (updated)

Published on: 06 - May - 2020

For more information, please refer to:

[Clinical pharmacology and pharmacokinetics: questions and answers | European Medicines Agency](#)

Medizinprodukte - Medical Device / Health technology assessment

Medical devices (updated)

“Update: On 23 April 2020, the European Parliament and the Council of the EU adopted a proposal to extend the transitional period of the Medical Devices Regulation by one year - until 26 May 2021. This measure aims to avoid shortages of medical devices during the ongoing COVID-19 pandemic due to the limited capacity of national competent authorities or notified bodies to implement the Regulation.

EMA will update its regulatory guidance in June 2020 to reflect the new date of application of the Regulation.

For more information, see:

•Regulation (EU) 2020/561 of the European Parliament and of the Council of 23 April 2020 amending Regulation (EU) 2017/745 on medical devices, as regards the dates of application of certain of its provisions.” [...]

Published on: 06 - May - 2020

For more information, please refer to:

[Medical devices | European Medicines Agency](#)

(Prä-) Klinische Forschung – Research and Development

Good clinical practice (updated)

“Update: An update to this guidance on 28 April 2020 provided additional flexibility and clarification on:

- the distribution of medicines to trial participants. This takes into account social-distancing measures and possible limitations in trial site and hospital resources;
- the remote verification of source data (SDV) in the context of social distancing measures. This aims to facilitate activities that support the approval of COVID-19 and other life-saving medicines;
- notifying authorities of urgent actions taken to protect trial participants against an immediate hazard, or of other changes taken to support patient safety or data robustness.

For more information on the changes introduced by this update, see the press release published by the European Commission:

European Commission: Coronavirus: Commission issues guidance to mitigate clinical trial disruption in the EU.” [...]

Published on: 28 - April - 2020

Humanarzneimittel - EU

For more information, please refer to:

[Good clinical practice | European Medicines Agency](#)

Guidance for medicine developers and companies on COVID-19 (updated)

“Update: Guidance is available for developers of potential COVID-19 treatments and vaccines on the rapid review procedures EMA has put in place to speed up development and approval:

- EMA initiatives for acceleration of development support and evaluation procedures for COVID-19 treatments and vaccines

These rapid procedures can accelerate every step of the regulatory pathway while ensuring that robust evidence on efficacy, safety and quality is generated to support scientific and regulatory decisions.

They are available for initial marketing authorisation applications and extension applications for authorised medicines that are being repurposed for the treatment of COVID-19.” [...]

Published on: 04 - May - 2020

For more information, please refer to:

[Guidance for medicine developers and companies on COVID-19 | European Medicines Agency](#)

Kinderarzneimittel – Paediatrics

PDCO monthly report of opinions on paediatric investigation plans and other activities 24-27 March 2020 (new) - EMA/175935/2020

Published on: 28 - April – 2020

For more information, please refer to:

https://www.ema.europa.eu/en/documents/committee-report/pdco-monthly-report-opinions-paediatric-investigation-plans-other-activities-24-27-march-2020_en.pdf

Paediatric investigation plans (updated)

“Update: EMA will review applications for agreement of a PIP, deferrals or waivers for treatments and vaccines for COVID-19 in an expedited manner, in order to speed up these products' development and approval.

The compliance check can also be expedited, if necessary.

For COVID-19 products:

- there are no pre-specified PIP submission deadlines;
- review of a PIP is reduced to a minimum of 20 days (from 120 days). Exact timeline depends on complexity of PIP and the preparedness by the sponsor to respond to questions;
- EMA decision following a review is reduced to 2 days (from 10 days);
- there is a possibility for the developer to provide a focused scientific documentation, agreed on a case-by-case basis;
- compliance check can be reduced to 4 days.

For more information, see:

- [Guidance for medicine developers and companies on COVID-19: Accelerated procedures for COVID-19 treatments and vaccines](#)
- [EMA initiatives for acceleration of development support and evaluation procedures for COVID-19 treatments and vaccines.](#) [...]

Published on: 05 - May – 2020

For more information, please refer to:

[Paediatric investigation plans | European Medicines Agency](#)

Pflanzliche Arzneimittel – Herbal medicines

Allii sativi bulbus, Allii sativi bulbus, F: Assessment finalised (updated)

Published on: 28 - April - 2020

For more information, please refer to:

[Allii sativi bulbus | European Medicines Agency](#)

Pistacia lentiscus, resinum (mastic), Pistacia lentiscus, resinum (mastic), F: Assessment finalised (updated))

Published on: 05 - May - 2020

For more information, please refer to:

[Pistacia lentiscus, resinum \(mastic\) | European Medicines Agency](#)

EDQM

Pharmacopoeial Discussion Group videoconference meeting

“The Pharmacopoeial Discussion Group (PDG) held its interim videoconference on Thursday 12 March 2020. The PDG – which brings together the European Pharmacopoeia (Ph. Eur.), the Japanese Pharmacopoeia (JP) and the United States Pharmacopoeia (USP), with WHO (International Pharmacopoeia) as Observer, to discuss international harmonisation of quality standards – has now completed work on 28 of the 31 general chapters and 46 of the 60 excipient monographs on its current work programme.

The primary focus of the videoconference was to finalise a proposal to send to ICH regarding maintenance of the ICH Q4B Annexes.” [...]

Published on: 28 – April - 2020

For more information, please refer to:

[Pharmacopoeial Discussion Group videoconference meeting | EDQM - European Directorate for the Quality of Medicines](#)

EDQM webinar: tissue donation from deceased donors during the COVID-19 pandemic

“Maintaining a safe, sufficient and accessible supply of critical and essential tissues for human application during a pandemic is of vital importance to public health systems that support donation and transplantation. With this in mind, the EDQM organised a webinar for the tissue donation and transplantation communities on 28 April 2020 to discuss how the COVID-19 pandemic is affecting national programmes for tissue donation from deceased donors and daily practice in tissue establishments, and to support forward-looking decisions.” [...]

Published on: 30 – April - 2020

For more information, please refer to:

[EDQM webinar: tissue donation from deceased donors during the COVID-19 pandemic | EDQM - European Directorate for the Quality of Medicines](#)

New and improved WebStore for EDQM Reference Standards

Published on: 15 – April - 2020

For more information, please refer to:

[New and improved WebStore for EDQM Reference Standards | EDQM - European Directorate for the Quality of Medicines](#)

Outcome of the 166th session European Pharmacopoeia Commission

“By mid-March this year, announcements regarding the postponement or cancellation of meetings due to the COVID-19 pandemic had been made and an almost global lockdown was underway.

Humanarzneimittel - EU

In this unprecedented context, the European Pharmacopoeia (Ph. Eur.) Commission and its 60 groups of experts and working parties, with the support of the national pharmacopoeia authorities and the EDQM, demonstrated their commitment to public health protection by adapting their traditional method of working to the new situation and constraints. Thanks to their efforts, the work of the Ph. Eur. continues to be assured.” [...]

Published on: 06 –May - 2020

For more information, please refer to:

[Outcome of the 166th session European Pharmacopoeia Commission | EDQM - European Directorate for the Quality of Medicines](#)

The EDQM’s contributions to the protection of public health in the COVID-19 pandemic: latest information

“The EDQM’s core activities include the provision of documentary and physical (reference) standards to ensure the quality of medicines and their ingredients. Availability of and access for patients to quality medicines is more important than ever in the context of the current COVID-19 pandemic.” [...]

Published on: 06 - May - 2020

For more information, please refer to:

[The EDQM’s contributions to the protection of public health in the COVID-19 pandemic: latest information | EDQM - European Directorate for the Quality of Medicines](#)

9 new reference standards and 18 replacement batches released in April 2020

Published on: 06 - May - 2020

For more information, please refer to:

[9 new reference standards and 18 replacement batches released in April 2020 | EDQM - European Directorate for the Quality of Medicines](#)

European Commission

Updated - Guidance on the management of clinical trials during the COVID-19 (coronavirus) pandemic

Published on: 28 - April - 2020

For more information, please refer to:

https://ec.europa.eu/health/sites/health/files/files/eudralex/vol-10/guidanceclinicaltrials_covid19_en.pdf

Coronavirus: Commission issues guidance to mitigate clinical trial disruption in the EU

Published on: 28 – April - 2020

For more information, please refer to:

[Press corner | European Commission](#)

First ECDC update - Coronavirus disease 2019 (COVID-19) and supply of substances of human origin in the EU/EEA

Published on: 29 – April - 2020

For more information, please refer to:

[Coronavirus disease 2019 \(COVID-19\) and supply of substances of human origin in the EU/EEA - First update](#)

NEW - March 2020 CMDh Minutes

Published on: 04 - May - 2020

For more information, please refer to:

https://www.hma.eu/fileadmin/dateien/Human_Medicines/CMD_h_/Agendas_and_Minutes/Minutes/2020_03_CMDh_Minutes.pdf

NEW - Report from the meeting held on 28-29 April 2020 - EMA/CMDh/70731/2020

Published on: 06 - May - 2020

For more information, please refer to:

https://www.hma.eu/fileadmin/dateien/Human_Medicines/CMD_h_/cmdh_pressreleases/2020/04_2020_CMDh_Press_release.pdf

UPDATE - List of safety concerns per approved Risk Management Plan (RMP) of active substances per product

Published on: 08 - May - 2020

For more information, please refer to:

https://www.hma.eu/fileadmin/dateien/Human_Medicines/CMD_h_/Pharmacovigilance_Legislation/RMPs/CMDh_330_2015_Rev25_2020_05.xlsx

UPDATE - updated HaRP assessment report for vinorelbine

Published on: 08 - May - 2020

For more information, please refer to:

https://www.hma.eu/fileadmin/dateien/Human_Medicines/CMD_h_/Pharmacovigilance_Legislation/RMPs/HaRP_ARs/Vinorelbine_04_2020_HaRP_AR.pdf

NEW - HaRP assessment reports for aciclovir; cineolium; diazepam; dienogest_ ethinylestradiol; diosminium; doxazosin; ethosuximide; fexofenadine; gemcitabine; meropenem; thiamazole; trospium chloride; zolpidem

Published on: 08 - May - 2020

For more information, please refer to:

[Heads of Medicines Agencies: HaRP Assessment Reports](#)

Humanarzneimittel - Deutschland

Klinische Prüfungen während der COVID-19 Pandemie

„Hinweise zur Genehmigung und Durchführung klinischer Arzneimittelprüfungen während der COVID-19 Pandemie (Version 2.2)“ [...]

Veröffentlicht am: 28 - April - 2020

Weitere Informationen finden Sie unter:

[BfArM - Klinische Prüfung - Klinische Prüfungen während der COVID-19 Pandemie](#)

Vereinfachte Prüfmöglichkeit für medizinische Gesichtsmasken für Anträge auf Sonderzulassung

„Vereinfachte Prüfmöglichkeit für medizinische Gesichtsmasken für Anträge auf Sonderzulassung gemäß § 11 Abs. 1 des Medizinproduktegesetzes bzw. ab 26.05.2020 gemäß Art. 59 der Verordnung (EU) 2017/745 im Zusammenhang mit der SARS-CoV-2-Pandemie.“ [...]

Veröffentlicht am: 29 - April - 2020

Weitere Informationen finden Sie unter:

[BfArM - Empfehlungen des BfArM - Vereinfachte Prüfmöglichkeit für medizinische Gesichtsmasken für Anträge auf Sonderzulassung](#)

Prozedurale Hinweise zu Zulassungsverfahren während der COVID-19 Pandemie

Veröffentlicht am: 30 - April - 2020

Weitere Informationen finden Sie unter:

[Paul-Ehrlich-Institut - Mitteilungen für Zulassungsinhaber](#)

Listen der als versorgungsrelevant bzw. mit einem akut erhöhten Versorgungsrisiko eingestuften Wirkstoffe

„Listen der als versorgungsrelevant bzw. mit einem akut erhöhten Versorgungsrisiko eingestuften Wirkstoffe wurden aktualisiert.“ [...]

Veröffentlicht am: 30 - April - 2020

Weitere Informationen finden Sie unter:

[BfArM - Lieferengpässe - Listen der als versorgungsrelevant bzw. mit einem akut erhöhten Versorgungsrisiko eingestuften Wirkstoffe](#)

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: 30. – April - 2020

Weitere Informationen finden Sie unter:

[BfArM - Arzneibücher](#)

Gesetze und Verordnungen zur Änderung der Arzneimittelverschreibungsverordnung (AMVV)

Veröffentlicht am: 30 - April - 2020

Weitere Informationen finden Sie unter:

[BfArM - Verschreibungspflicht - Gesetze und Verordnungen zur Änderung der Arzneimittelverschreibungsverordnung \(AMVV\)](#)

Empfehlung des Paul-Ehrlich-Instituts zur Gewinnung und Herstellung von COVID-19-Rekonvaleszentenplasma

Veröffentlicht am: 20 - April - 2020

Weitere Informationen finden Sie unter:

[Paul-Ehrlich-Institut - Meldungen - Empfehlung des Paul-Ehrlich-Instituts zur Gewinnung und Herstellung von COVID-19-Rekonvaleszentenplasma](#)

PSUR Single Assessment (PSUSA)

„Hier finden Sie Informationen und Hinweise zum Ergebnis einzelner Verfahren des PSUR Single Assessment (PSUSA).“ [...]

Veröffentlicht am: 06 – Mai - 2020

Weitere Informationen finden Sie unter:

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

Sartane: Verunreinigungen der Wirkstoffe

„Das BfArM hat nach Anhörung das Ruhen der Zulassungen bis zur vollständigen Umsetzung angeordnet.“ [...]

Veröffentlicht am: 06 – Mai - 2020

Weitere Informationen finden Sie unter:

[BfArM - Risikobewertungsverfahren - Sartane: Verunreinigungen der Wirkstoffe](#)

Coronavirus SARS-CoV-2

„Hier finden Sie Informationen zum Coronavirus im Zusammenhang mit den regulatorischen Aufgabenstellungen des BfArM.“ [...]

Veröffentlicht am: 08 – Mai - 2020

Weitere Informationen finden Sie unter:

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

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

Veröffentlicht am: 24 - April - 2020

Weitere Informationen finden Sie unter:

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

PEI Lieferengpässe von Human-Impfstoffen:

Veröffentlicht am: 24 - April - 2020

Weitere Informationen finden Sie unter:

https://www.pei.de/SiteGlobals/Functions/RSSFeed/RSSGenerator_Lieferengpaesse.xml;jsessionid=0339FDDA55D40E1EE4EEED05D9CDEA28.1_cid319?nn=11245824

Humanarzneimittel - Österreich

Statistiken - Übersicht über zugelassene/registrierte Arzneispezialitäten und Antragskategorien (Stand: 01.01.2020)

Veröffentlicht am: 27 - April – 2020

Weitere Informationen finden Sie unter:

[Statistiken - BASG](#)

Update: Blut & Gewebe und COVID-19

Veröffentlicht am: 30- April – 2020

Weitere Informationen finden Sie unter:

[Update: Blut & Gewebe und COVID-19 - BASG](#)

Und

[Update: Blut & Gewebe und COVID-19 - BASG](#)

Häufige Fragen - während der COVID-19 Pandemie

Veröffentlicht am: 29 - April– 2020

Weitere Informationen finden Sie unter:

[Häufige Fragen - BASG](#)

COVID-19: Nebenwirkungsmeldungen

Veröffentlicht am: 30 - April – 2020

Weitere Informationen finden Sie unter:

[COVID-19: Nebenwirkungsmeldungen - BASG](#)

Warnung vor unkontrollierten zell-basierten Therapien mit mangelnder Evidenz

Veröffentlicht am: 30 - April – 2020

Weitere Informationen finden Sie unter:

[Warnung vor unkontrollierten zell-basierten Therapien mit mangelnder Evidenz - BASG](#)

Alle Mitarbeiterinnen und Mitarbeiter der AGES Medizinmarktaufsicht

Veröffentlicht am: 05 - Mai – 2020

Weitere Informationen finden Sie unter:

https://www.basg.gv.at/fileadmin/redakteure/ueber_uns/Kontakte/Liste_Ansprechpartner_Mai_b_arierefrei.pdf

Humanarzneimittel - Schweiz

Swissmedic weist auf das Risiko von schwerwiegenden unerwünschten Arzneimittelwirkungen durch Hydroxychloroquin und Chloroquin hin

„Beide Wirkstoffe werden zurzeit in der Behandlung von Patienten mit COVID-19 im Rahmen von klinischen Studien eingesetzt.“ [...]

Veröffentlicht am: 29 - April – 2020

Weitere Informationen finden Sie unter:

[Swissmedic weist auf das Risiko von schwerwiegenden unerwünschten Arzneimittelwirkungen durch Hydroxychloroquin und Chloroquin hin](#)

Inverkehrbringung wichtiger nicht-konformer Medizinprodukte zur Bekämpfung der COVID-19 Pandemie

„Der Bundesrat hat am 3. April 2020 Massnahmen beschlossen, um die Versorgung mit medizinischen Gütern, die zur Verhütung und Bekämpfung der Coronavirus-Krankheit COVID-19 entscheidend sind, zu gewährleisten.

Gemäss der Verordnung 2 über Massnahmen zur Bekämpfung des Coronavirus (COVID-19, COVID-19-Verordnung 2; SR 818.101.24) kann Swissmedic im Kampf gegen das neue Coronavirus SARS-CoV-2 das Inverkehrbringen von Medizinprodukten, die zur Bewältigung der COVID-19-Epidemie dringend benötigt werden, mit einer Ausnahmewilligung nach einer Risikoabwägung erlauben, auch wenn die erforderliche Konformitätsbewertungsverfahren gemäss Art. 10 der Medizinprodukteverordnung (MepV, SR 812.213) nicht oder nicht vollständig durchgeführt wurden.“ [...]

Veröffentlicht am: 01 - Mai – 2020

Weitere Informationen finden Sie unter:

[Inverkehrbringung wichtiger nicht-konformer Medizinprodukte zur Bekämpfung der COVID-19 Pandemie](#)

Neues Coronavirus: Swissmedic warnt vor illegalen Arzneimitteln aus dem Internet und vor falschen Heilversprechen

„Während der fortdauernden COVID-19-Pandemie bieten Händler über das Internet oder über Social Media illegale Arzneimittel gegen das neue Coronavirus (SARS-CoV-2) an. Gleichzeitig nutzen vereinzelt selbsternannte Heiler oder Betrüger bestehende Ängste und Unsicherheiten aus und versuchen, verschiedene «Wundermittel» gegen die Coronavirus-Krankheit (COVID-19) zu verkaufen. Swissmedic wiederholt deshalb ihre Warnungen vor illegalen Arzneimitteln und Heilanpreisungen in Zusammenhang mit der COVID-19 Pandemie. Wer solche unlauteren Angebote nutzt, gefährdet nicht nur sich selbst, sondern auch andere. Nur Medikamente aus offiziell bewilligten und kontrollierten Vertriebskanälen sind qualitativ einwandfrei und sicher.“ [...]

Veröffentlicht am: 01 - Mai – 2020

Weitere Informationen finden Sie unter:

[Neues Coronavirus: Swissmedic warnt vor illegalen Arzneimitteln aus dem Internet und vor falschen Heilversprechen](#)

Gesetzliche Rahmenbedingungen zur COVID-19 Testung in der Schweiz

„Die aktuellen Möglichkeiten und Bedingungen zur Durchführung von COVID-19 Tests in der Schweiz werden intensiv diskutiert. Um auch in der aktuellen Pandemiesituation die Qualität der Tests und der Testung zu gewährleisten und stets eine dem Testsystem entsprechende, gestützt auf die aktuelle wissenschaftliche Kenntnis zum Erreger und zur Immunität, korrekte klinische Interpretation der Resultate sicherstellen zu können, fasst Swissmedic vorliegend die aktuell geltenden rechtlichen Rahmenbedingungen für die COVID-19 Testung zusammen. Nur so können der Schutz und die angemessene Orientierung der Patienten, der getesteten Personen und der Bevölkerung gewährleistet und die richtigen Schlussfolgerungen zur Bekämpfung der Pandemie gezogen werden.“ [...]

Veröffentlicht am: 01 - Mai – 2020

Weitere Informationen finden Sie unter:

[Gesetzliche Rahmenbedingungen zur COVID-19 Testung in der Schweiz](#)

Neues Coronavirus: Swissmedic warnt vor nicht konformen medizinischen Gesichtsmasken

„Medizinische Gesichtsmasken (auch «chirurgische Masken», «OP-Masken» oder «Hygienemasken») gemäss der Norm EN 14683 sind Medizinprodukte und müssen somit CE-markiert sein. Auf dem Schweizer Markt werden vermehrt nicht konforme oder nur vorgeblich konforme medizinische Gesichtsmasken angeboten.“ [...]

Veröffentlicht am: 01 - Mai – 2020

Weitere Informationen finden Sie unter:

[Neues Coronavirus: Swissmedic warnt vor nicht konformen medizinischen Gesichtsmasken](#)

Das ACSS Consortium unterstützt den Kampf gegen COVID-19

„Die Regulierungsbehörden des ACSS Consortium (Australia, Canada, Singapore, Switzerland Consortium) haben ihre gemeinsame Unterstützung im Kampf gegen die COVID-19-Pandemie zugesagt.“ [...]

Veröffentlicht am: 05 – Mai – 2020

Weitere Informationen finden Sie unter:

[Das ACSS Consortium unterstützt den Kampf gegen COVID-19](#)

Swissmedic Journal

„Auszug aus dem Inhaltsverzeichnis:

- Umfrage zu Monographien der Pharmacopoea Helvetica
- Zulassung eines Arzneimittels mit neuem Wirkstoff: Hemo 125 mg/ml ad us. vet., Injektionslösung für Rinder, Schweine und Hunde (Etamsylatum)
- Anpassung der Wegleitung Zulassung nach Art. 14 Abs. 1 Bst. abis-quater HMG HMGV4
- Bewertung potentieller Nitrosamine im Rahmen von Neuzulassungen
- Informationen aus der Rubrik "Arzneimittel Statistik" [...]

Veröffentlicht am: 07 – Mai – 2020

Weitere Informationen finden Sie unter:

[Swissmedic Journal](#)

Durchführung von Inspektionen in der Schweiz während der COVID-19 Pandemie – Update

„Von den zahlreichen Beeinträchtigungen im Rahmen der COVID-19-Pandemie sind auch Inspektionen betroffen, die Swissmedic gestützt auf das Heilmittelrecht durchführt. Ende März 2020 hat Swissmedic bekanntgegeben, Routineinspektionen bis Ende April auszusetzen. Mit den Beschlüssen des Bundesrats, die Massnahmen zur Eindämmung der Pandemie etappenweise zu lockern, passt Swissmedic die Praxis an. Inspektionen vor Ort werden in Absprache mit den Betroffenen, unter Einhaltung der offiziellen Hygiene- und Verhaltensregeln, schrittweise wiederaufgenommen. Bis auf weiteres können auch Fernbeurteilungen erfolgen. Dabei werden Dokumente oder betriebliche Prozesse digital geprüft und Gespräche zwischen Prüfungsteilnehmern und Inspektoren über Videokonferenzen geführt.“ [...]

Veröffentlicht am: 08 – Mai – 2020

Weitere Informationen finden Sie unter:

[Durchführung von Inspektionen in der Schweiz während der COVID-19 Pandemie – Update](#)

Aktualisierte Dokumente

Veröffentlicht am: 08 – Mai – 2020

Weitere Informationen finden Sie unter:

[Mai 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 \(IPES\)](#)

Österreich

BASG-Gespräch: Pharmakovigilanz

Termin: 15.06.2020

AGES-Akademie, Spargelfeldstrasse 191, 1220 Wien

Weitere Informationen finden Sie unter:

<https://www.basg.gv.at/news-center/veranstaltungen-vorschau/>

BASG-Gespräch: AT als RMS – Meet the Case Manager

Termin: 13.10.2020

AGES-Akademie, Spargelfeldstrasse 191, 1220 Wien

Weitere Informationen finden Sie unter:

<https://www.basg.gv.at/news-center/veranstaltungen-vorschau/>

Schweiz

Veranstaltungen über Medizinprodukte mit Swissmedic Referenten

In der Liste finden sich die Veranstaltungen mit Swissmedic Referentin, die zur Zeit für dieses Jahr geplant sind.

Weitere Informationen finden Sie unter:

[Veranstaltungen über Medizinprodukte](#)

Externe Veranstaltungen mit Swissmedic Referenten

In der Liste finden sich die Veranstaltungen mit Swissmedic Referentin, die zur Zeit für dieses Jahr geplant sind.

Weitere Informationen finden Sie unter:

[Kurse, Vorträge und andere Referententätigkeiten](#)

Europa

eXtended EudraVigilance Medicinal Product Dictionary training course,

European Medicines Agency, Amsterdam, the Netherlands,
from 18/06/2020 to 19/06/2020

Weitere Informationen finden Sie unter:

[eXtended EudraVigilance Medicinal Product Dictionary training course \(Amsterdam\) | European Medicines Agency](#)

eXtended EudraVigilance Medicinal Product Dictionary training course

Ort: Munich, Germany,

from 02/07/2020 to 03/07/2020

Weitere Informationen finden Sie unter:

[eXtended EudraVigilance Medicinal Product Dictionary training course \(Munich\) | European Medicines Agency](#)

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](#)