


16. – 27. März
2020



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Allgemeines – General

EMA gives advice on the use of non-steroidal anti-inflammatories for COVID-19

“EMA is aware of reports, especially on social media, which raise questions about whether non-steroidal anti-inflammatory medicines (NSAIDs) such as ibuprofen could worsen coronavirus disease (COVID-19).

There is currently no scientific evidence establishing a link between ibuprofen and worsening of COVID-19. EMA is monitoring the situation closely and will review any new information that becomes available on this issue in the context of the pandemic.” [...]

Published on: 18 - March - 2020

For more information, please refer to:

[EMA gives advice on the use of non-steroidal anti-inflammatories for COVID-19 | European Medicines Agency](#)

Brexit-related guidance for companies (updated)

Published on: 19 - March - 2020

For more information, please refer to:

[Brexit-related guidance for companies | European Medicines Agency](#)

Outcome of written procedures finalised during the period from 23 November 2019 to 20 February 2020 (new) - EMA/MB/91576/2020 Noted

Published on: 11 - March - 2020

For more information, please refer to:

https://www.ema.europa.eu/en/documents/other/outcome-written-procedures-finalised-during-period-23-november-2019-20-february-2020_en.pdf

Buying medicines online

“Update: EMA is urging patients to beware of potential falsified medicines sold by unregistered websites and vendors. These vendors may be exploiting fears during the COVID-19 pandemic and claiming that their products can prevent or cure COVID-19. They may also appear to provide easy access to medicines that are otherwise not readily available.

There are no authorised medicines in the EU to prevent or treat COVID-19. For advice on treating symptoms, speak to your doctor or pharmacist or follow advice from health authorities.

When buying medicines online, you can stay safe by looking out for the EU logo and buying only from registered retailers.” [...]

Published on: 24 - March - 2020

For more information, please refer to:

[Buying medicines online | European Medicines Agency](#)

Global regulators map out data requirements for phase 1 COVID-19 vaccine trials

“Global regulators have published a report today presenting the outcomes of a workshop on COVID-19 vaccine development that was convened under the umbrella of the International Coalition of Medicines Regulatory Authorities (ICMRA).

The meeting report provides an overview of regulatory considerations related to COVID-19 vaccine development and data required for regulatory decision-making on two key points:

- Pre-clinical data required to support proceeding to first-in-human clinical trials with investigational medicinal products; and
- The need to address the known theoretical risk that vaccines against COVID-19 enhance the disease prior to starting first-in-human clinical trials.” [...]

Published on: 24 - March - 2020

Humanarzneimittel - EU

For more information, please refer to:

[Global regulators map out data requirements for phase 1 COVID-19 vaccine trials | European Medicines Agency](#)

Coronavirus disease (COVID-19)

Published on: 27 - March - 2020

For more information, please refer to:

[Coronavirus disease \(COVID-19\) | European Medicines Agency](#)

Pharmakovigilanz – PRAC

EudraVigilance - Inclusion/exclusion criteria for the 'Important medical events' list (updated) - EMA/136938/2020

Published on: 16 - March - 2020

For more information, please refer to:

https://www.ema.europa.eu/en/documents/other/eudravigilance-inclusion/exclusion-criteria-important-medical-events-list_en.pdf

and

https://www.ema.europa.eu/en/documents/other/important-medical-event-terms-list-version-meddra-version-230_en.xls

Eudravigilance

“Update: From 30 June 2022, it will be mandatory to report side effects to EudraVigilance using a data format based on international standards set by the International Organization for Standardization (ISO). This will help increase the data quality and analytical capabilities in EudraVigilance.

Two ISO standards will apply:

- the Individual Case Safety Report (ICSR) standard (ISO 27953-2:2011) and the modalities on how to implement this standard, as defined in the ICH E2B(R3) guideline;*
- terminology on pharmaceutical dose forms and routes of administration (ISO/FDIS 11239:2012), in line with EMA's Referentials Management Service (RMS).*

These standards are referred to in Commission Implementing Regulation (EU) No 520/2012 on the performance of pharmacovigilance activities, in articles 26(2)(a) and 25(1)(f) of chapter IV ('Use of terminology, formats and standards').

EMA's Management Board endorsed this approach on 19 December 2019, based on a recommendation by EMA's Pharmacovigilance Risk Assessment Committee (PRAC).

To help stakeholders prepare for this new requirement, EMA will update the EU ICSR Implementation Guide and provide face-to-face and online training, including webinars, to address technical and operational questions during 2020.” [...]

Published on: 25 - March – 2020

For more information, please refer to:

[EudraVigilance | European Medicines Agency](#)

List of medicines under additional monitoring (updated)

“Update - Summary of changes in March 2020:

The following CAPs have been added to the list up to 20 March 2020:

- Givlaari (givosiran) - New active substance*

The following NAP has been withdrawn from the list:

- Sonazoid (perflurobutan) - Five years following its authorisation (July 2014), Sonazoid no longer qualifies for additional monitoring as a new active substance and therefore is removed from this list.*

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In addition, Annex IV (List of thiocolchicoside-containing medicinal products in the EU) has been removed (the PASS has been finalised).” [...]

Published on: 25 - March – 2020

For more information, please refer to:

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

Zulassung – Regulatory Affairs

Referral: Leuprorelin-containing depot medicinal products , leuprorelin , Daronda, Depo-Eligard, Eligard, Eligard Depot, Eligard Mensua, Eligard Semestral, Elityran 1 Month Depot (Dps), Elityran 3 Month Depot (Dps), Enanton Depot Dual, Enanton Depot Set, Enantone, Enantone L.P, Enantone Lp, Enantone Monats-Depot, Enantone-Gyn Monats-Depot, Ginecrin Depot, Klebrocid 3-Monats-Depot, Klebrocid Depot Zweikammerspritze, Leptoprol, Lerin, Leugon, Leuprex 3, Leuprol, Leuprolin Ratiopharm, Leuprone 1-Monatsdepot, Leuprone 3-Monatsdepot, Leuprorelin 1-Month Depot Gp-Pharm, Leupro-Sandoz 3-Monats-Depot, Leuprostin, Lucrin, Lucrin Depot, Lucrin Pds Depot, Lucrin Pds Depot 1 Maand, Lucrin Pds Depot 3 Maanden, Lucrin Pds Depot 6 Maanden, Lupron Depo, Lutrate 1 Month Depot, Lutrate 3 Month Depot, Lutrate Depo, Lutrate Depot, Lutrate Depot Trimestral, Politrade, Politrade Politrade Depot, Procren Depot, Procren Depot Pds, Procrin Mensual, Procrin Semestral, Procrin Trimestral, Prostag 3 Dcs, Prostag 6 Dcs, Prostag Sr Dcs, Prostaglant, Sixantone, Trenantone, Trenantone-Gyn, Zeulide, Енузапд, Лымпам Дено, Article 31 referrals, Under evaluation, 16/03/2020 (updated)

“[...] under evaluation: EMA has started a review of leuprorelin medicines after reports indicated that handling errors with the products during preparation and administration can cause some patients to receive insufficient amounts of their medicine, thus reducing the benefits of treatment.

This review covers formulations called depot formulations which are given by injection under the skin or into a muscle and release the active substance slowly over 1 to 6 months. These include implants as well as powders and solvents for the preparation of injections.

Several of these formulations require complex steps to prepare the injection. Handling errors with these formulations have reportedly led to problems such as leakages from the syringe or failure to deliver implants from the applicator.

EMA’s safety committee, PRAC, will now evaluate all available data and determine whether measures are needed to ensure that the medicines are prepared and administered appropriately.

While the review is ongoing, healthcare professionals should carefully follow the handling instructions for leuprorelin medicines. Patients prescribed leuprorelin medicines who have any concerns should discuss them with their doctor.” [...]

Published on: 16 - March - 2020

For more information, please refer to:

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

Other: Outcome of written procedures finalised during the period from 23 November 2019 to 20 February 2020 (new) - EMA/MB/91576/2020 Noted

Published on: 20 - March - 2020

For more information, please refer to:

https://www.ema.europa.eu/en/documents/other/outcome-written-procedures-finalised-during-period-23-november-2019-20-february-2020_en.pdf

Regulatory and procedural guideline: Rules for the implementation of Council Regulation (EC) No 297/95 on fees payable to the European Medicines Agency and other measures - Revised implementing rules to the Fee Regulation as of 1 April 2020 (new) - EMA/MB/332998/2019

Published on: 20- March - 2020

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For more information, please refer to:

https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/rules-implementation-council-regulation-ec-no-297/95-fees-payable-european-medicines-agency-other-measures-revised-implementing-rules-fee-regulation-1_en-0.pdf

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

“Update: Medicine regulatory authorities worldwide are cooperating under the umbrella of ICMRA with the aim of expediting and streamlining the development of COVID-19 vaccines.

EMA and the United States Food and Drug Administration (FDA) jointly chaired the first global regulatory meeting on 18 March 2020, which brought together delegates from 17 countries and experts from the World Health Organization and the European Commission.

The summary report from the meeting sets out the data requirements for first-in-human studies, including the need for data evaluating the theoretical risk that vaccines against COVID-19 might enhance the disease prior to starting first-in-human clinical trials:” [...]

Published on: 25 – March - 2020

For more information, please refer to:

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

Medicinal products for human use: monthly figures - February 2020 (new) - EMA/160030/2020

Published on: 27 - March - 2020

For more information, please refer to

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

Referral: Methocarbamol / paracetamol-containing medicinal products, methocarbamol / paracetamol, Robaxisal compuesto, Article 31 referrals, Opinion provided by Committee for Medicinal Products for Human Use, 26/03/2020, 27/03/2020 (updated)

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

Published on: 27 - March - 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, InfeurAdulti, Interfos, Monural, Monuril, Monurol, Rapidnorm, Solufos, Symural, Uridoz, Urifos, Urinex, Urofast, Uromaste, Uroseptic, Article 31 referrals, Opinion provided by Committee for Medicinal Products for Human Use, 26/03/2020, 27/03/2020 (updated)

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

Published on: 27 - March - 2020

For more information, please refer to:

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

Referral: Budesonide SUN, budesonide, Article 29(4) referrals, Opinion provided by Committee for Medicinal Products for Human Use, 26/03/2020

“[...] Current status: Opinion provided by Committee for Medicinal Products for Human Use. EMA recommends refusal of authorisation for Budesonide Sun (budesonide, nebuliser suspension) in the EU. On 26 March 2020, the European Medicines Agency completed a review of Budesonide Sun and associated names following a disagreement among EU Member States regarding its authorisation. The Agency concluded that the benefits of Budesonide Sun do not outweigh its risks, and the

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marketing authorisation cannot be granted in the Netherlands or in other Member States of the EU where the company has applied for a marketing authorisation (Germany, Italy, Poland, Spain and Sweden), or the United Kingdom.” [...]

Published on: 27 - March - 2020

For more information, please refer to:

[Budesonide SUN | European Medicines Agency](#)

Meeting highlights from the Committee for Medicinal Products for Human Use (CHMP) 23-26 March 2020

Published on: 27 - March - 2020

For more information, please refer to:

[Meeting highlights from the Committee for Medicinal Products for Human Use \(CHMP\) 23-26 March 2020 | European Medicines Agency](#)

Referral: Cyproterone-containing medicinal products, cyproterone, Article 31 referrals, Position provided by CMDh, 25/03/2020, 27/03/2020 (updated)

“[...]On 13 February 2020, EMA’s safety committee (PRAC) recommended that medicines with daily doses of 10 mg or more of cyproterone should only be used for androgen-dependent conditions such as hirsutism (excessive hair growth), alopecia (hair loss), acne and seborrhoea (excessively oily skin) once other treatment options, including treatment with lower doses, have failed. Once higher doses have started working, the dose should be gradually reduced to the lowest effective dose.

The medicines should only be used for reduction of sex drive in sexual deviations in men when other treatment options are not suitable.

There is no change in use of the medicines in men for prostate cancer.

The recommendations follow a review of the risk of the rare tumour meningioma with cyproterone. Overall, this side effect is rare: it may affect between 1 and 10 in 10,000 people, depending on the dose and duration of treatment. The risk increases with increasing cumulative doses (the total amount of medicine a patient has taken over time).

Available data do not indicate a risk for low-dose cyproterone medicines containing 1 or 2 milligrams cyproterone in combination with ethinylestradiol or estradiol valerate and used for acne, hirsutism, contraception, or hormone replacement therapy. However, as a precaution, they should not be used in people who have or have had a meningioma. This restriction is already in place for the higher dose medicines.” [...]

Published on: 27 - March - 2020

For more information, please refer to:

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

Orphan Drugs und neuartige Therapierichtungen (ATMP)

No news available this week.

Qualität – Quality

International Council on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) (updated)

“Update: The results of a survey commissioned by ICH show that the EC and EMA, in collaboration with EU Member States, adequately implement and adhere to ICH guidelines, without introducing unjustified modifications:

- Adequacy of Implementation and Adherence to International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) Guidelines: centralised procedure with EMA

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These results are part of a 2019 study to monitor the adequacy of implementation and adherence to ICH guidelines in regulatory member and observer countries and regions. The study report provides a gap analysis based on authorities' and companies' views on the implementation and adherence of regulators to ICH guidelines. It reveals a close alignment between the self-declaration of the authorities and perception among companies.

For more information, see ICH guideline implementation on the ICH website." [...]

Published on: 26 - March - 2020

For more information, please refer to:

[International Council on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use \(ICH\) | European Medicines Agency](#)

Nitrosamine impurities (updated)

"Update: Conduct a risk evaluation to identify active substances and finished products at risk of N-nitrosamine formation or (cross-)contamination and report the outcome by 1 October 2020 at the latest.

- *If a risk for an active substance is identified, marketing authorisation holders should submit the step response template and proceed with step 2 confirmatory testing of the finished product.*
- *If no risk for an active substance is identified, marketing authorisation holders should conduct a risk evaluation of the finished product and submit the outcome of step 1 only when they reach a final conclusion on the active substance and finished product.*

Marketing authorisation holders can submit a single email notification grouping products with identical outcome of step 1. For more information, see question 5 of Questions and answers on 'Information on nitrosamines for marketing authorisation holders.' [...]

Published on: 27 - March - 2020

For more information, please refer to:

[Nitrosamine impurities | European Medicines Agency](#)

Medizinprodukte - Medical Device / Health technology assessment

Good clinical practice

"Update: The guidance was updated on 27 March 2020 to cover safety reporting, the distribution of in-vitro diagnostics, medical devices and auditing. The updated version also incorporates changes in other sections, in particular on communicating with authorities, informed consent and the distribution of investigational medicines." [...]

Published on: 27 - March - 2020

For more information, please refer to:

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

(Prä-) Klinische Forschung - Research and Development

Call to pool research resources into large multi-centre, multi-arm clinical trials to generate sound evidence on COVID-19 treatments

"EMA's Human Medicines Committee (CHMP) has published a PDF iconstatement urging the EU research community to prioritise large randomised controlled studies because they are most likely to generate the conclusive evidence needed to enable rapid development and approval of potential treatments of COVID-19. The statement promotes a harmonised approach to data collection and a robust methodology for COVID-19 clinical trials across the EU to make best use of the available supply of investigational agents. It emphasises the need to include all EU countries in these trials." [...]

Published on: 19 - March - 2020

For more information, please refer to:

Humanarzneimittel - EU

[Call to pool research resources into large multi-centre, multi-arm clinical trials to generate sound evidence on COVID-19 treatments | European Medicines Agency](#)

Clinical Trial Regulation (updated)

“Update: In March 2020, EMA's Management Board endorsed the audit methodology for CTIS enabling the process for the selection of the supplier for the audit of the system to commence. EMA, together with product owners, is carrying out a second readiness assessment in the first months of 2020 to identify critical items that must be addressed prior to the audit. This will be followed by a further operational assessment (including of the public portal) to determine the full scope of the auditable version. Specialised users, in collaboration with the product owners, have already assessed the 'union control' and 'inspection' modules of CTIS.

EMA is closely monitoring performance of the IT supplier to ensure timely delivery of a reliable audit version of CTIS.” [...]

Published on: 20 – March - 2020

For more information, please refer to:

[Clinical Trial Regulation | European Medicines Agency](#)

Good clinical practice (updated)

“Update: Guidance is available for clinical-trial sponsors on how they should adjust the management of clinical trials and participants during the COVID-19 pandemic: [...]

Published on: 20 – March - 2020

For more information, please refer to:

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

Clinical trials in human medicines (updated)

Update: EudraCT database and the EU Clinical Trials Register are unavailable from 18:30 on Friday 27 March to 8:00 on Monday 30 March (Central European Time, CET) due to essential maintenance.” [...]

Published on: 25 – March - 2020

For more information, please refer to:

[Clinical trials in human medicines | European Medicines Agency](#)

Biostatistics

Published on: 25 – March - 2020

For more information, please refer to:

[Biostatistics | European Medicines Agency](#)

Implications of coronavirus disease (COVID-19) on methodological aspects of ongoing clinical trials

Published on: 25 – March - 2020

For more information, please refer to:

[Implications of coronavirus disease \(COVID-19\) on methodological aspects of ongoing clinical trials | European Medicines Agency](#)

Kinderarzneimittel – Paediatrics

Paediatric Committee (PDCO) (updated) - EMA/PDCO/523933/2019

Submission Period: 01 – 31 May 2020

Published on: 16 - March – 2020

For more information, please refer to:

https://www.ema.europa.eu/en/documents/minutes/minutes-pdco-minutes-15-18-october-2019-meeting_en.pdf

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Minutes - PDCO minutes of the 15-18 October 2019 meeting (new)

Published on: 19 - March – 2020

For more information, please refer to:

[Paediatric Committee \(PDCO\) | European Medicines Agency](#)

Paediatric Committee (PDCO): 12-15 November 2019, European Medicines Agency, Amsterdam, The Netherlands, from 12/11/2019 to 15/11/2019 (updated)

Published on: 23 - March - 2020

[Paediatric Committee \(PDCO\): 12-15 November 2019 | European Medicines Agency](#)

Paediatric investigation plans: questions and answers

“Update: 23 March 2020

- Letters of intent are no longer required for paediatric procedure submissions.
- PDF iconGuidance on paediatric submissions has been revised.
- The paediatrics(@ema.europa.eu) inbox will be discontinued from 31 May 2020.” [...]

Published on: 23 - March – 2020

For more information, please refer to:

[Paediatric investigation plans: questions and answers | European Medicines Agency](#)

Guidance on paediatric submissions - EMA/672643/2017 Rev.2

“A letter of intent to submit a paediatric investigation plan (PIP) or a product specific waiver is no longer required nor processed.

When creating a delivery file at the time of submission via eSubmission Gateway / Web Client, the following six-digit code is to be used:

- the six digits of the already assigned paediatric procedure number (e.g. 001234) - for any follow-up submissions, such as the second or further PIP/waiver submissions for identical active substances; for responses to PDCO requests for modifications; modifications on agreed PIPs, requests for compliance checks, re-examination grounds, withdrawal of procedure instructions, notifications of change; annual reports for deferrals; information on discontinuations; [...]

Published on: 23 - March – 2020

For more information, please refer to:

https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/guidance-paediatric-submissions_en.pdf

PDCO monthly report of opinions on paediatric investigation plans and other activities 25-28

February 2020 (new) - EMEA/120052/2020

Published on: 25 - March – 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-25-28-february-2020_en.pdf

Pflanzliche Arzneimittel – Herbal medicines

HMPC meeting report on European Union herbal monographs, guidelines and other activities - 2-4

March 2020 (new) - EMA/HMPC/121831/2020

Published on: 27 - March - 2020

For more information, please refer to:

https://www.ema.europa.eu/en/documents/committee-report/hmpc-meeting-report-european-union-herbal-monographs-guidelines-other-activities-2-4-march-2020_en.pdf

EDQM

New Council of Europe resolution to promote pharmaceutical care in Europe

“A new Council of Europe resolution on the implementation of pharmaceutical care for the benefit of patients and health services has been adopted by the Committee of Ministers of the Council of Europe to improve medication use and the quality of care across Europe. The resolution defines a framework for promoting and implementing the concept of pharmaceutical care in health systems at national level.” [...]

Published on: 18 - March - 2020

For more information, please refer to:

[New Council of Europe resolution to promote pharmaceutical care in Europe | EDQM - European Directorate for the Quality of Medicines](#)

Covid-19 - Processing and shipment of orders

“Due to the global impact of Covid-19, there have been disruptions to flights as well as restrictions on the fulfilment of services by designated courier companies. Limitations on deliveries and extra precautions, such as quarantine and restricted capacity of customs are also causing some delays.” [...]

Published on: 18 - March - 2020

For more information, please refer to:

[Covid-19 - Processing and shipment of orders | EDQM - European Directorate for the Quality of Medicines](#)

Covid-19 – How to contact the EDQM

Published on: 19 - March - 2020

For more information, please refer to:

[Covid-19 – How to contact the EDQM | EDQM - European Directorate for the Quality of Medicines](#)

European Pharmacopoeia on tetanus vaccines – Rationalising toxicity testing requirements

“At its 165th session (November 2019), the European Pharmacopoeia (Ph. Eur.) Commission adopted 16 revised monographs on tetanus vaccines, following a re-assessment of toxicity testing requirements. The revisions include the suppression of three tests and the harmonisation, as far as possible, of the Ph. Eur.’s toxicity testing requirements for tetanus vaccines for human and veterinary use.

The Test for specific toxicity of tetanus vaccines for human use and the Test for residual toxicity of tetanus vaccines for veterinary use (using guinea pigs), both carried out on the final lot, have been deleted. The tests were considered redundant because a more sensitive test (Test for absence of toxin) is performed routinely at an earlier stage of the process. The revised monographs emphasise the need to validate the detoxification process to demonstrate that the toxoid is stably detoxified.” [...]

Published on: 24 - March - 2020

For more information, please refer to:

[European Pharmacopoeia on tetanus vaccines – Rationalising toxicity testing requirements | EDQM - European Directorate for the Quality of Medicines](#)

Deadline extension to all CEP holders to complete step 1 Risk Assessments regarding presence of nitrosamines (now 31st July 2020).

“The EDQM recognises that due to the impact of the global outbreak of COVID-19, many CEP holders are encountering significant challenges in completing the work within the timelines previously announced in the EDQM request to CEP holders to perform a risk evaluation of their chemically

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synthesised APIs with regards nitrosamine formation, published on the EDQM Website (EDQM request October 2019).“ [...]

Published on: 24 - March - 2020

For more information, please refer to:

Deadline extension to all CEP holders to complete step 1 Risk Assessments regarding presence of nitrosamines (now 31st July 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: 24 - March - 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

European Commission

Human Pharmaceutical Committee - Meetings

Published on: 16 – March - 2020

For more information, please refer to:

[Human Pharmaceutical Committee - Meetings | Public Health](#)

UPDATED – Notice to stakeholders ‘Withdrawal of the United Kingdom and EU rules for medicinal products for human and veterinary use’

Published on: 18 – March - 2020

For more information, please refer to:

https://ec.europa.eu/info/sites/info/files/notice_to_stakeholders_medicinal_products.pdf

Targeted stakeholders' consultation - Annex 21: Importation of medicinal products, of the Eudralex volume 4 (20 March 2020 - 20 June 2020)

Published on: 19 – March - 2020

For more information, please refer to:

[Targeted stakeholders' consultation on Annex 21: Importation of medicinal products, of the Eudralex volume 4 | Public Health](#)

Guidance to sponsors on how to manage clinical trials during the COVID-19 pandemic

Published on: 20 – March - 2020

For more information, please refer to:

[Guidance to sponsors on how to manage clinical trials during the COVID-19 pandemic | European Medicines Agency](#)

ECDC guidance document on COVID-19 and Substances of Human Origin (SoHO)

Published on: 25 – March - 2020

For more information, please refer to:

<https://www.ecdc.europa.eu/sites/default/files/documents/covid-19-supply-substances-human-origin.pdf>

Commission working on proposal to postpone Medical Device Regulation (MDR) application date for one year

Published on: 25 – March - 2020

For more information, please refer to:

https://ec.europa.eu/health/sites/health/files/docs/20200325_news_md_en.pdf

UPDATE - Q&As on Variations;

Published on: 16 – March - 2020

For more information, please refer to:

https://www.hma.eu/fileadmin/dateien/Human_Medicines/CMD_h/Questions_Answers/CMDh_132_2009_Rev55_2020_02_clean_QA_on_Variations.pdf

UPDATE - Q&As on Biologicals;

Published on: 16 – March - 2020

For more information, please refer to:

https://www.hma.eu/fileadmin/dateien/Human_Medicines/CMD_h/Questions_Answers/CMDh_269_2012_Rev.2_2020_02_clean_Q_A_on_biologicals.pdf

UPDATE - Flow chart of the Mutual Recognition Procedure (MRP) and Repeat Use Procedures (RUP);

Published on: 16 – March - 2020

For more information, please refer to:

https://www.hma.eu/fileadmin/dateien/Human_Medicines/CMD_h/procedural_guidance/Application_for_MA/MRP_RUP/CMDh_081_2007_Rev.3_2020_02_clean_Flowchart_MRP_RUP.pdf

UPDATE - Best Practice Guide for the Reference Member State in the MRP/DCP;

Published on: 16 – March - 2020

For more information, please refer to:

https://www.hma.eu/fileadmin/dateien/Human_Medicines/CMD_h/procedural_guidance/01_General_Info/CMDh_062_2001_Rev.4_2020_02_clean_-_BPG_for_RMS_in_the_MRP_and_DCP.pdf

UPDATE - Best Practice Guide for the Decentralised and Mutual Recognition Procedures;

Published on: 16 – March - 2020

For more information, please refer to:

https://www.hma.eu/fileadmin/dateien/Human_Medicines/CMD_h/procedural_guidance/Application_for_MA/CMDh_068_1996_Rev.12_2020_02_clean_CMDh_BPG_for_DCP_and_MRP.pdf

UPDATE - CMDh Best Practice Guide on the compilation of the dossier for New Applications submitted in Mutual Recognition and Decentralised Procedures;

Published on: 16 – March - 2020

For more information, please refer to:

https://www.hma.eu/fileadmin/dateien/Human_Medicines/CMD_h/procedural_guidance/Application_for_MA/CMDh_077_2008_Rev4_2020_02_clean_BPG_on_the_compilation_of_the_dossier.pdf

NEW - CMDh Guidance Document on the Numbering System for the Procedures for Mutual Recognition and Decentralised;

Published on: 16 – March - 2020

For more information, please refer to:

https://www.hma.eu/fileadmin/dateien/Human_Medicines/CMD_h/procedural_guidance/01_General_Info/CMDh_415_2020_Rev0_2020_02_BPG_on_numbering_system_for_MRP_and_DCP.pdf

CMDh

UPDATE - Information on nitrosamines for marketing authorisation holders

Published on: 25 – March - 2020

For more information, please refer to:

[Heads of Medicines Agencies: Nitrosamine impurities](#)

UPDATE - National recommendations for requests to act as RMS in DCPs;

Published on: 10 – March - 2020

For more information, please refer to:

https://www.hma.eu/fileadmin/dateien/Human_Medicines/CMD_h_/procedural_guidance/Application_for_MA/DCP/CMDh_020_2009_Rev28_02_2020_DCP_Requests_to_act_as_RMS.pdf

Humanarzneimittel - Deutschland

Versagungen und Rücknahmen von Zulassungsanträgen

„An dieser Stelle veröffentlicht das Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM) gemäß §34 Abs. 1b Satz 1 AMG monatlich die Rücknahmen von Zulassungsanträgen sowie Versagungen der Zulassung und die Gründe hierfür.“ [...]

Veröffentlicht am: 16 – März - 2020

Weitere Informationen finden Sie unter:

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

Verkehrsfähige Arzneimittel im Zuständigkeitsbereich des BfArM

„Auf der folgenden Seite finden Sie die Anzahl der verkehrsfähigen Arzneimittel im Zuständigkeitsbereich des BfArM, aufgeschlüsselt nach Art des Zulassungsverfahrens, sowie Angaben zum Zulassungsstatus. Die Zahlen werden monatlich aktualisiert.“

Veröffentlicht am: 16 – März - 2020

Weitere Informationen finden Sie unter:

[BfArM - Statistiken - Arzneimittel - Verkehrsfähige Arzneimittel im Zuständigkeitsbereich des BfArM](#)

Bearbeitungsstatistiken

„An dieser Stelle veröffentlicht das BfArM monatlich die aktuelle Bearbeitungsstatistik der Zulassungen und Registrierungen sowie der Verlängerungen.“ [...]

Veröffentlicht am: 16 – März - 2020

Weitere Informationen finden Sie unter:

[BfArM - Statistiken - Arzneimittel - Bearbeitungsstatistiken](#)

Aktuelle Bearbeitungsstatistik des Bundesinstituts für Arzneimittel und Medizinprodukte

„Die Arzneimittelzahlen und Statistiken wurden aktualisiert.“ [...]

Veröffentlicht am: 16 – März - 2020

Weitere Informationen finden Sie unter:

[BfArM - Aktuelle Bearbeitungsstatistik des Bundesinstituts für Arzneimittel und Medizinprodukte](#)

PSUR Single Assessment (PSUSA)

Veröffentlicht am: 17 – März - 2020

Weitere Informationen finden Sie unter:

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

Mitteilungen zu Pharmakovigilanzinspektionen

Veröffentlicht am: 18 – März - 2020

Weitere Informationen finden Sie unter:

[BfArM - Pharmakovigilanzinspektionen](#)

Wissenschaftliche und verfahrenstechnische Beratung durch das BfArM

Veröffentlicht am: 18 – März - 2020

Weitere Informationen finden Sie unter:

[BfArM - Wissenschaftliche und verfahrenstechnische Beratung](#)

Neue Verordnung über die Verschreibungspflicht von Arzneimittel (AMVV) mit neu gefasster Anlage in Kraft getreten

Veröffentlicht am:19 – März - 2020

Weitere Informationen finden Sie unter:

[BfArM - Verschreibungspflicht - Neue Verordnung über die Verschreibungspflicht von Arzneimittel \(AMVV\) mit neu gefasster Anlage in Kraft getreten](#)

Formulare – Medizinprodukte

„Neues Meldeformular für Hersteller und Bevollmächtigte: Die europäischen Behörden haben sich zusammen mit den Herstellerverbänden auf ein neues Meldeformular geeinigt. Das BfArM hat die Version 2.27 am 31.12.2019 offiziell zurückgezogen. Damit ist per 1.1.2020 ausschließlich die Version 7.2 für Vorkommismeldungen zu verwenden. Auf § 7 Absatz 2 der Medizinprodukte-Sicherheitsplanverordnung wird hingewiesen.“ [...]

Veröffentlicht am:20 – März - 2020

Weitere Informationen finden Sie unter:

[BfArM - Formulare Medizinprodukte - Formulare - Medizinprodukte](#)

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:23 – März - 2020

Weitere Informationen finden Sie unter:

[BfArM - Arzneibücher](#)

Coronavirus SARS-CoV-2

„Neues Meldeformular für Hersteller und Bevollmächtigte: Die europäischen Behörden haben sich zusammen mit den Herstellerverbänden auf ein neues Meldeformular geeinigt. Das BfArM hat die Version 2.27 am 31.12.2019 offiziell zurückgezogen. Damit ist per 1.1.2020 ausschließlich die Version 7.2 für Vorkommismeldungen zu verwenden. Auf § 7 Absatz 2 der Medizinprodukte-Sicherheitsplanverordnung wird hingewiesen.“ [...]

Veröffentlicht am:25 – März - 2020

Weitere Informationen finden Sie unter:

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

Coronavirus SARS-CoV-2

„Das BfArM und die EMA weisen die Öffentlichkeit darauf hin, keine Arzneimittel von nicht autorisierten Webseiten zu erwerben.“ [...]

Veröffentlicht am:26 – März - 2020

Weitere Informationen finden Sie unter:

[BfArM - Arzneimittelfälschungen - COVID-19: Vorsicht vor gefälschten Arzneimitteln von nicht registrierten Webseiten](#)

Klinische Prüfungen während der COVID-19 Pandemie

„Das BfArM und die EMA weisen die Öffentlichkeit darauf hin, keine Arzneimittel von nicht autorisierten Webseiten zu erwerben.“ [...]

Veröffentlicht am:26 – März - 2020

Weitere Informationen finden Sie unter:

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

Klinische Prüfungen während der COVID-19-Pandemie

Veröffentlicht am: 27 – März - 2020

Weitere Informationen finden Sie unter:

[Paul-Ehrlich-Institut - Klinische Prüfungen während der COVID-19-Pandemie - Klinische Prüfungen während der COVID-19-Pandemie](#)

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

Veröffentlicht am: 27 – März - 2020

Weitere Informationen finden Sie unter:

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

PEI Lieferengpässe von Human-Impfstoffen:

Veröffentlicht am: 27 – März - 2020

Weitere Informationen finden Sie unter:

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

Humanarzneimittel - Österreich

Arzneimittelversorgung aktuell gesichert. Kein Grund für private Überbevorratung ("Hamsterkäufe")

Veröffentlicht am: 14 – März – 2020

Weitere Informationen finden Sie unter:

[Arzneimittelversorgung aktuell gesichert. Kein Grund für private Überbevorratung \("Hamsterkäufe"\) - BASG](#)

Serologische Schnelltests zum Nachweis einer akuten Infektion mit SARS-CoV-2 ungeeignet

Veröffentlicht am: 15 – März – 2020

Weitere Informationen finden Sie unter:

[Serologische Schnelltests zum Nachweis einer akuten Infektion mit SARS-CoV-2 ungeeignet - BASG](#)

Klinische Studien

„COVID-19 und Klinische Forschung

Information zur Beforschung und Anwendung von Arzneimitteln und Medizinprodukten/IVDs in Zusammenhang mit COVID-19 finden sie hier.

Das Arzneimittelgesetz (AMG) unterscheidet zwei Kategorien: Nicht-Interventionelle Studien (NIS, vormals Anwendungsbeobachtungen) und Interventionelle Arzneimittelprüfungen. Um eine NIS durchführen zu dürfen, muss das Arzneimittel zugelassen sein und streng nach den Vorgaben dieser Zulassung angewendet werden. Weiters darf es keine Untersuchungen außerhalb der Routine oder sonstige Belastungen für die Patienten geben. Im Gegensatz dazu können in der Interventionellen Arzneimittelstudie auch nicht zugelassene Arzneimittel erforscht werden und es sind zusätzliche Untersuchungen erlaubt. Beide Formen dienen der Beantwortung von wissenschaftlichen Fragestellungen.“ [...]

Veröffentlicht am: 16 – März – 2020

Weitere Informationen finden Sie unter:

[Klinische Studien - BASG](#)

Und

[Klinische Studien - BASG](#)

Update: Blut & Gewebe und COVID-19

Veröffentlicht am: 16 – März – 2020

Weitere Informationen finden Sie unter:

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

COVID-19 und Klinische Forschung

„Das Bundesamt priorisiert alle Erstanträge, Änderungsanträge und Meldungen betreffend COVID-19.

Bitte reichen Sie ausschließlich elektronisch über clinicaltrials@basg.gv.at ein und markieren Sie alle Anträge deutlich mit 'COVID-19' im Betreff-Feld.

Wichtig! Alle Projekte müssen im Titel die WHO Bezeichnung "COVID-19" enthalten, um international auffindbar zu sein.“ [...]

Veröffentlicht am: 17 – März – 2020

Weitere Informationen finden Sie unter:

[Klinische Studien und COVID-19 - BASG](#)

Humanarzneimittel - Österreich

Mustertexte

„Hier finden Sie sicherheitsrelevante Informationen, die aufgrund eines PHV issues in die entsprechende Produktinformation zu implementieren sind. [...]

Veröffentlicht am: 18 – März – 2020

Weitere Informationen finden Sie unter:

[Mustertexte - BASG](#)

Häufige Fragen - Klinische Studien und COVID-19

Veröffentlicht am: 17 – März – 2020

Weitere Informationen finden Sie unter:

[Häufige Fragen - BASG](#)

BREXIT Übergangsperiode

„Am 29.03.2017 übermittelte das Vereinigte Königreich (UK) dem Europäischen Rat sein Austrittsansuchen aus der Europäischen Union („BREXIT“). Gemäß Artikel 50 des Vertrages über die Europäische Union hat UK die Union am 31.01.2020 verlassen und wurde zu einem Drittland. Die beiden Zulassungsbehörden MHRA (Medicines and Healthcare Products Regulatory Agency) und VMD (Veterinary Medicines Directorate) stehen daher nicht mehr für die Verfahrensführung in EU-Zulassungs- und Lifecycle-Verfahren zur Verfügung.“ [...]

Veröffentlicht am: 18 – März – 2020

Weitere Informationen finden Sie unter:

[BREXIT Übergangsperiode - BASG](#)

Verwendung von Ibuprofen und anderer nichtsteroidaler Entzündungshemmer bei COVID-19

Veröffentlicht am: 19 – März – 2020

Weitere Informationen finden Sie unter:

[Verwendung von Ibuprofen und anderer nichtsteroidaler Entzündungshemmer bei COVID-19 - BASG](#)

Blutsicherheit, Spendekriterien und Blutversorgung bei COVID-19-Pandemie

Veröffentlicht am: 20 – März – 2020

Weitere Informationen finden Sie unter:

[Blutsicherheit, Spendekriterien und Blutversorgung bei COVID-19-Pandemie - BASG](#)

Compassionate Use und Heilversuch/Named Patient Use

Veröffentlicht am: 24 – März – 2020

Weitere Informationen finden Sie unter:

[Compassionate Use und Heilversuch/Named Patient Use - BASG](#)

COVID-19: Vorsicht vor gefälschten Arzneimitteln von illegalen Online-Apotheken

„Das BASG erinnert die Bevölkerung daran, keine Arzneimittel von nicht autorisierten Websites und/oder illegalen Anbietern zu kaufen. Gerade in Zeiten der Pandemie mit der Coronavirus-Krankheit (COVID-19) wollen Verbrecher die Ängste und Sorgen der Menschen ausnutzen. Illegale Anbieter könnten behaupten, dass ihre Produkte COVID-19 behandeln oder verhindern könnten, oder sie geben vor, einen einfachen und raschen Zugang zu echten Arzneimitteln bieten zu können, die ansonsten nur beschränkt verfügbar sind. Derartige Angebote und Produkte sind mit höchster Wahrscheinlichkeit gefälschte Arzneimittel.“ [...]

Veröffentlicht am: 25 – März – 2020

Weitere Informationen finden Sie unter:

[COVID-19: Vorsicht vor gefälschten Arzneimitteln von illegalen Online-Apotheken - BASG](#)

Humanarzneimittel - Österreich

Arzneimittelqualität - Risikobewertung Nitrosamine in Arzneimitteln

Veröffentlicht am: 25 – März – 2020

Weitere Informationen finden Sie unter:

[Arzneimittelqualität - BASG](#)

Risikoevaluierung Nitrosamine: Fristerstreckung Stufe 1 auf 01. Oktober 2020

Veröffentlicht am: 26 – März – 2020

Weitere Informationen finden Sie unter:

[Risikoevaluierung Nitrosamine: Fristerstreckung Stufe 1 auf 01. Oktober 2020 - BASG](#)

Leitfaden: Benutzerhandbuch eService Inspektionen (L_I253)

Veröffentlicht am: 26 – März – 2020

Weitere Informationen finden Sie unter:

https://www.basg.gv.at/fileadmin/redakteure/A/eservices/leitf%C3%A4den/L_I253_Benutzerhandbuch_eService_Inspektionen.pdf

Anwendung von Arzneimitteln gegen Bluthochdruck-, Herz- oder Nierenerkrankungen während COVID-19-Pandemie beibehalten

Veröffentlicht am: 27 – März – 2020

Weitere Informationen finden Sie unter:

[Anwendung von Arzneimitteln gegen Bluthochdruck-, Herz- oder Nierenerkrankungen während COVID-19-Pandemie beibehalten - BASG](#)

Humanarzneimittel - Schweiz

Internationale Aktionswoche «PANGEA»: Behörden beschlagnahmen weltweit 48'564

Sendungen mit illegalen Heilmitteln

„Sinkende Tendenz bei den über das Internet bestellten und illegal in die Schweiz importierten Arzneimitteln.“ [...]

Veröffentlicht am: 19 - März – 2020

Weitere Informationen finden Sie unter:

[Internationale Aktionswoche «PANGEA»: Behörden beschlagnahmen weltweit 48'564 Sendungen mit illegalen Heilmitteln](#)

Inverkehrbringung lebenswichtiger Beatmungsgeräte

„Ausnahmebewilligungen für nicht konforme Medizinprodukte“ [...]

Veröffentlicht am: 24 - März – 2020

Weitere Informationen finden Sie unter:

[Inverkehrbringung lebenswichtiger Beatmungsgeräte](#)

SARS-CoV-2 Pandemie

„Die Verbreitung des neuen Coronavirus (SARS-CoV-2) stellt auch die Durchführung klinischer Versuche mit Arzneimitteln in der Schweiz vor grosse Herausforderungen.“

Veröffentlicht am: 26 - März – 2020

Weitere Informationen finden Sie unter:

[Klinische Versuche mit Arzneimitteln](#)

Umsetzung der neuen Medizinprodukte-Regulierung – Update

„Ab 26. Mai 2020 wird die neue Regulierung für Medizinprodukte in der EU und in der Schweiz anwendbar.“ [...]

Veröffentlicht am: 27 - März – 2020

Weitere Informationen finden Sie unter:

[Umsetzung der neuen Medizinprodukte-Regulierung – Update](#)

Aktualisierte Dokumente

Veröffentlicht am: 27 - März - 2020

Weitere Informationen finden Sie unter:

[März 2020](#)



Fragen an das Netzwerk

Falls Sie eine Frage haben, die Sie gerne in unserem Netzwerk diskutieren würden, senden Sie uns einfach eine E-Mail an info-as@megra.org zur anonymen Publikation im nächsten Newsletter.*

*Bei der Beantwortung der Fragen handelt es sich um eine Zusammenfassung von persönlichen Meinungen und Erfahrungswerten der MEGRA Mitglieder mit keinem Anspruch auf Rechtssicherheit. Wir empfehlen zur Absicherung die Konsultation entsprechender zugrunde liegender Regularien.

Veranstaltungen / Events – Behörden und andere Veranstalter

Deutschland

16th International Paul-Ehrlich-Seminar (IPES)

Termin: 02.09.2020 - 05.09.2020

Ort: Maritim Hotel Bad Homburg, Germany

Weitere Informationen finden Sie unter:

[Paul-Ehrlich-Institut - Veranstaltungen - 16th International Paul-Ehrlich-Seminar \(IPES\)](#)

Digitalisierung und Telemedizin in klinischen Prüfungen – Chancen und Herausforderungen?

Termin: 05.05.2020

Ort: Stifterverband für die Deutsche Wissenschaft, Wissenschaftszentrum, Ahrstr. 45, 53175

Bonn
Weitere Informationen finden Sie unter:

[BfArM - Dialog-Veranstaltungen - Digitalisierung und Telemedizin in klinischen Prüfungen – Chancen und Herausforderungen?](#)

Österreich

BASG-Gespräch: Qualitätsmängel bei Arzneimitteln

Termin: 06.05.2020

AGES-Akademie, Spargelfeldstrasse 191, 1220 Wien

Weitere Informationen finden Sie unter:

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

BASG-Gespräch: Pharmakovigilanz

Termin: 15.06.2020

AGES-Akademie, Spargelfeldstrasse 191, 1220 Wien

Weitere Informationen finden Sie unter:

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

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

Termin: 13.10.2020

AGES-Akademie, Spargelfeldstrasse 191, 1220 Wien

Weitere Informationen finden Sie unter:

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

Schweiz

Veranstaltungen über Medizinprodukte mit Swissmedic Referenten

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

Weitere Informationen finden Sie unter:

Veranstaltungen über Medizinprodukte

Externe Veranstaltungen mit Swissmedic Referenten

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

Weitere Informationen finden Sie unter:

[Kurse, Vorträge und andere Referententätigkeiten](#)

Europa

eXtended EudraVigilance Medicinal Product Dictionary training course,

Ort: Lisbon, Portugal,

from 14/05/2020 to 15/05/2020

Weitere Informationen finden Sie unter:

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

eXtended EudraVigilance Medicinal Product Dictionary training course,

European Medicines Agency, Amsterdam, the Netherlands,

from 18/06/2020 to 19/06/2020

Weitere Informationen finden Sie unter:

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

eXtended EudraVigilance Medicinal Product Dictionary training course

Ort: Munich, Germany,

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

Weitere Informationen finden Sie unter:

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

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](#)