## TABLE OF CONTENTS



## HEADS OF AGENCIES – CMDh

No updates since December 20th 2023.

## HEADS OF AGENCIES – PAEDIATRIC REGULATION

Article 45 work-sharing: *click here*

## EUROPEAN MEDICINES AGENCY (EMA)

| | | |
|---|---|---|
| 19/01/2024 | Document: Regulatory Procedure Management (RPM) for the Product Lifecycle Management (PLM) - Frequently asked questions | New |
| 19/01/2024 | Page: Orphans: Regulatory and procedural guidance and forms | Updated |
| 19/01/2024 | PSUSA: PSUSA/00002192/202303 - periodic safety update report single assessment | New |
| 19/01/2024 | Event: European Medicines Agency (EMA) Patients' and Consumers' (PCWP) and Healthcare Professionals' (HCPWP) Working Parties joint meeting | New |
| 19/01/2024 | Event: Third Veterinary Big Data Stakeholder Forum | Updated |
| 19/01/2024 | Orphan: EU/3/23/2761 - orphan designation for treatment of erythropoietic protoporphyria | New |
| 19/01/2024 | Orphan: EU/3/23/2762 - orphan designation for treatment of GM2 gangliosidosis | New |
| 19/01/2024 | Orphan: EU/3/23/2749 - orphan designation for treatment of mucormycosis | New |
| 19/01/2024 | Medicine: Methylthioninium chloride Proveblue | Updated |
| 19/01/2024 | Orphan: EU/3/23/2751 - orphan designation for treatment of glycogen storage disease type II (Pompe's disease) | New |
| 19/01/2024 | Orphan: EU/3/23/2759 - orphan designation for treatment of amyotrophic lateral sclerosis | New |
| 19/01/2024 | Orphan: EU/3/23/2756 - orphan designation for treatment of facioscapulohumeral muscular dystrophy | New |
| 19/01/2024 | Post-authorisation: Metacam - opinion on variation to marketing authorisation | New |
| 19/01/2024 | News: Meeting highlights from the Committee for Veterinary Medicinal Products (CVMP) 16-17 January 2024 | New |
| 19/01/2024 | Event: Orphan medicines development - ask the European regulator | Updated |
| 19/01/2024 | Page: Applying for orphan designation | Updated |

| | | |
|---|---|---|
| 19/01/2024 | Event: European Medicines Agency (EMA) Patients' and Consumers' (PCWP) and Healthcare Professionals' (HCPWP) Working Parties meeting with all eligible organisations | Updated |
| 19/01/2024 | Page: Website outages and upgrades | Updated |
| 19/01/2024 | Document: Recommended submission dates for veterinary medicinal products | Updated |
| 19/01/2024 | Document: IRIS guide for applicants - How to create and submit scientific applications, for industry and individual applicants | Updated |
| 18/01/2024 | Document: Contact details of national competent authorities for requests of translation exemptions falling under Art. 63.3 of Directive 2001/83/EC and cases of shortages | Updated |
| 18/01/2024 | Document: Member states contact points for review of national versions of the content of mobile scanning and other technologies | Updated |
| 18/01/2024 | Document: Contact details of national competent authorities for requests to use a sticker to place the Unique Identifier on the outer/immediate packaging of centrally approved products | Updated |
| 18/01/2024 | Medicine: Prevymis | Updated |
| 18/01/2024 | Medicine: Dapagliflozin Viatris | Updated |
| 18/01/2024 | Medicine: Imbruvica | Updated |
| 18/01/2024 | Medicine: Teysuno | Updated |
| 18/01/2024 | Document: Chapter 3.II: XEVPRM user guidance of the Detailed guidance on the electronic submission of information on medicinal products for human use by marketing authorisation holders to the EMA | Updated |
| 18/01/2024 | Document: Chapter 3.I: Technical specifications of the Detailed guidance on the electronic submission of information on medicinal products for human use by marketing authorisation holders to the EMA | Updated |
| 18/01/2024 | Medicine: Ontozry | Updated |
| 17/01/2024 | Medicine: Nemdatine | Updated |
| 17/01/2024 | Medicine: Tegsedi | Updated |
| 17/01/2024 | Medicine: Lynparza | Updated |
| 17/01/2024 | Medicine: Prasugrel Viatris (previously Prasugrel Mylan) | Updated |
| 17/01/2024 | Medicine: Amvuttra | Updated |
| 17/01/2024 | Medicine: Nepexto | Updated |
| 17/01/2024 | Medicine: Spexotras | Updated |
| 17/01/2024 | Document: List of centrally authorised products requiring a notification of a change for update of annexes | Updated |
| 17/01/2024 | Document: Membership list: HMA-EMA joint Big Data Steering Group | Updated |
| 17/01/2024 | Document: Policy on the determination of the condition(s) for a paediatric investigation plan (PIP) / waiver (scope of the PIP / waiver) | Updated |
| 17/01/2024 | Medicine: Omvoh | Updated |
| 17/01/2024 | Event: Second European Medicines Agency (EMA) and European Confederation of Pharmaceutical Entrepreneurs (EUCOPE) bilateral meeting | Updated |
| 17/01/2024 | Page: Clinical Trials Information System: training and support | Updated |
| 17/01/2024 | Medicine: Clopidogrel / Acetylsalicylic acid Viatris (previously Clopidogrel / Acetylsalicylic acid Mylan) | Updated |
| 17/01/2024 | Document: Article 57 product data | Updated |
| 17/01/2024 | Event: Clinical Trials Information System (CTIS) sponsor end user training programme - February 2024 | New |
| 17/01/2024 | Event: Clinical Trials Information System (CTIS) sponsor end user training programme - April 2024 | New |
| 17/01/2024 | Event: Clinical Trials Information System (CTIS) sponsor end user training programme - June 2024 | New |

| | | |
|---|---|---|
| 17/01/2024 | Document: Joint HMA/EMA multi-stakeholder workshop on Patient Registries | New |
| 17/01/2024 | Event: Committee for Medicinal Products for Veterinary Use (CVMP): 16-18 January 2024 | Updated |
| 17/01/2024 | Medicine: Anagrelide Viatris (previously Anagrelide Mylan) | Updated |
| 17/01/2024 | Medicine: Imjudo | Updated |
| 17/01/2024 | Medicine: Bemfola | Updated |
| 17/01/2024 | Document: Integrilin (eptifibatide) supply shortage | New |
| 16/01/2024 | Medicine: Entecavir Viatris (previously Entecavir Mylan) | Updated |
| 16/01/2024 | Medicine: Febuxostat Viatris (previously Febuxostat Mylan) | Updated |
| 16/01/2024 | Page: Quality of medicines questions and answers: Part 2 | Updated |
| 16/01/2024 | Medicine: Pradaxa | Updated |
| 16/01/2024 | Medicine: Terrosa | Updated |
| 16/01/2024 | Herbal: Cnici benedicti herba - herbal medicinal product | Updated |
| 16/01/2024 | Medicine: Talzenna | Updated |
| 16/01/2024 | Medicine: Brintellix | Updated |
| 16/01/2024 | PSUSA: PSUSA/00003155/202305 - periodic safety update report single assessment | New |
| 16/01/2024 | Medicine: Veltassa | Updated |
| 16/01/2024 | PSUSA: PSUSA/00002320/202304v - periodic safety update report single assessment | New |
| 16/01/2024 | Medicine: Spikevax (previously COVID-19 Vaccine Moderna) | Updated |
| 16/01/2024 | News: Human medicines: highlights of 2023 | New |
| 16/01/2024 | Document: Human medicines highlights 2023 | New |
| 16/01/2024 | Medicine: Mayzent | Updated |
| 15/01/2024 | Document: Big Data Steering Group (BDSG): 2023 report | New |
| 15/01/2024 | Medicine: Revatio | Updated |
| 15/01/2024 | Medicine: Grepid | Updated |
| 15/01/2024 | PSUSA: PSUSA/00000715/202305 - periodic safety update report single assessment | New |
| 15/01/2024 | Medicine: Viagra | Updated |
| 15/01/2024 | Medicine: Trazimera | Updated |
| 15/01/2024 | Medicine: Mozobil | Updated |
| 15/01/2024 | Page: Product-specific bioequivalence guidance | Updated |
| 15/01/2024 | Medicine: Tibsovo | Updated |
| 15/01/2024 | Event: Conversations on Cancer: Transforming Patient Lives by Therapeutic and Regulatory Innovations | New |
| 15/01/2024 | Medicine: Menveo | Updated |
| 15/01/2024 | Medicine: Beyfortus | Updated |
| 15/01/2024 | PSUSA: PSUSA/00001834/202304 - periodic safety update report single assessment | New |
| 15/01/2024 | Medicine: Intrarosa | Updated |
| 15/01/2024 | Medicine: Leflunomide Zentiva (previously Leflunomide Winthrop) | Updated |
| 15/01/2024 | Document: Applications for new human medicines under evaluation: January 2024 | New |

## NOTICE TO APPLICANTS

No updates since January 30th 2023.

## BFARM - PHARMAKOVIGILANZ (SPECIFIC FOR GERMANY)

| | |
|---|---|
| 22.01.2024 | Hinweise zum Antrag auf Änderung der Verkaufsabgrenzung<br><br>Anleitung zur Stellung eines Antrags auf Änderung der Verkaufsabgrenzun |
| 19.01.2024 | Umsetzung des einstimmigen Beschlusses der Koordinierungsgruppe EMA/CMDh/268636/2023 vom 22.06.2023 betreffend die Zulassungen für Humanarzneimittel mit dem Wirkstoff Morphin und der Wirkstoffkombination Morphin/Cyclizin (unter Berücksichtigung der auf der EMA-Webseite seit 3.10.2023 veröffentlichten Korrektur der deutschen Übersetzung)<br><br>Das BfArM veröffentlicht den Umsetzungsbescheid für den Wirkstoff Morphin und der Wirkstoffkombination Morphin/Cyclizin infolge des Europäischen PSUR Single Assessment Verfahrens nach Artikel 107d) bis g) der Richtlinie 2001/83/EG. |
| 19.01.2024 | Umsetzung des einstimmigen Beschlusses der Koordinierungsgruppe EMA/CMDh/321522/2023 vom 20.07.2023 betreffend die Zulassungen für Humanarzneimittel mit dem Wirkstoff Lamotrigin<br><br>Das BfArM veröffentlicht den Umsetzungsbescheid für den Wirkstoff Lamotrigin infolge des Europäischen PSUR Single Assessment Verfahrens nach Artikel 107d) bis g) der Richtlinie 2001/83/EG. |
| 19.01.2024 | Informationen zu Rote-Hand-Briefen und Informationsbriefen<br><br>Das Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM) veröffentlicht neue Hinweise zu anstehenden Rote-Hand-Briefen und Informationsbriefen. |
| 15.01.2024 | Informationen zu Einreichung und Genehmigung von Schulungsmaterial<br><br>Aktuelle Hinweise für pharmazeutische Unternehmen zu Valproat wurden veröffentlicht. |

## BFARM – MEDIZINPRODUKTE (SPECIFIC FOR GERMANY)

No updates since December 28th 2023.

## PEI - VIGILANZ (SPECIFIC FOR GERMANY)

No updates since November 16th 2023.

## PHARMEUROPA TEXTS FOR COMMENT

Information on Pharmeuropa updates will be presented quarterly.