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## HEADS OF AGENCIES – CMDh

No updates since February 29th 2024.

## HEADS OF AGENCIES – PAEDIATRIC REGULATION

Article 45 work-sharing: *click here*

## EUROPEAN MEDICINES AGENCY (EMA)

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|---|---|---|
| 08/03/2024 | Medicine: Emend | Updated |
| 08/03/2024 | PSUSA: PSUSA/00010007/202307 - periodic safety update report single assessment | New |
| 08/03/2024 | Medicine: Prevenar 13 | Updated |
| 08/03/2024 | PIP: EMEA-001397-PIP04-17-M01 - paediatric investigation plan | Updated |
| 08/03/2024 | PIP: EMEA-001312-PIP02-19 - paediatric investigation plan | Updated |
| 08/03/2024 | PIP: EMEA-001312-PIP03-19 - paediatric investigation plan | Updated |
| 08/03/2024 | Event: European Medicines Agency (EMA) Patients' and Consumers' (PCWP) and Healthcare Professionals' (HCPWP) Working Parties joint meeting | Updated |
| 08/03/2024 | PSUSA: PSUSA/00001738/202307 - periodic safety update report single assessment | New |
| 08/03/2024 | Medicine: Zalasta | Updated |
| 08/03/2024 | Medicine: Kinpeygo | Updated |
| 08/03/2024 | Medicine: Skyclarys | Updated |
| 08/03/2024 | Medicine: Eliquis | Updated |
| 08/03/2024 | Medicine: Ivemend | Updated |
| 08/03/2024 | News: Meeting highlights from the Pharmacovigilance Risk Assessment Committee (PRAC) 4-7 March 2024 | New |
| 08/03/2024 | Medicine: Quofenix | Updated |
| 08/03/2024 | Medicine: HyQvia | Updated |
| 08/03/2024 | Page: Liposomal amphotericin B product-specific bioequivalence guidance | Updated |
| 08/03/2024 | Document: Note on the HORIZON-JU-IHI-2024-06-two-stage funding call: Development of evidence based practical guidance for sponsors on the use of real-world data / real-world evidence | New |

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|---|---|---|
| 07/03/2024 | Page: Scientific and technical recommendations: Veterinary Medicines Regulation | Updated |
| 07/03/2024 | Document: EudraVigilance user declaration for qualified person for pharmacovigilance/responsible person for EudraVigilance | Updated |
| 07/03/2024 | Document: EudraVigilance Form A | Updated |
| 07/03/2024 | Document: Connection template - EMA ESTRI Gateway using an AS2 compatible product | Updated |
| 07/03/2024 | Document: Vendor registration in the EudraVigilance external compliance testing environment (XCOMP) - Registration procedure | Updated |
| 07/03/2024 | Document: Connecting to the Agency ESTRI Gateway using an AS2 compatible product | Updated |
| 07/03/2024 | Document: EudraVigilance - EVWEB user manual | Updated |
| 07/03/2024 | Document: EudraVigilance support guide | Updated |
| 07/03/2024 | PSUSA: PSUSA/00002151/202308 - periodic safety update report single assessment | New |
| 07/03/2024 | PSUSA: PSUSA/00011039/202307 - periodic safety update report single assessment | New |
| 07/03/2024 | PSUSA: PSUSA/00000210/202308 - periodic safety update report single assessment | New |
| 07/03/2024 | Page: Vaccine Monitoring Platform | Updated |
| 07/03/2024 | Medicine: Imbruvica | Updated |
| 07/03/2024 | PIP: EMEA-002440-PIP01-18-M04 - paediatric investigation plan | Updated |
| 07/03/2024 | Document: Vaccine Monitoring Platform: List of EMA-funded studies | New |
| 07/03/2024 | Event: Multi-stakeholder webinar on the HMA-EMA Catalogues of real-world data sources and studies | Updated |
| 07/03/2024 | PIP: EMEA-002435-PIP01-18-M03 - paediatric investigation plan | Updated |
| 07/03/2024 | PIP: EMEA-002298-PIP01-17-M05 - paediatric investigation plan | Updated |
| 07/03/2024 | Medicine: Mekinist | Updated |
| 07/03/2024 | Document: Deadlines for submission of applications for orphan medicinal product designation to the EMA and corresponding COMP timetable for valid applications - 2024-2025 | Updated |
| 07/03/2024 | Medicine: Tafinlar | Updated |
| 07/03/2024 | Document: Meeting Report of the second Listen and Learn Focus Group (LLFG) meeting of the Quality Innovation Group (QIG) | New |
| 07/03/2024 | Page: Big data | Updated |
| 07/03/2024 | Document: Final Minutes – HMA-EMA joint Big Data Steering Group teleconference - 30 January 2024 | New |
| 07/03/2024 | Event: 3Rs Working Party (3RsWP) plenary meeting – Public session on the 2024 work plan | Updated |
| 07/03/2024 | PIP: EMEA-003341-PIP01-22 - paediatric investigation plan | New |
| 07/03/2024 | PIP: EMEA-003342-PIP01-22 - paediatric investigation plan | New |
| 07/03/2024 | PIP: EMEA-003340-PIP01-22 - paediatric investigation plan | New |
| 07/03/2024 | Page: Opinions and letters of support on the qualification of novel methodologies for medicine development | Updated |
| 06/03/2024 | Medicine: Mounjaro | Updated |
| 06/03/2024 | Medicine: Apealea | Updated |
| 06/03/2024 | Medicine: Doptelet | Updated |
| 06/03/2024 | Medicine: Revestive | Updated |
| 06/03/2024 | Medicine: Kaftrio | Updated |
| 06/03/2024 | Page: Data Analysis and Real World Interrogation Network (DARWIN EU) | Updated |
| 06/03/2024 | Document: DARWIN EU data partners onboarded in phases I and II | Updated |
| 06/03/2024 | Document: DARWIN EU: Making health data count | New |

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| 06/03/2024 | News: DARWIN EU® continues expanding its capacity to deliver real-world data studies | New |
| 06/03/2024 | PSUSA: PSUSA/00001504/202304 - periodic safety update report single assessment | New |
| 06/03/2024 | Medicine: Cholib | Updated |
| 06/03/2024 | Document: List of signals discussed at PRAC since September 2012 | Updated |
| 06/03/2024 | Document: PRAC recommendations on signals adopted at the 5-8 February 2024 PRAC meeting | New |
| 06/03/2024 | Event: EMA Veterinary Medicines Info Day 2024 | Updated |
| 05/03/2024 | Medicine: Filspari | Updated |
| 05/03/2024 | Medicine: Dynastat | Updated |
| 05/03/2024 | Medicine: VeraSeal | Updated |
| 05/03/2024 | Herbal: Silybi mariani fructus - herbal medicinal product | Updated |
| 05/03/2024 | Document: Minutes of the PRAC meeting 8-11 January 2024 | New |
| 05/03/2024 | Medicine: Enhertu | Updated |
| 05/03/2024 | Page: Templates for assessors | Updated |
| 05/03/2024 | Document: CHMP rapporteurs' assessment report for paediatric studies submitted in accordance with Article 46 | Updated |
| 05/03/2024 | Document: Assessment report for post-authorisation measures (PAMs) | Updated |
| 05/03/2024 | Medicine: Clopidogrel TAD | Updated |
| 05/03/2024 | Medicine: Imcivree | Updated |
| 05/03/2024 | Medicine: Kalydeco | Updated |
| 05/03/2024 | Medicine: Ameluz | Updated |
| 05/03/2024 | Medicine: Vafseo | Updated |
| 05/03/2024 | Event: Sixth European Medicines Agency (EMA) and EFPIA bilateral meeting | Updated |
| 05/03/2024 | Medicine: Dupixent | Updated |
| 05/03/2024 | Medicine: Otezla | Updated |
| 05/03/2024 | Document: CHMP PROM minutes for the meeting on 12 February 2024 | New |
| 05/03/2024 | Document: CHMP PROM minutes for the meeting on 15 January 2024 | New |

## NOTICE TO APPLICANTS

No updates since January 30th 2023.

## BFARM - PHARMAKOVIGILANZ (SPECIFIC FOR GERMANY)

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| 08.03.2024 | Informationsbrief zu Spiolto Respimat: möglicherweise defekter Dosiszähler<br><br>Wirkstoff: Tiotropiumbromid/Olodaterolhydrochlorid<br><br>Die Firma Boehringer Ingelheim Pharma GmbH & Co. KG informiert über möglicherweise defekte Dosiszähler bei zwei Chargen des Arzneimittels Spiolto Respimat 2,5 Mikrogramm/2,5 Mikrogramm. |
| 08.03.2024 | Pharmacovigilance Risk Assessment Committee (PRAC)<br><br>Das Bundesinstitut für Arzneimittel und Medizinprdoukte (BfArM) veröffentlicht die neuen Signale, die im Rahmen der PRAC-Sitzung vom 04.03-07.03.2024 behandelt wurden. |
| 07.03.2024 | Umsetzung des Durchführungsbeschlusses der Europäischen Kommission zum PSUR Single Assessment betreffend die Zulassungen für Humanarzneimittel mit dem Wirkstoff Tacrolimus (topische Darreichungsformen) vom 22.02.2024 |

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| | Das BfArM veröffentlicht den Umsetzungsbescheid für den Wirkstoff Tacrolimus (topische Darreichungsformen) infolge des Europäischen PSUR Single Assessment Verfahrens nach Artikel 107d) bis g) der Richtlinie 2001/83/EG. |
| 04.03.2024 | Umsetzung des einstimmigen Beschlusses der Koordinierungsgruppe EMA/CMDh/395608/2023 vom 14.09.2023 betreffend die Zulassungen für Humanarzneimittel mit dem Wirkstoff Paroxetin<br><br>Das BfArM veröffentlicht den Umsetzungsbescheid für den Wirkstoff Paroxetin infolge des Europäischen PSUR Single Assessment Verfahrens nach Artikel 107d) bis g) der Richtlinie 2001/83/EG. |
| 04.03.2024 | Vorläufige Tagesordnung der 94. Routinesitzung am 19. März 2024<br><br>Die 94. Routinesitzung nach § 63 AMG wird am 19. März 2024 stattfinden. |
| 04.03.2024 | Ergebnisprotokoll zur 93. Routinesitzung nach § 63 AMG am 21. November 2023 (Online-Veranstaltung)<br><br>Das BfArM gibt das Ergebnisprotokoll der 93. Routinesitzung vom 21. November 2023 bekannt. |

## BFARM – MEDIZINPRODUKTE (SPECIFIC FOR GERMANY)

No updates since February 28th 2024.

## PEI - VIGILANZ (SPECIFIC FOR GERMANY)

No updates since February 27th 2024.

## PHARMEUROPA TEXTS FOR COMMENT

Information on Pharmeuropa updates will be presented quarterly.