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## HEADS OF AGENCIES – CMDh

29 February

[NEW - Statistics for New Applications \(MRP/DCP\), Variations, Referrals and Paediatric Worksharing procedures in 2023](#)

28 February

[NEW - Art 46 PAR on Infarix-IPV+Hib](#)

[NEW - CMDh Summary of activities 2023](#)

[NEW - Presentations from the meeting of a subgroup of CMDh with Interested Parties dedicated to LoSC and publication of PI updates](#)

[UPDATE - D70 Preliminary AR Quality template](#)

[UPDATE - CMDh Best Practice Guide on Multilingual Packaging](#)

[NEW - Report from the meeting held on 20-22 February 2024](#)

26 February

[NEW - 23-25 January 2024 CMDh minutes](#)

20 February

[NEW - 20-21 February 2024 CMDh agenda](#)

## HEADS OF AGENCIES – PAEDIATRIC REGULATION

Article 45 work-sharing: [click here](#)

## EUROPEAN MEDICINES AGENCY (EMA)

|            |                                                                             |         |
|------------|-----------------------------------------------------------------------------|---------|
| 04/03/2024 | Page: <a href="#">Procedures for monograph and list entry establishment</a> | Updated |
| 04/03/2024 | Herbal: <a href="#">Gentianae radix - herbal medicinal product</a>          | Updated |

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| 04/03/2024 | Herbal: <a href="#">Calendulae flos - herbal medicinal product</a>                                                                  | Updated |
| 04/03/2024 | Herbal: <a href="#">Boldi folium - herbal medicinal product</a>                                                                     | Updated |
| 04/03/2024 | Herbal: <a href="#">Avenae herba - herbal medicinal product</a>                                                                     | Updated |
| 04/03/2024 | Herbal: <a href="#">Avenae fructus - herbal medicinal product</a>                                                                   | Updated |
| 01/03/2024 | Herbal: <a href="#">Lupuli flos - herbal medicinal product</a>                                                                      | Updated |
| 01/03/2024 | Herbal: <a href="#">Lini semen - herbal medicinal product</a>                                                                       | Updated |
| 01/03/2024 | Herbal: <a href="#">Rusci rhizoma - herbal medicinal product</a>                                                                    | Updated |
| 01/03/2024 | Herbal: <a href="#">Sambuci flos - herbal medicinal product</a>                                                                     | Updated |
| 01/03/2024 | Herbal: <a href="#">Combination: Thymi herba and Primulae radix - herbal medicinal product</a>                                      | Updated |
| 01/03/2024 | Document: <a href="#">ICH E2D(R1) Guideline on post-approval safety data Step 2b - Revision 1</a>                                   | New     |
| 01/03/2024 | PSUSA: <a href="#">PSUSA-00002110-202305 - periodic safety update report single assessment</a>                                      | New     |
| 01/03/2024 | PSUSA: <a href="#">PSUSA/00000613/202305 - periodic safety update report single assessment</a>                                      | New     |
| 01/03/2024 | PSUSA: <a href="#">PSUSA/00001500/202304 - periodic safety update report single assessment</a>                                      | New     |
| 01/03/2024 | Medicine: <a href="#">Zinplava</a>                                                                                                  | Updated |
| 01/03/2024 | Medicine: <a href="#">MabThera</a>                                                                                                  | Updated |
| 01/03/2024 | Medicine: <a href="#">Rxulti</a>                                                                                                    | Updated |
| 01/03/2024 | Medicine: <a href="#">Blincyto</a>                                                                                                  | Updated |
| 01/03/2024 | Medicine: <a href="#">Saxenda</a>                                                                                                   | Updated |
| 01/03/2024 | Document: <a href="#">List of centrally authorised products requiring a notification of a change for update of annexes</a>          | Updated |
| 01/03/2024 | Medicine: <a href="#">Toviaz</a>                                                                                                    | Updated |
| 01/03/2024 | Herbal: <a href="#">Foeniculi amari fructus - herbal medicinal product</a>                                                          | Updated |
| 01/03/2024 | Herbal: <a href="#">Foeniculi dulcis fructus - herbal medicinal product</a>                                                         | Updated |
| 01/03/2024 | Document: <a href="#">QRD Appendix III to the Quality Review of Documents templates for human medicinal products (Cover page)</a>   | Updated |
| 01/03/2024 | Medicine: <a href="#">Aldara</a>                                                                                                    | Updated |
| 01/03/2024 | Page: <a href="#">Network Portfolio</a>                                                                                             | Updated |
| 01/03/2024 | Medicine: <a href="#">Tepadina</a>                                                                                                  | Updated |
| 01/03/2024 | Page: <a href="#">Data protection and privacy</a>                                                                                   | Updated |
| 01/03/2024 | Event: <a href="#">Quarterly System Demo Q1 2024</a>                                                                                | New     |
| 01/03/2024 | Document: <a href="#">Organisation chart: Information Management</a>                                                                | Updated |
| 01/03/2024 | Event: <a href="#">Meeting of the Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG) - January 2024</a>  | Updated |
| 01/03/2024 | Document: <a href="#">Minutes - Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG) (29 January 2024)</a> | New     |
| 01/03/2024 | Document: <a href="#">Shortage of Ixiaro (Japanese encephalitis vaccine (inactivated, adsorbed))</a>                                | Updated |
| 01/03/2024 | Document: <a href="#">Recommendations on eligibility to PRIME scheme adopted at the CHMP meeting of 19-22 February 2024</a>         | New     |
| 01/03/2024 | Document: <a href="#">List of medicines currently in PRIME scheme</a>                                                               | Updated |
| 29/02/2024 | Page: <a href="#">PRIME: priority medicines</a>                                                                                     | Updated |
| 29/02/2024 | Document: <a href="#">Preliminary QIG Considerations regarding Pharmaceutical Process Models</a>                                    | New     |
| 29/02/2024 | PIP: <a href="#">EMA-003334-PIP01-22 - paediatric investigation plan</a>                                                            | New     |
| 29/02/2024 | Document: <a href="#">ATMP product information template version 1.1 - highlighted</a>                                               | New     |
| 29/02/2024 | Event: <a href="#">Management Board meeting: 13-14 December 2023</a>                                                                | Updated |
| 29/02/2024 | PIP: <a href="#">EMA-003330-PIP01-22 - paediatric investigation plan</a>                                                            | New     |

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|------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------|
| 29/02/2024 | Document: <a href="#">QRD Appendix II - Medical Dictionary for Regulatory Activities terminology to be used in section 4.8 'undesirable effects' of the summary of product characteristics</a>              | Updated |
| 29/02/2024 | Document: <a href="#">Mutual-recognition, decentralised and referral product-information template version 4.2</a>                                                                                           | Updated |
| 29/02/2024 | Document: <a href="#">QRD Appendix II - Medical Dictionary for Regulatory Activities terminology to be used in section 4.8 'undesirable effects' of the summary of product characteristics (Cover page)</a> | Updated |
| 29/02/2024 | Document: <a href="#">Compilation of quality review of documents (QRD) on stylistic matters in product information</a>                                                                                      | Updated |
| 29/02/2024 | Document: <a href="#">QRD Appendix V - Adverse-drug-reaction reporting details</a>                                                                                                                          | Updated |
| 29/02/2024 | Event: <a href="#">ACT EU Training for non-commercial sponsors: Transitioning trials to the CTR (CTIS)</a>                                                                                                  | Updated |
| 29/02/2024 | Event: <a href="#">Product Management Services (PMS) deep-dive webinar</a>                                                                                                                                  | Updated |
| 29/02/2024 | PSUSA: <a href="#">PSUSA/00009231/202305 - periodic safety update report single assessment</a>                                                                                                              | New     |
| 29/02/2024 | Document: <a href="#">QRD product-information template version 10.4 - highlighted</a>                                                                                                                       | Updated |
| 29/02/2024 | Document: <a href="#">QRD product-information template version 10.4</a>                                                                                                                                     | Updated |
| 29/02/2024 | Document: <a href="#">QRD product-information annotated template (English) version 10.4</a>                                                                                                                 | Updated |
| 29/02/2024 | Medicine: <a href="#">Viread</a>                                                                                                                                                                            | Updated |
| 29/02/2024 | Medicine: <a href="#">Yargesa</a>                                                                                                                                                                           | Updated |
| 29/02/2024 | Page: <a href="#">Product-information templates - Human</a>                                                                                                                                                 | Updated |
| 29/02/2024 | Medicine: <a href="#">Truvada</a>                                                                                                                                                                           | Updated |
| 29/02/2024 | Medicine: <a href="#">Deltysba</a>                                                                                                                                                                          | Updated |
| 29/02/2024 | Medicine: <a href="#">Spravato</a>                                                                                                                                                                          | Updated |
| 29/02/2024 | Medicine: <a href="#">Stelara</a>                                                                                                                                                                           | Updated |
| 29/02/2024 | Medicine: <a href="#">Nevanac</a>                                                                                                                                                                           | Updated |
| 29/02/2024 | Medicine: <a href="#">Clopidogrel Teva (hydrogen sulphate)</a>                                                                                                                                              | Updated |
| 29/02/2024 | Document: <a href="#">QRD product-information annotated template (English) version 10.4 - highlighted</a>                                                                                                   | Updated |
| 29/02/2024 | Medicine: <a href="#">Zyllt</a>                                                                                                                                                                             | Updated |
| 29/02/2024 | Medicine: <a href="#">Clopidogrel Krka d.d. (previously Zopya)</a>                                                                                                                                          | Updated |
| 29/02/2024 | Event: <a href="#">Cancer Medicines Forum workshop: April 2024</a>                                                                                                                                          | Updated |
| 29/02/2024 | PSUSA: <a href="#">PSUSA/00001502/202304 - periodic safety update report single assessment</a>                                                                                                              | New     |
| 29/02/2024 | PSUSA: <a href="#">PSUSA/00001509/202304 - periodic safety update report single assessment</a>                                                                                                              | New     |
| 29/02/2024 | Medicine: <a href="#">Ofev</a>                                                                                                                                                                              | Updated |
| 29/02/2024 | Document: <a href="#">Methodology European Specialised Expert Community (ESEC)</a>                                                                                                                          | New     |
| 29/02/2024 | PSUSA: <a href="#">PSUSA/00001507/202304 - periodic safety update report single assessment</a>                                                                                                              | New     |
| 29/02/2024 | Medicine: <a href="#">Nordimet</a>                                                                                                                                                                          | Updated |
| 28/02/2024 | Medicine: <a href="#">Entyvio</a>                                                                                                                                                                           | Updated |
| 28/02/2024 | Medicine: <a href="#">Tyenne</a>                                                                                                                                                                            | Updated |
| 28/02/2024 | PIP: <a href="#">EMA-002741-PIP01-20-M01 - paediatric investigation plan</a>                                                                                                                                | Updated |
| 28/02/2024 | Page: <a href="#">Plasma master file certificates</a>                                                                                                                                                       | Updated |
| 28/02/2024 | Event: <a href="#">Cancer medicines forum meeting 4 December 2023</a>                                                                                                                                       | New     |
| 28/02/2024 | PIP: <a href="#">EMA-001652-PIP01-14-M04 - paediatric investigation plan</a>                                                                                                                                | Updated |
| 28/02/2024 | Medicine: <a href="#">Benlysta</a>                                                                                                                                                                          | Updated |
| 28/02/2024 | Medicine: <a href="#">Lyrica</a>                                                                                                                                                                            | Updated |
| 28/02/2024 | Document: <a href="#">List of European Union reference dates and frequency of submission of periodic safety update reports (PSURs)</a>                                                                      | Updated |

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| 28/02/2024 | Medicine: <a href="#">Emtricitabine/Tenofovir disoproxil Zentiva</a>                                                                                                                                                                                                                     | Updated |
| 28/02/2024 | Page: <a href="#">List of medicines under additional monitoring</a>                                                                                                                                                                                                                      | Updated |
| 28/02/2024 | Document: <a href="#">List of medicinal products under additional monitoring</a>                                                                                                                                                                                                         | Updated |
| 28/02/2024 | Document: <a href="#">List of medicinal products under additional monitoring</a>                                                                                                                                                                                                         | Updated |
| 28/02/2024 | Document: <a href="#">Procedural advice for requests for the classification of variations not already listed in Commission Implementing Regulation (EU) 2021/17 or EMA/CMDv guidance on the details of the classification of variations requiring assessment according to Article 62</a> | Updated |
| 28/02/2024 | Document: <a href="#">Timetable: Extension application</a>                                                                                                                                                                                                                               | Updated |
| 28/02/2024 | Medicine: <a href="#">Casgevya</a>                                                                                                                                                                                                                                                       | Updated |
| 28/02/2024 | PIP: <a href="#">EMA-002024-PIP02-22 - paediatric investigation plan</a>                                                                                                                                                                                                                 | New     |
| 28/02/2024 | PIP: <a href="#">EMA-003051-PIP05-22 - paediatric investigation plan</a>                                                                                                                                                                                                                 | New     |
| 28/02/2024 | Document: <a href="#">Scientific advice and protocol assistance adopted during the CHMP meeting 19-22 February 2024</a>                                                                                                                                                                  | New     |
| 28/02/2024 | Event: <a href="#">Joint Heads of Medicines Agencies (HMA)/European Medicines Agency (EMA) Multistakeholder workshop on Patient Registries</a>                                                                                                                                           | Updated |
| 28/02/2024 | Medicine: <a href="#">Torisel</a>                                                                                                                                                                                                                                                        | Updated |
| 28/02/2024 | Medicine: <a href="#">Bevespi Aerosphere</a>                                                                                                                                                                                                                                             | Updated |
| 28/02/2024 | Document: <a href="#">Minutes of the PRAC meeting on 27-30 November 2023</a>                                                                                                                                                                                                             | Updated |
| 28/02/2024 | Document: <a href="#">Minutes of the CAT meeting 17-19 January 2024</a>                                                                                                                                                                                                                  | New     |
| 27/02/2024 | Medicine: <a href="#">Zypadhera</a>                                                                                                                                                                                                                                                      | Updated |
| 27/02/2024 | Event: <a href="#">Multi-stakeholder webinar on the HMA-EMA Catalogues of real-world data sources and studies</a>                                                                                                                                                                        | Updated |
| 27/02/2024 | Event: <a href="#">European Medicines Agency (EMA) Patients' and Consumers' (PCWP) and Healthcare Professionals' (HCPWP) Working Parties joint meeting</a>                                                                                                                               | Updated |
| 27/02/2024 | Medicine: <a href="#">Zyprexa Velotab</a>                                                                                                                                                                                                                                                | Updated |
| 27/02/2024 | Medicine: <a href="#">Lumykras</a>                                                                                                                                                                                                                                                       | Updated |
| 27/02/2024 | Medicine: <a href="#">Doptelet</a>                                                                                                                                                                                                                                                       | Updated |
| 27/02/2024 | Event: <a href="#">EMA and European Organisation for Research and Treatment of Cancer (EORTC) workshop: How can patient-reported outcomes (PRO) and health-related quality of life (HRQoL) data inform regulatory decisions?</a>                                                         | Updated |
| 27/02/2024 | Page: <a href="#">Industry annual bilateral meetings</a>                                                                                                                                                                                                                                 | Updated |
| 27/02/2024 | Event: <a href="#">Third European Medicines Agency (EMA) and MedTech Europe bilateral meeting</a>                                                                                                                                                                                        | New     |
| 27/02/2024 | Page: <a href="#">Scientific publications</a>                                                                                                                                                                                                                                            | Updated |
| 27/02/2024 | Medicine: <a href="#">Aripiprazole Sandoz</a>                                                                                                                                                                                                                                            | Updated |
| 27/02/2024 | EU-M4all: <a href="#">Fexinidazole Winthrop</a>                                                                                                                                                                                                                                          | Updated |
| 27/02/2024 | Medicine: <a href="#">Naveruclif</a>                                                                                                                                                                                                                                                     | New     |
| 27/02/2024 | Medicine: <a href="#">Aripiprazole Mylan Pharma (previously Aripiprazole Pharmathen)</a>                                                                                                                                                                                                 | Updated |
| 27/02/2024 | Medicine: <a href="#">NovoRapid</a>                                                                                                                                                                                                                                                      | Updated |
| 27/02/2024 | PSUSA: <a href="#">PSUSA/00002201/202306 - periodic safety update report single assessment</a>                                                                                                                                                                                           | New     |
| 26/02/2024 | Document: <a href="#">Organisation chart: Human Medicines</a>                                                                                                                                                                                                                            | Updated |
| 26/02/2024 | Medicine: <a href="#">Zyprexa</a>                                                                                                                                                                                                                                                        | Updated |
| 26/02/2024 | Medicine: <a href="#">Sugammadex Piramal</a>                                                                                                                                                                                                                                             | Updated |
| 26/02/2024 | Medicine: <a href="#">Axura</a>                                                                                                                                                                                                                                                          | Updated |
| 26/02/2024 | Medicine: <a href="#">Memantine Merz</a>                                                                                                                                                                                                                                                 | Updated |
| 26/02/2024 | Page: <a href="#">Nitrosamine impurities</a>                                                                                                                                                                                                                                             | Updated |
| 26/02/2024 | Document: <a href="#">Appendix 1: Acceptable intakes established for N-nitrosamines</a>                                                                                                                                                                                                  | Updated |
| 26/02/2024 | Page: <a href="#">Industry Standing Group meetings</a>                                                                                                                                                                                                                                   | Updated |

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| 26/02/2024 | Event: <a href="#">Eighth Industry Standing Group (ISG) meeting</a>                           | New     |
| 26/02/2024 | Event: <a href="#">Clinical Trials Information System (CTIS): Walk-in clinic - March 2024</a> | Updated |
| 26/02/2024 | Medicine: <a href="#">Yescarta</a>                                                            | Updated |
| 26/02/2024 | Page: <a href="#">Medicine Shortages Single Point of Contact (SPOC) Working Party</a>         | Updated |
| 26/02/2024 | Medicine: <a href="#">Rystiggo</a>                                                            | Updated |
| 26/02/2024 | Medicine: <a href="#">Skyclarys</a>                                                           | Updated |

## NOTICE TO APPLICANTS

No updates since January 30<sup>th</sup> 2023.

## BFARM - PHARMAKOVIGILANZ (SPECIFIC FOR GERMANY)

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| 01.03.2024 | <a href="#">88. Sitzung (23. Januar 2024 per Videokonferenz) – Ergebnisprotokoll</a>                                                                                                                                                                                                                                                                                                                                                                                 |
| 01.03.2024 | <p>Sachverständigen-Ausschuss für Verschreibungspflicht nach § 53 Absatz 2 AMG</p> <p><a href="#">Informationsbrief zu Spiolto Respimat: möglicherweise defekter Dosiszähler</a></p> <p>Wirkstoff: Tiotropiumbromid/Olodaterolhydrochlorid</p> <p>Die Firma Boehringer Ingelheim Pharma GmbH &amp; Co. KG informiert über möglicherweise defekte Dosiszähler bei zwei Chargen des Arzneimittels Spiolto Respimat 2,5 Mikrogramm/2,5 Mikrogramm.</p>                  |
| 26.02.2024 | <p><a href="#">Umsetzung des einstimmigen Beschlusses der Koordinierungsgruppe EMA/CMDh/409038/2023 vom 14.09.2023 (in der Fassung des Corrigendums Corr.1 vom 25.10.2023) betreffend die Zulassungen für Humanarzneimittel mit dem Wirkstoff Gemcitabin</a></p> <p>Das BfArM veröffentlicht den Umsetzungsbescheid für den Wirkstoff Gemcitabin infolge des Europäischen PSUR Single Assessment Verfahrens nach Artikel 107d) bis g) der Richtlinie 2001/83/EG.</p> |

## BFARM – MEDIZINPRODUKTE (SPECIFIC FOR GERMANY)

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| 28.02.2024 | <p><a href="#">Risiken melden</a></p> <p>Die Verantwortlichen für das erstmalige Inverkehrbringen von Medizinprodukten (Hersteller, Bevollmächtigte oder Einführer) sind nach den Bestimmungen der Medizinprodukte-Sicherheitsplanverordnung (MPSV) verpflichtet, Vorkommnisse, die in Deutschland aufgetreten sind (unter bestimmten Voraussetzungen auch Vorkommnisse, die sich in Drittländern ereignet haben), sowie in Deutschland durchgeführte Rückrufe an das Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM) bzw. entsprechend seiner Zuständigkeit an das Paul-Ehrlich-Institut (PEI) zu melden.</p> |
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## PEI - VIGILANZ (SPECIFIC FOR GERMANY)

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| 27.02.2024 | <a href="#">Rabipur in fehlerhaft bedruckter, deutscher Verpackung eingeschränkt verfügbar</a> |
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## PHARMEUROPA TEXTS FOR COMMENT

Information on Pharmeuropa updates will be presented quarterly.

Trotz regelmäßiger Aktualisierung und sorgfältiger Überwachung der Veröffentlichungen können wir keine Haftung oder Garantie für die Aktualität, Richtigkeit und Vollständigkeit der hier bereitgestellten Informationen übernehmen.  
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Despite regular updating and careful monitoring of the publications, we cannot take any responsibility or guarantee for the topicality, correctness and completeness of the information provided here.  
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