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HEADS OF AGENCIES – CMDh

22 April

[NEW - 23-25 April CMDh agenda](#)

HEADS OF AGENCIES – PAEDIATRIC REGULATION

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

EUROPEAN MEDICINES AGENCY (EMA)

Date	Content	Status
29/04/2024	Event: Enpr-EMA Coordinating Group meeting March 2024	New
26/04/2024	Medicine: Prevenar 20 (previously Apexxnar)	Updated
26/04/2024	Medicine: Xevudy	Updated
26/04/2024	Event: Product Management Service (PMS) Info-Day	Updated
26/04/2024	Document: Organisation chart of the European Medicines Agency	Updated
26/04/2024	Page: Guidance on good manufacturing practice and good distribution practice: Questions and answers	Updated
26/04/2024	News: Meeting highlights from the Committee for Veterinary Medicinal Products (CVMP) 16-18 April 2024	Updated
26/04/2024	Page: Development of a guideline on the safety of nanoparticles – in the context of the establishment of maximum residue limits and veterinary marketing authorisations	New
26/04/2024	Page: Scientific guidelines for veterinary medicines	Updated
26/04/2024	Document: Concept paper for the development of a guideline on the safety of nanoparticles – in the context of the establishment of maximum residue limits and veterinary marketing authorisations	New
26/04/2024	News: Confidentiality arrangement between the EU and the Republic of Korea	New
26/04/2024	Document: Working arrangement between the Ministry of Food and Drug Safety of the Republic of Korea and the Directorate-General for Health and Food Safety of the European Commission and EMA for the Exchange of Non-Public Information on Medicinal Products	New

26/04/2024	Document: Guidance on the anonymisation of protected personal data and assessment of commercially confidential information during the preparation of RMPs (main body and annexes 4 and 6)	Updated
26/04/2024	Document: QRD Form 2 and checklist for the submission of day +25 files - veterinary	Updated
26/04/2024	Post-authorisation: Alecensa - opinion on variation to marketing authorisation	New
26/04/2024	Post-authorisation: Reyataz - opinion on variation to marketing authorisation	New
26/04/2024	Post-authorisation: Triumeq - opinion on variation to marketing authorisation	New
26/04/2024	Post-authorisation: Sirturo - opinion on variation to marketing authorisation	New
26/04/2024	Post-authorisation: Rybrevant - opinion on variation to marketing authorisation	New
26/04/2024	Medicine: Truqap	New
26/04/2024	Post-authorisation: Rozlytrek - opinion on variation to marketing authorisation	New
26/04/2024	Post-authorisation: Opdivo - opinion on variation to marketing authorisation	New
26/04/2024	Medicine: Wezenla	New
26/04/2024	Medicine: GeGant	New
26/04/2024	Medicine: Eribulin Baxter	New
26/04/2024	Medicine: Altuvoct	New
26/04/2024	Medicine: Obgemsa	New
26/04/2024	Medicine: Jeraygo	New
26/04/2024	News: Meeting highlights from the Committee for Medicinal Products for Human Use (CHMP) 22-25 April 2024	New
26/04/2024	Page: SME Regulation and reports	Updated
26/04/2024	Document: Small and medium-sized enterprise (SME) office annual report 2023	New
26/04/2024	Event: Follow up EMA and EORTC multi-stakeholder workshop on soft tissue and bone sarcoma	New
26/04/2024	Page: Procurement	Updated
26/04/2024	Medicine: Spikevax (previously COVID-19 Vaccine Moderna)	Updated
26/04/2024	Event: Committee for Medicinal Products for Veterinary Use (CVMP): 12-14 March 2024	Updated
26/04/2024	Document: Minutes of the CVMP meeting 12-13 March 2024	New
25/04/2024	Medicine: Xtandi	Updated
25/04/2024	Event: Committee for Medicinal Products for Veterinary Use (CVMP): 16-18 April 2024	Updated
25/04/2024	Medicine: Innovax-ND-H5	New
25/04/2024	Document: List of centrally authorised products requiring a notification of a change for update of annexes	Updated
25/04/2024	Page: Non-clinical Working Party	Updated
25/04/2024	Document: Guide on access to unpublished documents	Updated
25/04/2024	Event: SPOR Status Update	Updated
25/04/2024	Event: EMA workshop on the challenges in drug development, regulation and clinical practice in hemoglobinopathies	New
25/04/2024	Event: Joint HMA/EMA Big Data Steering Group workshop on RWE methods	Updated
25/04/2024	Document: Agenda - Joint HMA/EMA Big Data Steering Group Workshop on RWE methods	Updated
25/04/2024	Medicine: Teriflunomide Accord	Updated

25/04/2024	PSUSA: PSUSA/00002068/202308 - periodic safety update report single assessment	New
25/04/2024	Medicine: Sifrol	Updated
25/04/2024	Medicine: Quviviq	Updated
25/04/2024	Medicine: Nepexto	Updated
25/04/2024	Medicine: Bimervax	Updated
24/04/2024	Medicine: Tecartus	Updated
24/04/2024	Document: List of eligible industry stakeholder organisations	Updated
24/04/2024	Medicine: Pandemic influenza vaccine H5N1 AstraZeneca (previously Pandemic influenza vaccine H5N1 Medimmune)	Updated
24/04/2024	Medicine: Spedra	Updated
24/04/2024	Document: Agenda - Fourth EMA-AESGP bilateral meeting	New
24/04/2024	Event: Fifth European Medicines Agency (EMA) and the Association of the European Self-Medication Industry (AESGP) bilateral meeting	New
24/04/2024	Document: Minimum inhibitory concentration (MIC) breakpoints	Updated
24/04/2024	Event: Psychedelics and their therapeutic use - LinkedIn Live interview with Steffen Thirstrup, EMA's Chief Medical Officer	New
24/04/2024	Medicine: Fruzaqla	New
23/04/2024	Page: Training and resources for patients and consumers	Updated
23/04/2024	Page: Republic of Korea	New
23/04/2024	Medicine: Pramipexole Teva	Updated
23/04/2024	Medicine: Sivextro	Updated
23/04/2024	Medicine: Ontozry	Updated
23/04/2024	Medicine: Emend	Updated
23/04/2024	Document: Emend (aprepitant) supply shortage	Updated
23/04/2024	Medicine: Kaftrio	Updated
23/04/2024	Medicine: Sitagliptin / Metformin hydrochloride Accord	Updated
23/04/2024	Medicine: Revatio	Updated
23/04/2024	Medicine: Oyavas	Updated
23/04/2024	News: New recommendations to strengthen supply chains of critical medicines	New
23/04/2024	Page: Executive Steering Group on Shortages and Safety of Medicinal Products	Updated
23/04/2024	Document: MSSG recommendations to strengthen supply chains of critical medicinal products	New
23/04/2024	Medicine: Hukyndra	Updated
23/04/2024	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
23/04/2024	Document: Member states contact points for review of national versions of the content of mobile scanning and other technologies	Updated
23/04/2024	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
23/04/2024	Document: Table of decisions of labelling exemption requests falling under article 63 of Directive 2001/83/EC examined by the Quality Review of Documents (QRD) Group	Updated
23/04/2024	Event: Paediatric Committee (PDCO): 23-26 April 2024	Updated
23/04/2024	Document: Agenda - PDCO agenda of the 23-26 April 2024 meeting	New
23/04/2024	Document: Agenda of the CHMP meeting 22-25 April 2024	Updated
22/04/2024	Medicine: Lunsumio	Updated
22/04/2024	PSUSA: PSUSA/00010425/202308 - periodic safety update report single assessment	New

22/04/2024	PSUSA: PSUSA/00010163/202308 - periodic safety update report single assessment	New
22/04/2024	Document: List of medicinal products under additional monitoring	Updated
22/04/2024	Document: List of medicinal products under additional monitoring	Updated
22/04/2024	Medicine: Lorviqua	Updated
22/04/2024	Medicine: Tofidence	New
22/04/2024	Page: List of medicines under additional monitoring	Updated
22/04/2024	Medicine: Jentadueto	Updated
22/04/2024	Medicine: Posaconazole AHCL	Updated
22/04/2024	Event: Information and Q&A session on updated CAPs in web-based eAF	New
22/04/2024	Medicine: Posaconazole Accord	Updated
22/04/2024	Medicine: Lemtrada	Updated
22/04/2024	Page: Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG) meetings	Updated
22/04/2024	Event: Clinical Trials Information System (CTIS) Bitesize Talk: How to submit a transitional trial in CTIS	Updated
22/04/2024	Medicine: Granupas (previously Para-aminosalicylic acid Lucane)	Updated
22/04/2024	Event: Meeting of the Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG) - April 2024	Updated
22/04/2024	Medicine: Nintedanib Accord	Updated

NOTICE TO APPLICANTS

No updates since January 30th 2023.

BFARM - PHARMAKOVIGILANZ (SPECIFIC FOR GERMANY)

26.04.2024	Umsetzung des einstimmigen Beschlusses der Koordinierungsgruppe EMA/CMDh/478151/2023 vom 09.11.2023 betreffend die Zulassungen für Humanarzneimittel mit dem Wirkstoff Oxycodon Das BfArM veröffentlicht den Umsetzungsbescheid für den Wirkstoff Oxycodon infolge des Europäischen PSUR Single Assessment Verfahrens nach Artikel 107d) bis g) der Richtlinie 2001/83/EG.
24.04.2024	Hinweis zur Korrektur der am 13.03.2024 publizierten Textänderung im Rahmen eines Outcomes of imposed non-interventional PASS-Verfahrens zu Chlormadinonacetat (CMA), Ethinylestradiol (EE) Wirkstoff: Chlormadinonacetat, Ethinylestradiol Im Verfahren EMEA/H/N/PSR/J/0042 Chlormadinonacetat (CMA), Ethinylestradiol (EE) gibt es im aktuell publizierten Dokument einen Fehler, dessen Korrektur in der aktuellen CMDh-Sitzung beschlossen werden soll.

BFARM – MEDIZINPRODUKTE (SPECIFIC FOR GERMANY)

25.04.2024	Vorkommismeldung durch Hersteller und Bevollmächtigte Vorkommismeldung durch Hersteller und Bevollmächtigte
24.04.2024	Prüfkriterien für die von digitalen Gesundheitsanwendungen (DiGA) und digitalen Pflegeanwendungen (DiPA) nachzuweisenden Anforderungen an den Datenschutz Version 1.0 vom 24.04.2024

24.04.2024	DiGA und DiPA Datenschutzkriterien Das BfArM hat im Einvernehmen mit der oder dem Bundesbeauftragten für den Datenschutz und die Informationsfreiheit (BfDI) und im Benehmen mit dem Bundesamt für Sicherheit in der Informationstechnik (BSI) die Prüfkriterien für die Anforderungen an den Datenschutz bei DiGA und DiPA aktualisiert.
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PEI - VIGILANZ (SPECIFIC FOR GERMANY)

No updates since February 27th 2024.

PHARMEUROPA TEXTS FOR COMMENT

Information on Pharmeuropa updates will be presented quarterly.

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