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HEADS OF AGENCIES – CMDh

16 September

- [CORRECTION - 24-25 February CMDh minutes](#)

14 September

- [NEW - 15-17 September CMDh Agenda](#)

HEADS OF AGENCIES – PAEDIATRIC REGULATION

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

EUROPEAN MEDICINES AGENCY (EMA)

Date	Content	Status
18/09/2026	Document: Programme of the 2026 annual meeting of the European network of paediatric research at EMA (EnprEMA)	Updated
18/09/2026	Medicine: Nucalamepolizumab	Updated
18/09/2026	Medicine: Steqeymaustekinumab	Updated
18/09/2026	Medicine: Avtozmatocilizumab	Updated
18/09/2026	Post-authorisation: Enhertu - opinion on variation to marketing authorisation trastuzumab deruxtecan	New
18/09/2026	Event: Quarterly System Demo - Q3 2026	Updated
18/09/2026	Document: MedDRA important medical event terms list - version 29.1	Updated
18/09/2026	Page: User safety for pharmaceutical veterinary medicinal products - Scientific guideline	Updated
18/09/2026	Document: Organisation chart: Human Medicines	Updated
18/09/2026	Document: Draft guideline on user safety for pharmaceutical veterinary medicinal products - Revision 2	New
18/09/2026	Page: User safety of topically administered products - Scientific guideline	Updated
18/09/2026	Document: Pharmacovigilance-related regulatory recommendations for centrally authorised veterinary medicinal products during 2026	Updated
18/09/2026	Document: Draft guideline on user safety of topically administered veterinary medicinal products - Revision 1	New
18/09/2026	Document: Highlight report - Combination Products Operational Group (COMBO) - Medical Devices stream - July 2026	New

Date	Content	Status
18/09/2026	Event: Regulatory sandboxes: Joint European Commission (EC) / European Medicines Agency (EMA) multi-stakeholder workshop	Updated
18/09/2026	Event: EMA annual call with General Practitioner Organisations' representatives	New
18/09/2026	Document: Antimicrobial Sales and Use (ASU) Platform: Release notes	Updated
18/09/2026	Shortage: Dynastatparecoxib	Updated
18/09/2026	Shortage: NexoBrid concentrate of proteolytic enzymes enriched in bromelain	Updated
18/09/2026	Event: Workshop on advancing proof-of-concept data in paediatric oncology drug development	Updated
18/09/2026	Medicine: Povofortay povorcitinib	New
18/09/2026	Medicine: Pebrilzo pertuzumab	New
18/09/2026	Medicine: Adcomfo malizumab	New
18/09/2026	Medicine: Ruxolitinib Zentivar uxolitinib	New
18/09/2026	Medicine: Inijaq tofacitinib	New
18/09/2026	Medicine: Zeydoviog lepaglutide	New
18/09/2026	Medicine: Sepalnasenaparib	New
18/09/2026	Medicine: Frehemgo denecimig	New
18/09/2026	Medicine: Lifyorli relacorilant	New
18/09/2026	Post-authorisation: Anzupgo - opinion on variation to marketing authorisationdelgocitinib	New
18/09/2026	Post-authorisation: Cosentyx - opinion on variation to marketing authorisationsecukinumab	New
18/09/2026	Post-authorisation: Ocrevus - opinion on variation to marketing authorisationocrelizumab	New
18/09/2026	Medicine: Xervyteg Allogeneic faecal microbiota, pooled	Updated
18/09/2026	Medicine: VaxRabeo rabies vaccine (inactivated) for human	New
18/09/2026	Referral: Ipidacrine-containing medicinal products - referralipidacrine	Updated
18/09/2026	Referral: Sodium oxybate-containing syrup and oral solution for alcohol dependence - referralsodium oxybate	Updated
18/09/2026	News: Benefits of sodium oxybate continue to outweigh risks in people with alcohol dependency	New
18/09/2026	News: EMA concludes review of ipidacrine-containing medicines	New
18/09/2026	News: Meeting highlights from the Committee for Medicinal Products for Human Use (CHMP) 14-17 September 2026	New
18/09/2026	Post-authorisation: Keytruda - opinion on variation to marketing authorisationpembrolizumab	New
18/09/2026	Post-authorisation: Pradaxa - opinion on variation to marketing authorisationdabigatran etexilate	New
18/09/2026	Post-authorisation: Kaftrio - withdrawal of application for variation to marketing authorisationivacaftor; tezacaftor; elexacaftor	New
18/09/2026	Post-authorisation: Kalydeco - withdrawal of application for variation to marketing authorisationivacaftor	New
18/09/2026	Post-authorisation: Alhemo - withdrawal of application for variation to marketing authorisationconcizumab	New
18/09/2026	Post-authorisation: Abiraterone Mylan - opinion on variation to marketing authorisationabiraterone acetate	New
18/09/2026	Post-authorisation: Jyseleca - opinion on variation to marketing authorisationfilgotinib	New
18/09/2026	Post-authorisation: Sogroya - opinion on variation to marketing authorisationsomapacitan	Updated
18/09/2026	Post-authorisation: Tecvayli - opinion on variation to marketing authorisationteclistamab	New

Date	Content	Status
18/09/2026	Page: Veterinary good pharmacovigilance practices (VGVP)	Updated
18/09/2026	Document: Draft guideline on veterinary good pharmacovigilance practices (VGVP) Module: Signal Management - Revision 1	New
18/09/2026	Post-authorisation: Padcev - opinion on variation to marketing authorisation enfortumab vedotin	New
18/09/2026	Document: Antimicrobial Sales and Use (ASU) - Use data template	Updated
18/09/2026	Document: Antimicrobial Sales and Use (ASU) - Sales data template	Updated
18/09/2026	Page: Clinical investigation of medicinal products for the treatment of systemic sclerosis	Updated
18/09/2026	Document: Draft reflection paper on the clinical investigation of medicinal products for the treatment of systemic sclerosis	New
18/09/2026	Page: Questions and answers on post approval change management protocols (veterinary) - Scientific guideline	New
18/09/2026	Document: Questions and answers on post approval change management protocols for veterinary medicinal products	New
18/09/2026	Page: Guideline on the summary of product characteristics (SPC) for veterinary medicinal products containing antimicrobial substances - Scientific guideline	Updated
18/09/2026	Document: Concept paper on the revision of the CVMP guideline on the summary of product characteristics (SPC) for veterinary medicinal products containing antimicrobial substances (EMA/CVMP/383441/2005-Rev.1 Corr.1)	New
17/09/2026	Medicine: Grasustek pegfilgrastim	Updated
17/09/2026	Medicine: Fintepla fenfluramine	Updated
17/09/2026	Medicine: Vevzu denosumab	Updated
17/09/2026	Medicine: Denbray cedenosumab	Updated
17/09/2026	Medicine: Paxneury guanfacine	Updated
17/09/2026	Medicine: Qinlock ripretinib	Updated
17/09/2026	Medicine: Olumiant baricitinib	Updated
17/09/2026	Document: Plasma master file timetable: 60-day - Period 2026-2028	Updated
17/09/2026	Document: Plasma master file timetable: 30-day - Period 2026-2028	Updated
16/09/2026	Page: Electronic product information (ePI)	Updated
16/09/2026	Medicine: Mepact mifamurtide	Updated
16/09/2026	Page: ICH E14/S7B (R1) Q&As: The clinical evaluation of QT/ QTc interval prolongation and proarrhythmic potential for non-antiarrhythmic drugs - Questions and Answers	Updated
16/09/2026	Page: Scientific publications	Updated
16/09/2026	Medicine: Wezenlaustekinumab	Updated
16/09/2026	Medicine: Procysb imercaptamine	Updated
16/09/2026	Medicine: Ontruzan trastuzumab	Updated
16/09/2026	Medicine: Ezmekly mirdametinib	Updated
16/09/2026	Medicine: Symtuzada ronavir; cobicistat; emtricitabine; tenofovir alafenamide	Updated
16/09/2026	Medicine: Piqray alpelisib	Updated
16/09/2026	Medicine: Brinsupri Brensocatib	Updated
16/09/2026	Document: List of eligible industry stakeholder organisations	Updated
15/09/2026	Medicine: Jaypirca pirtobrutinib	Updated
15/09/2026	Document: Nominations to the Network Portfolio Advisory Group	Updated
15/09/2026	Medicine: Trodelvy sacituzumab govitecan	Updated
15/09/2026	Document: Medicinal products for human use: monthly figures - August 2026	New
15/09/2026	Event: Meeting of the Medicine Shortages Single Point of Contact (SPOC) Working Party	Updated

Date	Content	Status
15/09/2026	Medicine: Bekemveculizumab	Updated
15/09/2026	Medicine: Camcevilleuprorelin	Updated
15/09/2026	Medicine: DuoPlavinclopidogrel; acetylsalicylic acid	Updated
15/09/2026	Medicine: Enwylmadenosumab	Updated
15/09/2026	Medicine: Joenjaleniolisib	Updated
14/09/2026	PSUSA: EMA/PASS/0000287665 - periodic safety update report single assessmentvalproate	New
14/09/2026	PSUSA: PSUSA/00010000/202601 - periodic safety update report single assessment5 fluorouracil (topical application)	New
14/09/2026	Medicine: Zumradasanlimab	Updated
14/09/2026	Document: Annex to agenda of the CHMP meeting 14-17 September 2026	New
14/09/2026	Document: Agenda of the CHMP meeting 14-17 September 2026	New
14/09/2026	Medicine: Zonisamide Viatriis (previously Zonisamide Mylan)zonisamide	Updated
14/09/2026	Event: Committee for Medicinal Products for Human Use (CHMP): 14-17 September 2026	Updated
14/09/2026	Medicine: Zynlontaloncastuximab tesirine	Updated
14/09/2026	Medicine: Idefiriximlifidase	Updated
14/09/2026	Medicine: Abrysvorespiratory syncytial virus vaccine (bivalent, recombinant)	Updated
14/09/2026	Medicine: Fasenrabenralizumab	Updated
14/09/2026	Medicine: Xolremdimavorixafor	Updated
14/09/2026	Page: International collaboration on GMP inspections	Updated
14/09/2026	Document: Report on the International Active Pharmaceutical Ingredient Inspection Programme 2017 – 2024	

NOTICE TO APPLICANTS

No updates since July 10th, 2026.

BFARM - PHARMAKOVIGILANZ (SPECIFIC FOR GERMANY)

Date	Title
17.09.2026	Umsetzung des einstimmigen Beschlusses der Koordinierungsgruppe vom 23.07.2026 betreffend die Zulassungen für Humanarzneimittel mit dem Wirkstoff Coffein/Dimenhydrinat, Dimenhydrinat Das BfArM veröffentlicht den Umsetzungsbescheid für den Wirkstoff Coffein/Dimenhydrinat, Dimenhydrinat (d.h. Monoarzneimittel mit dem Wirkstoff Dimenhydrinat und Kombinationsarzneimittel mit der Wirkstoffkombination Coffein/Dimenhydrinat) infolge des Europäischen PSUR Single Assessment Verfahrens nach Artikel 107d) bis g) der Richtlinie 2001/83/EG.
15.09.2026	Aktuelle Hinweise zu Einreichung und Genehmigung von Schulungsmaterial Aktualisierung der Hilfestellungsdokumente zur Einreichung und Genehmigung von behördlich genehmigten Schulungsmaterialien.
08.09.2026	Vorläufige Tagesordnung der 99. Routinesitzung am 28. September 2026 Die 99. Routinesitzung nach § 63 AMG wird am 28. September 2026 ab 10:00 Uhr als Videokonferenz stattfinden.

BFARM – MEDIZINPRODUKTE (SPECIFIC FOR GERMANY)

Date	Title
08.09.2026	Die Handreichung für das Verzeichnis der Hilfsmittel- und Implantat-Schnittstellen nach § 374a SGB V Version 1.1 vom 31.08.2026

PEI - VIGILANZ (SPECIFIC FOR GERMANY)

Date	Title
17.09.2026	Informationsbrief von Biotest Pharma GmbH: Yimmugo

PHARMEUROPA TEXTS FOR COMMENT

Information on Pharmedeuropa updates will be presented quarterly.

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