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HEADS OF AGENCIES – CMDh

15 September

NEW - 16-18 September CMDh agenda

HEADS OF AGENCIES – PAEDIATRIC REGULATION

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

EUROPEAN MEDICINES AGENCY (EMA)

Date	Content	Status
19/09/2025	Event: Questions and answers clinic on Product Management Service (PMS) Product User Interface (PUI) and Application Programming Interface (API) - August 2025	Updated
19/09/2025	Event: 1st EMA/HMA multi-stakeholder forum on EudraVigilance and signal detection	Updated
19/09/2025	Event: HMA/EMA multi-stakeholder workshop on reporting and qualification of mechanistic models for regulatory assessment	Updated
19/09/2025	Medicine: Epysqli	Updated
19/09/2025	Medicine: Jubbonti	Updated
19/09/2025	Medicine: Wezenla	Updated
19/09/2025	Medicine: Calquence	Updated
19/09/2025	Medicine: Ordspono	Updated
19/09/2025	Medicine: Tepkinly	Updated
19/09/2025	Medicine: Ervebo	Updated
19/09/2025	Referral: Ixchiq - referral	Updated

Date	Content	Status
19/09/2025	Document: EVVet3 EVWeb Production - Release notes	Updated
19/09/2025	Medicine: Enflonsia	New
19/09/2025	Medicine: Imaavy	New
19/09/2025	News: First treatment recommended for rare immunoglobulin-related autoimmune disease	New
19/09/2025	Medicine: Acvybra	New
19/09/2025	Medicine: Denosumab Intas	New
19/09/2025	Medicine: Degevma	New
19/09/2025	Medicine: Rivaroxaban Koanaa	New
19/09/2025	Medicine: Ponlimsi	New
19/09/2025	Medicine: Lynkuet	New
19/09/2025	Medicine: Kefdensis	New
19/09/2025	Medicine: Gobivaz	New
19/09/2025	Medicine: Usgena	New
19/09/2025	Medicine: Kyinsu	New
19/09/2025	Medicine: Zvogra	New
19/09/2025	Medicine: Atropine sulfate FGK	Updated
19/09/2025	Medicine: Omforro	New
19/09/2025	Medicine: Tuzodi	New
19/09/2025	Medicine: Lutathera	Updated
19/09/2025	News: Meeting highlights from the Committee for Medicinal Products for Human Use (CHMP) 15-18 September 2025	New
19/09/2025	Post-authorisation: Uplizna - opinion on variation to marketing authorisation	New
19/09/2025	Post-authorisation: Keytruda - opinion on variation to marketing authorisation	New
19/09/2025	Post-authorisation: Lunsumio - opinion on variation to marketing authorisation	New
19/09/2025	Post-authorisation: Bimervax - opinion on variation to marketing authorisation	New
19/09/2025	Post-authorisation: Norvir - opinion on variation to marketing authorisation	New
19/09/2025	Post-authorisation: Koselugo - opinion on variation to marketing authorisation	New

Date	Content	Status
19/09/2025	Post-authorisation: Tezspire - opinion on variation to marketing authorisation	New
19/09/2025	Post-authorisation: Keytruda - opinion on variation to marketing authorisation	New
19/09/2025	Post-authorisation: Dupixent - opinion on variation to marketing authorisation	New
19/09/2025	Document: Veterinary Dictionary for Drug Regulatory Activities (VeDDRA) dataload friendly file including deprecated terms	Updated
19/09/2025	Event: EMA Cancer Medicines Forum (CMF) meeting with industry stakeholders on cancer treatment optimisation	Updated
19/09/2025	Page: The procedure to be followed when a batch of a vaccine finished product is suspected to be contaminated with bovine viral diarrhoea virus - Scientific guideline	Updated
19/09/2025	Page: Duration of immunity achieved by veterinary vaccines - Scientific guideline	Updated
19/09/2025	Document: Substances considered as not falling within the scope of Regulation (EC) No. 470/2009, with regard to residues of veterinary medicinal products in foodstuffs of animal origin	Updated
19/09/2025	Document: Procedural advice on appointment and responsibilities of the CVMP rapporteur and co-rapporteur in accordance with Article 140(6) of Regulation (EU) 2019/6, and peer reviewer	Updated
19/09/2025	DHPC: Rapamune - direct healthcare professional communication (DHPC)	New
19/09/2025	Referral: Finasteride- and dutasteride-containing medicinal products - referral	Updated
18/09/2025	Medicine: mResvia	Updated
18/09/2025	Medicine: Zonegran	Updated
18/09/2025	Medicine: Obodence	Updated
18/09/2025	Medicine: Vfend	Updated
18/09/2025	Shortage: Visudyne	Updated
18/09/2025	Medicine: Increlex	Updated
18/09/2025	Medicine: Lyrica	Updated
18/09/2025	Event: ACT EU workshop on ICH E6 R3 (principles and Annex 1)	Updated
18/09/2025	Document: Management Board meeting dates 2026-2027	New
18/09/2025	Event: Q&A clinic on Substance, Organisation, Referentials Management Services	Updated
18/09/2025	Event: Cancer Medicines Forum: June 2025	New

Date	Content	Status
18/09/2025	Medicine: Leqvio	Updated
18/09/2025	Medicine: Replagal	Updated
18/09/2025	Page: Network Data Steering Group (NDSG)	Updated
18/09/2025	Document: Overview of Network Data Steering Group (NDSG) change management activities 2025-2026	New
17/09/2025	Document: Letter of intent for the submission of a worksharing procedure to the European Medicines Agency according to Article 65 of Regulation (EU) 2019/6	Updated
17/09/2025	Medicine: Jemperli	Updated
17/09/2025	Medicine: Ogluo	Updated
17/09/2025	Medicine: Roclanda	Updated
17/09/2025	Medicine: Abecma	Updated
17/09/2025	Medicine: Conexxence	Updated
17/09/2025	Document: Quick guide to competing interests for EMA experts	New
17/09/2025	Document: Questions and answers on Implementing Regulation (EU) 2025/1466: Amendment of Regulation (EU) No 520/2012 and Conclusion of the Signal Detection in EudraVigilance Pilot by marketing authorisation holders	Updated
17/09/2025	Document: Article 57 product data	Updated
17/09/2025	Page: Website outages and upgrades	Updated
17/09/2025	Medicine: Cabometyx	Updated
17/09/2025	Event: Workshop on a tailored clinical approach in biosimilar development	Updated
17/09/2025	Medicine: Viagra	Updated
17/09/2025	Medicine: Revatio	Updated
17/09/2025	Medicine: Pregabalin Viatris Pharma (previously Pregabalin Pfizer)	Updated
17/09/2025	Page: Worksharing of variations (veterinary medicines)	Updated
17/09/2025	Document: UPD registration guide for UI and API users	Updated
17/09/2025	Medicine: Stoboclo	Updated
17/09/2025	Medicine: Bomynta	Updated
17/09/2025	Medicine: Zirabev	Updated
17/09/2025	EU-M4all: Dengue Tetravalent Vaccine (Live, Attenuated) Takeda - opinion on medicine for use outside EU	Updated
17/09/2025	Medicine: Xalkori	Updated

Date	Content	Status
17/09/2025	Event: First European Medicines Agency (EMA) and Association of Clinical Research Organizations (ACRO) bilateral meeting	Updated
17/09/2025	Medicine: Vyndaqel	Updated
17/09/2025	Medicine: Rapamune	Updated
17/09/2025	Medicine: Pemetrexed Pfizer (previously Pemetrexed Hospira)	Updated
17/09/2025	Medicine: Mylotarg	Updated
17/09/2025	Medicine: Levetiracetam Hospira	Updated
17/09/2025	Medicine: Elrexfio	Updated
17/09/2025	Medicine: Daptomycin Hospira	Updated
17/09/2025	Medicine: Besponsa	Updated
17/09/2025	Medicine: Emblaveo	Updated
17/09/2025	Medicine: Attrogy	Updated
16/09/2025	Document: EU Implementation Guide (IG) on veterinary medicines product data in the Union Product Database - Chapter 2: Format for the electronic submission of veterinary medicinal product information	Updated
16/09/2025	Medicine: Tevimbra	Updated
16/09/2025	Page: Mpox	Updated
16/09/2025	Orphan: EU/3/07/434 - orphan designation for treatment of Leber's hereditary optic neuropathy	Updated
16/09/2025	Orphan: EU/3/12/1063 - orphan designation for treatment of multiple myeloma	Updated
16/09/2025	Event: LinkedIn Live: Smarter trials, stronger Europe. New targets for clinical research.	New
16/09/2025	Page: Human Medicines	Updated
16/09/2025	Document: Organisation chart: Human Medicines	Updated
15/09/2025	Medicine: Baqsimi	Updated
15/09/2025	Event: Committee for Advanced Therapies (CAT) workshop on gene editing	Updated
15/09/2025	Medicine: Emselex	Updated
15/09/2025	Event: Committee for Medicinal Products for Human Use (CHMP): 15-18 September 2025	Updated
15/09/2025	Document: Annex to agenda of the CHMP meeting 15-18 September 2025	New
15/09/2025	Document: Agenda of the CHMP meeting 15-18 September 2025	New
15/09/2025	Page: Scientific Advisory Group on Immune and Inflammatory Diseases	Updated

Date	Content	Status
15/09/2025	Document: Public call for expression of interest for experts to become members of the European Medicines Agency's Scientific Advisory Group on Immune and Inflammatory Diseases	Updated
15/09/2025	Medicine: Takhzyro	Updated
15/09/2025	Medicine: Locametz	Updated
15/09/2025	Medicine: Thalidomide Lipomed	Updated
15/09/2025	Document: Network Portfolio Roadmap	Updated

NOTICE TO APPLICANTS

No updates since September 03rd, 2025.

BFARM - PHARMAKOVIGILANZ (SPECIFIC FOR GERMANY)

Date	Title
17.09.2025	<p>Umsetzung des einstimmigen Beschlusses der Koordinierungsgruppe vom 24.07.2025 betreffend die Zulassungen für Humanarzneimittel mit der Wirkstoffkombination Acetylsalicylsäure/Bisoprolol</p> <p>Das BfArM veröffentlicht den Umsetzungsbescheid für die Wirkstoffkombination Acetylsalicylsäure/Bisoprolol infolge des Europäischen PSUR Single Assessment Verfahrens nach Artikel 107d) bis g) der Richtlinie 2001/83/EG.</p>
16.09.2025	<p>Finasterid- und dutasteridhaltige Arzneimittel: Suizidale Gedanken und Verhaltensweisen</p> <p>Wirkstoff: Finasterid, Dutasterid</p> <p>Das Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM) setzt mit Bescheid vom 09.09.2025 den Durchführungsbeschluss der EU-Kommission national um.</p>

BFARM – MEDIZINPRODUKTE (SPECIFIC FOR GERMANY)

No updates since August 26th, 2025.

PEI - VIGILANZ (SPECIFIC FOR GERMANY)

Date	Title
18.09.2025	Rote-Hand-Brief: Ixchiq (Chikungunya-Impfstoff)

PHARMEUROPA TEXTS FOR COMMENT

Information on Pharmeuropa updates will be presented quarterly.

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