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HEADS OF AGENCIES – CMDh

No updates since February 13th, 2026.

HEADS OF AGENCIES – PAEDIATRIC REGULATION

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

EUROPEAN MEDICINES AGENCY (EMA)

Date	Content	Status
20/02/2026	Medicine: Dawnzera donidalorsen	Updated
20/02/2026	Page: ICH M4Q - The Common Technical Document for the registration of pharmaceuticals for human use - Quality - Scientific guideline	Updated
20/02/2026	Document: Overview of comments on ICH M4Q(R2) : Guideline on the Common Technical Document for the registration of pharmaceuticals for human use - Quality - Step 2b	New
20/02/2026	Event: Committee for Medicinal Products for Veterinary Use (CVMP): 13-15 January 2026	Updated
20/02/2026	Document: Minutes of the CVMP meeting 13-15 January 2026	New
20/02/2026	Document: Minutes of the CVMP meeting 2-4 December 2025	New
20/02/2026	Medicine: Osqay denosumab	Updated
20/02/2026	Medicine: Semglee insulin glargine	Updated
20/02/2026	Document: Question and answer on the information contained within section 5.1 of the summary of product characteristics on pharmacodynamic properties for pharmaceutical products	Updated
20/02/2026	Medicine: Teizeild teplizumab	Updated
20/02/2026	Medicine: Vfend voriconazole	Updated
20/02/2026	Page: Guideline on quality aspects of mRNA vaccines for veterinary use	Updated

Date	Content	Status
20/02/2026	EU-M4all: Lenacapavir Gilead - opinion on medicine for use outside EU lenacapavir	Updated
20/02/2026	Page: ICH Q2(R2) Validation of analytical procedures - Scientific guideline	Updated
20/02/2026	News: Recruitment procedure opens for next Executive Director of the European Medicines Agency	New
20/02/2026	Medicine: Apremilast Accord apremilast	Updated
20/02/2026	Document: Draft guideline on quality aspects of mRNA vaccines for veterinary use	New
20/02/2026	PSUSA: PSUSA/00001307/202507 - periodic safety update report single assessment ethinylestradiol / etonogestrel	New
20/02/2026	Medicine: Palonosetron Accord palonosetron	Updated
20/02/2026	Medicine: Lyvdelzi (previously Seladelpar Gilead) seladelpar lysine dihydrate	Updated
20/02/2026	Medicine: Kevzara sarilumab	Updated
20/02/2026	Medicine: Ameluz 5-aminolevulinic acid hydrochloride	Updated
20/02/2026	Page: Risk management requirements for elemental impurities in veterinary medicinal products - Scientific guideline	Updated
19/02/2026	Medicine: Casgevy exagamglogene autotemcel	Updated
19/02/2026	Medicine: Dovprela (previously Pretomanid FGK) pretomanid	Updated
19/02/2026	Medicine: Lynparza olaparib	Updated
19/02/2026	Medicine: Waskyra etuvetidigene autotemcel	Updated
19/02/2026	Medicine: Imfinzi durvalumab	Updated
19/02/2026	Medicine: Klisyri tirbanibulin	Updated
19/02/2026	Medicine: Nuvaxovid COVID-19 Vaccine (recombinant, adjuvanted)	Updated
19/02/2026	Medicine: Uptravi selexipag	Updated
19/02/2026	Medicine: Kigabeq vigabatrin	Updated
19/02/2026	Medicine: Adzynma rADAMTS13	Updated
19/02/2026	Medicine: Enrylaze crisantaspase	Updated
19/02/2026	Document: Data access to medicinal products for human use - Chapter 5 Annex A: Product data elements accessible by stakeholder group	Updated

Date	Content	Status
19/02/2026	Document: Pharmacovigilance-related regulatory recommendations for centrally authorised veterinary medicinal products during 2026	New
19/02/2026	Medicine: Soliris eculizumab	Updated
19/02/2026	Medicine: Fulphila pegfilgrastim	Updated
19/02/2026	Medicine: Sibnaya potassium citrate; potassium hydrogen carbonate	Updated
19/02/2026	Medicine: Mysimba naltrexone; bupropion	Updated
19/02/2026	Medicine: Evfraxy denosumab	Updated
19/02/2026	Medicine: Hulio adalimumab	Updated
18/02/2026	Event: Committee for Advanced Therapies (CAT): 18-20 February 2026	Updated
18/02/2026	Document: Agenda of the CAT meeting 18-20 February 2026	New
18/02/2026	Event: European Medicines Regulatory Network (EMRN) workshop on Geographic Atrophy endpoints	Updated
18/02/2026	Medicine: Teriflunomide Accord teriflunomide	Updated
18/02/2026	Medicine: Orladeyo berotralstat	Updated
18/02/2026	Medicine: Zemcelpro allogeneic umbilical cord-derived CD34- cells, non-expanded; dorocubicel	Updated
18/02/2026	Medicine: Pluvicto lutetium (177Lu) vipivotide tetraxetan	Updated
18/02/2026	Page: Podcast: Inside EMA	Updated
18/02/2026	Medicine: Epysqli eculizumab	Updated
18/02/2026	Medicine: Wezenla ustekinumab	Updated
18/02/2026	Medicine: Cejemly sugemalimab	Updated
18/02/2026	Document: Vaccine Monitoring Platform: List of EMA-funded studies	Updated
17/02/2026	Medicine: Vevzuo denosumab	Updated
17/02/2026	Shortage: Trulicity dulaglutide	Updated
17/02/2026	Event: ACT EU multi-stakeholder platform annual meeting	Updated
17/02/2026	Medicine: Inflectra infliximab	Updated
17/02/2026	Document: Scientific advice and protocol assistance adopted during the CHMP meeting 26-29 January 2026	New
17/02/2026	Medicine: Uplizna inebilizumab	Updated

Date	Content	Status
17/02/2026	Medicine: Arexvy recombinant respiratory syncytial virus pre-fusion F protein, adjuvanted with AS01E	Updated
17/02/2026	Medicine: Bronchitol mannitol	Updated
17/02/2026	Medicine: Trecondi treosulfan	Updated
17/02/2026	Medicine: Imbruvica ibrutinib	Updated
17/02/2026	Page: Immune and Inflammatory Disease Working Party (IIWP)	Updated
17/02/2026	Document: Agenda - Medicine Shortages SPOC Working Party meeting 17 February 2026	New
17/02/2026	Medicine: Usrenty ustekinumab	Updated
17/02/2026	PSUSA: PSUSA/00010876/202506 - periodic safety update report single assessment amlodipine / irbesartan	New
16/02/2026	Document: Minutes of the CHMP meeting 21-24 July 2025	Updated
16/02/2026	Document: Minutes of the CHMP meeting 19-22 May 2025	Updated
16/02/2026	Page: Clinical Pharmacology Operational Expert Group	New
16/02/2026	Medicine: Lunsumio mosunetuzumab	Updated
16/02/2026	PSUSA: PSUSA/00010606/202506 - periodic safety update report single assessment itopride	New
16/02/2026	Medicine: Vaxelis diphtheria, tetanus, pertussis (acellular, component), hepatitis B (rDNA), poliomyelitis (inactivated) and Haemophilus type b conjugate vaccine (adsorbed)	Updated
16/02/2026	Medicine: Pregabalin Zentiva pregabalin	Updated
16/02/2026	Event: Committee for Orphan Medicinal Products (COMP): 17-19 February 2026	Updated
16/02/2026	Medicine: Orphacol cholic acid	Updated
16/02/2026	Medicine: Dovato dolutegravir; lamivudine	Updated
16/02/2026	PSUSA: PSUSA/00010572/202506 - periodic safety update report single assessment nitrous oxide / oxygen	New
16/02/2026	Medicine: Luxturna voretigene neparvovec	Updated
16/02/2026	Medicine: Jemperli dostarlimab	Updated
16/02/2026	Document: Overview of comments received on Q&A regarding co-processed excipients used in solid oral dosage forms H and V (EMA/CHMP/CVMP/QWP/422493/2024)	Updated
16/02/2026	Page: ICH E20 adaptive designs for clinical trials - Scientific guideline	Updated

Date	Content	Status
16/02/2026	Document: HMA-EMA joint Network Data Steering Group meeting - 13 January 2026	New
16/02/2026	Document: PDCO minutes of the 9-12 December 2025 meeting	New
16/02/2026	Medicine: Yesintek ustekinumab	Updated
16/02/2026	PSUSA: PSUSA/00002042/202507 - periodic safety update report single assessment chlorquinaldol / metronidazole	New
16/02/2026	Page: Good pharmacovigilance practices (GVP)	Updated
16/02/2026	Medicine: Hefiya adalimumab	Updated
16/02/2026	Medicine: Ibuprofen Gen.Orph ibuprofen	Updated
16/02/2026	Medicine: Enspryng satralizumab	Updated
16/02/2026	PSUSA: PSUSA/00000080/202506 - periodic safety update report single assessment alfacalcidol	New
16/02/2026	PSUSA: PSUSA/00009225/202506 - periodic safety update report single assessment magnesium sulfate	New
16/02/2026	Herbal: Ribis nigri folium - herbal medicinal product Blackcurrant Leaf	Updated
16/02/2026	Document: Draft European Union herbal monograph on Ribes nigrum L., folium - Revision 2	New

NOTICE TO APPLICANTS

No updates since October 30th, 2025.

BFARM - PHARMAKOVIGILANZ (SPECIFIC FOR GERMANY)

Date	Title
23.02.2026	Informationen zu Einreichung und Genehmigung von Schulungsmaterial Aktualisierung der Hilfestellungsdokumente zur Einreichung und Genehmigung von behördlich genehmigten Schulungsmaterialien.
18.02.2026	Gadoliniumhaltige Kontrastmittel: Gadoliniumablagerungen im Gehirn und anderen Geweben Wirkstoff: Gadolinium Für gadoliniumhaltige Kontrastmittel ist das Ruhen der Zulassungen bis zum 28.02.2028 verlängert worden.

BFARM – MEDIZINPRODUKTE (SPECIFIC FOR GERMANY)

No updates since January 27th, 2026.

PEI - VIGILANZ (SPECIFIC FOR GERMANY)

No updates since February 13th, 2026.

PHARMEUROPA TEXTS FOR COMMENT

Information on Pharmedropa updates will be presented quarterly.

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