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HEADS OF AGENCIES – CMDh

No updates since September 25th, 2025.

HEADS OF AGENCIES – PAEDIATRIC REGULATION

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

EUROPEAN MEDICINES AGENCY (EMA)

Date	Content	Status
10/10/2025	Medicine: Syfovre pegcetacoplan	Updated
10/10/2025	Medicine: Teriparatide Sun teriparatide	Updated
10/10/2025	Page: European Shortages Monitoring Platform (ESMP)	Updated
10/10/2025	Page: Interoperability assessment at EMA	New
10/10/2025	Document: Presentation - The summary-of-product-characteristics guideline and paediatric aspects	Updated
10/10/2025	Page: Medicines for human use under evaluation	Updated
10/10/2025	Document: Applications for new human medicines under evaluation: October 2025	New
10/10/2025	Document: HMPC meeting report on European Union herbal monographs, guidelines and other activities - 22-24 September 2025	New
10/10/2025	Event: PMS Product user interface (PUI) Training: Product data submission & bulk edit made easy	Updated
10/10/2025	Medicine: Vaxxitek HVT+IBD+H5 avian influenza vaccine (live recombinant)	New

Date	Content	Status
10/10/2025	Medicine: Leniviai zenivetmab	New
10/10/2025	News: Meeting highlights from the Committee for Veterinary Medicinal Products (CVMP) 7-9 October 2025	New
10/10/2025	Event: European Medicines Agency (EMA) and European Respiratory Society (ERS) bilateral meeting	New
10/10/2025	Medicine: Carvykti ciltacabtagene autoleucel	Updated
10/10/2025	Page: ICH M14 guideline on general principles on plan, design and analysis of pharmacoepidemiological studies that utilize real-world data for safety assessment of medicines - Scientific guideline	Updated
10/10/2025	Document: ICH M14 guideline on general principles on planning, designing, analysing, and reporting of non-interventional studies that utilise real-world data for safety assessment of medicines Step 5	New
10/10/2025	Document: Nitrosamines EMEA-H-A5(3)-1490 - Questions and answers for marketing authorisation holders / applicants on the CHMP Opinion for the Article 5(3) of Regulation (EC) No 726/2004 referral on nitrosamine impurities in human medicinal products	Updated
09/10/2025	Medicine: Novem meloxicam	Updated
09/10/2025	Medicine: Oncept IL-2 feline interleukin-2 recombinant canarypox virus (vCP1338 virus)	Updated
09/10/2025	Medicine: Osumnia terbinafine; florfenicol; betamethasone	Updated
09/10/2025	Medicine: Nobilis IB Primo QX avian infectious bronchitis virus strain D388	Updated
09/10/2025	Medicine: Nobivac Bb live vaccine against Bordetella bronchiseptica in cats	Updated
09/10/2025	Medicine: Novaquin meloxicam	Updated
09/10/2025	Medicine: Denbrayce denosumab	Updated
09/10/2025	Medicine: Porcilis Porcoli Diluvac Forte (previously Porcilis Porcoli) vaccine to provide passive immunity to the progeny against E. coli in pigs	Updated
09/10/2025	Medicine: Porcilis AR-T DF adjuvanted vaccine against progressive atrophic rhinitis in piglets	Updated

Date	Content	Status
09/10/2025	Medicine: Melosus meloxicam	Updated
09/10/2025	Medicine: Meloxidolor meloxicam	Updated
09/10/2025	Medicine: Meloxidyl meloxicam	Updated
09/10/2025	Medicine: Pexion imepitoïn	Updated
09/10/2025	Medicine: Loxicom meloxicam	Updated
09/10/2025	Medicine: Lydaxx tulathromycin	Updated
09/10/2025	Medicine: Masivet masitinib mesilate	Updated
09/10/2025	PIP: EMA-002640-PIP01-19-M01 - paediatric investigation plan cendakimab	Updated
09/10/2025	PIP: EMA-002944-PIP02-22 - paediatric investigation plan danuglipron	Updated
09/10/2025	Medicine: Comirnaty COVID-19 mRNA vaccine	Updated
09/10/2025	Medicine: Spikevax (previously COVID-19 Vaccine Moderna) COVID-19 mRNA vaccine	Updated
09/10/2025	Medicine: Fulvestrant Mylan fulvestrant	Updated
09/10/2025	Medicine: Emgality galcanezumab	Updated
09/10/2025	Medicine: Zeposia ozanimod	Updated
09/10/2025	Medicine: Gardasil 9 human papillomavirus 9-valent vaccine (recombinant, adsorbed)	Updated
09/10/2025	Medicine: Scemblix asciminib	Updated

Date	Content	Status
09/10/2025	Medicine: Nasym bovine respiratory syncytial virus vaccine (live)	Updated
09/10/2025	Medicine: MS-H Vaccine Mycoplasma synoviae (live)	Updated
09/10/2025	Medicine: Mirataz mirtazapine	Updated
09/10/2025	Medicine: Adasuve oxapine	Updated
09/10/2025	Document: Annual report of the Pharmacovigilance Inspectors Working Group for 2024	New
09/10/2025	Medicine: Tuznuet rastuzumab	Updated
09/10/2025	Medicine: Memantine Accord memantine	Updated
09/10/2025	Medicine: Neptra florfenicol; terbinafine hydrochloride; mometasone furoate	Updated
09/10/2025	Medicine: OvuGel triptorelin	Updated
09/10/2025	Medicine: Zadenvi denosumab	Updated
09/10/2025	Medicine: Oxyglobin haemoglobin glutamer-200 (bovine)	Updated
09/10/2025	Medicine: Locatim (previously Serinucoli) locatim, oral solution for neonatal calves less than 12 hours of age	Updated
09/10/2025	Medicine: Letifend canine leishmaniasis vaccine (recombinant protein)	Updated
09/10/2025	Medicine: Kriptazen halofuginone	Updated
08/10/2025	Event: Workshop on the use of external controls for evidence generation in regulatory decision-making	Updated
08/10/2025	PIP: EMA-003463-PIP01-23 - paediatric investigation plan human alpha-1 proteinase inhibitor, modified (SerpPC)	Updated
08/10/2025	Medicine: Ingelvac CircoFLEX	Updated

Date	Content	Status
	inactivated porcine circovirus vaccine	
08/10/2025	Medicine: Humira adalimumab	Updated
08/10/2025	Medicine: Azacitidine Accordia zacitidine	Updated
08/10/2025	Medicine: Inflacam meloxicam	Updated
08/10/2025	Medicine: Briumvi ublituximab	Updated
08/10/2025	Medicine: Tecvayli teclistamab	Updated
08/10/2025	Document: Agenda of the CAT meeting 8-9 October 2025	Updated
08/10/2025	Medicine: Gazyvaro obinutuzumab	Updated
08/10/2025	Event: EMA roundtable with stakeholders on the 20th anniversary of the SME Regulation	Updated
08/10/2025	Document: Union Product Database (UPD) - Quick guide for UPD notifications via the user interface and via email	Updated
08/10/2025	Event: EMA workshop: Non-clinical data for regulatory decision-making on the efficacy of medical countermeasures	New
08/10/2025	Medicine: Isemid torasemide	Updated
08/10/2025	Document: European Medicines Agency mid-year report 2025 (January-June 2025)	New
08/10/2025	Medicine: Ekterly sebetralstat	Updated
07/10/2025	PIP: EMEA-001073-PIP02-14 - paediatric investigation plan varicella-zoster virus (inactivated)	Updated
07/10/2025	PIP: EMEA-001207-PIP06-22 - paediatric investigation plan Obinutuzumab	Updated
07/10/2025	PSUSA: PSUSA/00010130/202502 - periodic safety update report single assessment potassium para-aminobenzoate	New
07/10/2025	Medicine: Bemrist Breezhaler	Updated

Date	Content	Status
	indacaterol; mometasone	
07/10/2025	Medicine: Selincro nalmefene	Updated
07/10/2025	Medicine: Benlysta belimumab	Updated
07/10/2025	Document: Minutes of the CHMP written procedure 18-21 August 2025	New
07/10/2025	Event: SPOR and XEVMPD status update webinar	Updated
07/10/2025	Medicine: Cinacalcet Viatris (previously Cinacalcet Mylan) cinacalcet	Updated
07/10/2025	Event: European Medicines Agency (EMA) Patients' and Consumers' (PCWP) and Healthcare Professionals' (HCPWP) Working Parties meeting with all eligible organisations - 2025	New
07/10/2025	Page: EU enlargement	Updated
07/10/2025	Medicine: Brukinsa zanubrutinib	Updated
07/10/2025	Document: HMA-EMA joint Network Data Steering Group meeting - 16 September 2025	New
07/10/2025	Event: Public webinar on shortages: putting patients first	Updated
07/10/2025	Document: Agenda - Instrument for Pre-accession Assistance (IPA) training on assessing medicinal products in the EU: A practical introduction	New
07/10/2025	Event: EMA/HMA annual data forum	Updated
07/10/2025	Medicine: Daxas roflumilast	Updated
07/10/2025	Medicine: Halocur halofuginone	Updated
07/10/2025	Page: Website outages and upgrades	Updated
07/10/2025	Medicine: Tepadina thiotepa	Updated
07/10/2025	Medicine: Halagon halofuginone	Updated
07/10/2025	Medicine: Galliprant grapiprant	Updated
07/10/2025	Document: Q&A on impact of EU-USA Mutual Recognition Agreement on marketing authorisation applications and relevant variations - Revised 1st October 2025	Updated

Date	Content	Status
07/10/2025	Document: Questions & Answers on the impact of Mutual Recognition Agreement (MRA) between the European Union and the United States as of 1st October 2025	Updated
07/10/2025	Document: Agenda of the CVMP meeting 7-9 October 2025	New
07/10/2025	DHPC: Finasteride / dutasteride - direct healthcare professional communication (DHPC) Finasteride; dutasteride	New
06/10/2025	PSUSA: PSUSA/00002413/202502 - periodic safety update report single assessment pimozide	New
06/10/2025	PSUSA: PSUSA/00003129/202501 - periodic safety update report single assessment warfarin	New
06/10/2025	Medicine: Minjuvit afasitamab	Updated
06/10/2025	Medicine: Lenalidomide Mylan lenalidomide	Updated
06/10/2025	Medicine: Aplidin plitidepsin	Updated
06/10/2025	Medicine: Imnovid (previously Pomalidomide Celgene) pomalidomide	Updated
06/10/2025	Event: Q&A clinic on web-based electronic application form (eAF) functionalities for CAPs and non-CAPs	Updated
06/10/2025	Medicine: Nuvaxovid COVID-19 Vaccine (recombinant, adjuvanted)	Updated
06/10/2025	Page: CAT: Working parties and other groups	Updated
06/10/2025	Page: CVMP: Working parties and other groups	Updated
06/10/2025	Page: CHMP: Working parties and other groups	Updated
06/10/2025	Medicine: Imlygic talimogene laherparepvec	Updated
06/10/2025	Document: Agenda of the COMP meeting 7-8 October 2025	New
06/10/2025	Medicine: Anzupgo delgocitinib	Updated
06/10/2025	Medicine: Rixathon rituximab	Updated

Date	Content	Status
06/10/2025	Page: Maximum residue limits (MRL)	Updated
06/10/2025	Document: Scientific advice on MRL classification of chemical-unlike biological substances considered as not requiring an MRL evaluation according to Regulation (EU) 2018/782	New
06/10/2025	Medicine: Pregabalin Sandoz pregabalin	Updated
06/10/2025	Page: Business hours and holidays	Updated
06/10/2025	Medicine: Capvaxive pneumococcal polysaccharide conjugate vaccine (21-valent)	Updated

NOTICE TO APPLICANTS

No updates since September 03rd, 2025.

BFARM - PHARMAKOVIGILANZ (SPECIFIC FOR GERMANY)

Date	Title
09.10.2025	Rote-Hand-Brief zu Caspofungin: Vermeidung der Verwendung von Polyacrylnitril-Membranen bei der kontinuierlichen Nierenersatztherapie Wirkstoff: Caspofungin Die Zulassungsinhaber von caspofunginhaltigen Arzneimitteln informieren darüber, dass während der Behandlung mit Caspofungin die Verwendung von Polyacrylnitril-Membranen bei der kontinuierlichen Nierenersatztherapie vermieden werden sollte.
07.10.2025	Pharmacovigilance Risk Assessment Committee (PRAC) Das Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM) veröffentlicht die neuen Signale, die im Rahmen der PRAC-Sitzung vom 29.09.-01.10.2025 behandelt wurden.

BFARM – MEDIZINPRODUKTE (SPECIFIC FOR GERMANY)

No updates since September 24th, 2025.

PEI - VIGILANZ (SPECIFIC FOR GERMANY)

Date	Title
09.10.2025	Rote-Hand-Brief: Crysvita (Burosumab)

PHARMEUROPA TEXTS FOR COMMENT

Information on Pharmeuropa updates will be presented quarterly.

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