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HEADS OF AGENCIES – CMDh

No updates since August 4th, 2026.

HEADS OF AGENCIES – PAEDIATRIC REGULATION

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

EUROPEAN MEDICINES AGENCY (EMA)

Date	Content	Status
28/08/2026	Document: Innovation Task Force (ITF) briefing meeting request form	Updated
28/08/2026	Medicine: Mounjaro tirzepatide	Updated
28/08/2026	PSUSA: PSUSA/00001088/202512 - periodic safety update report single assessment caffeine / dimenhydrinate, dimenhydrinate	New
28/08/2026	Medicine: Herzuma trastuzumab	Updated
28/08/2026	PSUSA: PSUSA/00000732/202512 - periodic safety update report single assessment choline salicylate	New
28/08/2026	Page: Electronic product information (ePI)	Updated
28/08/2026	PSUSA: PSUSA/00011041/202510 - periodic safety update report single assessment ramipril / bisoprolol	New
28/08/2026	Document: How to pay fees and charges levied by EMA: Guidance to marketing authorisation holders and applicants	Updated

Date	Content	Status
28/08/2026	Page: How to pay	Updated
28/08/2026	Document: SEPA Direct Debit B2B: Guidance for marketing authorisation holders and applicants	New
28/08/2026	Medicine: SomaKit TOC edotreotide	Updated
27/08/2026	Medicine: Vyndaqel tafamidis	Updated
27/08/2026	Page: Tackling antimicrobial resistance: Information for animal health practitioners	Updated
27/08/2026	Medicine: Bilprevda denosumab	Updated
27/08/2026	Medicine: Hulio adalimumab	Updated
27/08/2026	Medicine: Hemgenix etranacogene dezaparvovec	Updated
27/08/2026	Medicine: mResvia respiratory syncytial virus mRNA vaccine	Updated
27/08/2026	Medicine: Vorango vorasidenib	Updated
27/08/2026	Shortage: Paliperidone palmitate	New
27/08/2026	Medicine: Tecvayli teclistamab	Updated
27/08/2026	Medicine: Qinlock ripretinib	Updated
27/08/2026	Medicine: Kauliv teriparatide	Updated
27/08/2026	Document: Recommended submission dates for veterinary medicinal products	Updated
27/08/2026	Event: Paediatric Committee (PDCO): 23-26 June 2026	Updated
27/08/2026	Document: PDCO minutes of the 23-26 June 2026 meeting	New

Date	Content	Status
27/08/2026	Event: Committee for Medicinal Products for Human Use (CHMP): 23-26 February 2026	Updated
27/08/2026	Document: Annex to 23-26 February 2026 CHMP Minutes	New
27/08/2026	Document: Minutes of the CHMP meeting 23-26 February 2026	New
26/08/2026	Document: List of clinical evaluation consultation procedure (CECP) opinions issued for medical devices awaiting finalisation of conformity assessment	Updated
26/08/2026	Medicine: Blenrep belantamab mafodotin	Updated
26/08/2026	Medicine: Bysumlog insulin lispro	Updated
26/08/2026	Medicine: Tezspire tezepelumab	Updated
26/08/2026	Medicine: Vioice alpelisib	Updated
26/08/2026	Orphan: EU/3/18/2020 - orphan designation for treatment of AL amyloidosis daratumumab	Updated
26/08/2026	Medicine: Darzalex daratumumab	Updated
26/08/2026	Medicine: Neofordex dexamethasone	Updated
26/08/2026	Medicine: Skyrizi risankizumab	Updated
26/08/2026	Page: Medicines for human use under evaluation	Updated
26/08/2026	Document: Start of procedure: Type II Variation - Extension of indication under evaluation by the CHMP (24 July 2026 - 20 August 2026)	New
26/08/2026	Document: Start of procedure: Extension of marketing authorisation (24 July 2026 - 20 August 2026)	New
26/08/2026	Medicine: Comirnaty COVID-19 mRNA vaccine	Updated

Date	Content	Status
26/08/2026	Medicine: Spikevax (previously COVID-19 Vaccine Moderna) COVID-19 mRNA vaccine	Updated
26/08/2026	Event: Committee for Advanced Therapies (CAT): 17-19 June 2026	Updated
26/08/2026	Document: Minutes of the CAT meeting 17-19 June 2026	New
26/08/2026	Event: Committee for Advanced Therapies (CAT): 11-13 May 2026	Updated
26/08/2026	Document: Minutes of the CAT meeting 11-13 May 2026	New
26/08/2026	Page: QRD guidance on the use of adopted abbreviations and pictograms on the packaging of veterinary medicinal products authorised via the centralised (CP), mutual recognition (MRP), decentralised (DCP), subsequent recognition (SRP) and national procedures	Updated
26/08/2026	Document: List of European Union reference dates (EURD) and frequency of submission of periodic safety update reports (PSURs)	Updated
26/08/2026	Medicine: Byfavo remimazolam	Updated
26/08/2026	Medicine: Nobivac NXT FeLV feline leukemia (self-amplifying RNA particle) vaccine	Updated
26/08/2026	Medicine: Nobivac NXT HCPFeLV feline calicivirus, feline rhinotracheitis, feline panleucopenia and feline leukemia (self-amplifying RNA particle) vaccine	Updated
26/08/2026	Medicine: Wegovy semaglutide	Updated
25/08/2026	Medicine: Hopledo levodopa; carbidopa	Updated
25/08/2026	Medicine: Ablymico liraglutide	Updated
25/08/2026	Medicine: Akynzeo netupitant; palonosetron	Updated
25/08/2026	Medicine: Ozempic semaglutide	Updated
25/08/2026	Medicine: Zutectra human hepatitis B immunoglobulin	Updated
25/08/2026	Medicine: Aquipta atogepant	Updated

Date	Content	Status
25/08/2026	Medicine: Nobivac NXT HCPChFeLV feline calicivirus, feline rhinotracheitis, feline panleucopenia, feline chlamydiosis (live) and feline leukemia (self-amplifying RNA particle) vaccine	Updated
25/08/2026	Medicine: Verzenios abemaciclib	Updated
25/08/2026	Medicine: Liraglutide STADA liraglutide	Updated
25/08/2026	Medicine: Rezurock belumosudil	Updated
25/08/2026	Medicine: Svariya (previously Rivaroxaban Koanaa) rivaroxaban	Updated
25/08/2026	Medicine: Zinmyleo trilaciclib	Updated
25/08/2026	Event: Webinar on the use of platform approaches in the non-clinical and clinical domains	Updated
25/08/2026	Document: Annex to 8-11 December 2025 CHMP Minutes	New
25/08/2026	Document: Annex to 10-13 November 2025 CHMP Minutes	New
25/08/2026	Document: Annex to 13-16 October 2025 CHMP Minutes	New
25/08/2026	Document: Minutes of the CHMP meeting 8-11 December 2025	New
25/08/2026	Document: Minutes of the CHMP meeting 10-13 November 2025	New
25/08/2026	Document: Minutes of the CHMP meeting 13-16 October 2025	New
25/08/2026	Medicine: Vpriv velaglucerase alfa	Updated
24/08/2026	Medicine: Chenodeoxycholic acid Leadiant (previously Chenodeoxycholic acid sigma-tau) chenodeoxycholic acid	Updated
24/08/2026	Medicine: Izamby denosumab	Updated
24/08/2026	Page: Data in regulation: Big data and other sources	Updated

Date	Content	Status
24/08/2026	Medicine: Ixchiq Chikungunya vaccine (live)	Updated
24/08/2026	Medicine: Rotarix rotavirus vaccine, live	Updated
24/08/2026	Orphan: EU/3/26/3249 - orphan designation for treatment of myelin oligodendrocyte glycoprotein antibody-associated disease satralizumab	New
24/08/2026	Orphan: EU/3/26/3252 - orphan designation for treatment of glioma short hairpin RNA against NANOG mRNA	New
24/08/2026	Orphan: EU/3/26/3246 - orphan designation for treatment of Diamond-Blackfan anaemia dasatinib	New
24/08/2026	Orphan: EU/3/26/3247 - orphan designation for treatment of factor VII deficiency humanised IgG4 monoclonal antibody against activated protein C	New
24/08/2026	Orphan: EU/3/26/3245 - orphan designation for treatment of progressive multifocal leukoencephalopathy human IgG1 monoclonal antibody against JC polyomavirus, major capsid protein VP1	New
24/08/2026	Orphan: EU/3/26/3248 - orphan designation for treatment of Gaucher disease (S)-Quinuclidin-3-yl((R)-5-(3-chloro-4-isopropoxyphenyl)-2,2-dimethyl-2,3-dihydro-1H-inden-1-yl)carbamate ((1S,4R)-7,7-dimethyl-2-oxobicyclo[2.2.1]heptan-1-yl)methanesulfonate	New
24/08/2026	Orphan: EU/3/26/3251 - orphan designation for treatment of Ewing sarcoma dinutuximab beta	New
24/08/2026	Orphan: EU/3/26/3254 - orphan designation for treatment of ataxia telangiectasia 3-(Aminocarbonyl)-1-(2,3,5-tri-O-acetyl-beta-D-ribofuranosyl)-pyridinium chloride (1:1)	New
24/08/2026	Orphan: EU/3/26/3253 - orphan designation for treatment of head and neck cancer cyclo(arginyl-glycyl-aspartyl-D-tyrosyl-lysyl)-nizaracianine-1	New
24/08/2026	Medicine: Yuflyma adalimumab	Updated
24/08/2026	Medicine: Bomynta denosumab	Updated
24/08/2026	Orphan: EU/3/26/3244 - orphan designation for treatment of malignant mesothelioma	New

Date	Content	Status
	(S)-N-(2-Methoxy-5-((5-(trifluoromethyl)pyridin-2-yl)oxy)phenyl)-3-methyl-2-oxoimidazolidine-4-carboxamide	
24/08/2026	Orphan: EU/3/26/3257 - orphan designation for treatment of primary hyperoxaluria guide RNA against the human HAO1 gene, mRNA encoding an engineered variant of the Cas12 nuclease	New
24/08/2026	Orphan: EU/3/26/3255 - orphan designation for treatment of catecholaminergic polymorphic ventricular tachycardia adeno-associated viral vector serotype 8 containing the human CASQ2 gene	New
24/08/2026	Orphan: EU/3/26/3250 - orphan designation for treatment of neurotrophic keratitis herpes simplex virus, type 1, containing the human NGF gene	New
24/08/2026	Orphan: EU/3/26/3256 - orphan designation for treatment of cystic fibrosis modified mRNA encoding human cystic fibrosis transmembrane conductance regulator	New
24/08/2026	Orphan: EU/3/26/3274 - orphan designation for treatment of severe combined immunodeficiency (SCID) due to DCLRE1C (Artemis) deficiency autologous CD34+ haematopoietic stem and progenitor cells transduced with a lentiviral vector containing the human DCLRE1C gene	New
24/08/2026	Orphan: EU/3/26/3271 - orphan designation for treatment of pouchitis Lyophilized consortium of Faecalibacterium sp., strain PD09; Anaerostipes sp., strain PD10; Akkermansia sp., strain PD11; Butyrivibrio sp., strain PD12; Roseburia sp., strain PD14; and Lactiplantibacillus sp., strain PD15	New
24/08/2026	Orphan: EU/3/26/3259 - orphan designation for treatment of myelin oligodendrocyte glycoprotein antibody-associated disease rozanolixizumab	New
24/08/2026	Orphan: EU/3/26/3269 - orphan designation for treatment of TRPV4-related neuromuscular disease 1-((5S,7S,8R)-8-Fluoro-3-[5-(2-hydroxypropan-2-yl)pyrazin-2-yl]-7-methyl-2-oxo-1-oxa-3-azaspiro[4.5]decan-7-yl)methyl-1H-1,3-benzimidazole-6-carbonitrile	New
24/08/2026	Orphan: EU/3/26/3265 - orphan designation for treatment of gastro-entero-pancreatic neuroendocrine tumours lead (212Pb) bamzireotide navoxetan	New
24/08/2026	Orphan: EU/3/26/3270 - orphan designation for treatment of urea cycle disorders single stranded RNA editing oligonucleotide against GLUL mRNA	New

Date	Content	Status
24/08/2026	Orphan: EU/3/26/3273 - orphan designation for treatment of autosomal dominant polycystic kidney disease exaluren sulfate	New
24/08/2026	Orphan: EU/3/26/3258 - orphan designation for treatment of ovarian cancer cabazitaxel	New
24/08/2026	Orphan: EU/3/26/3264 - orphan designation for treatment of neonatal encephalopathy (2R)-2-[[[6-[Ethyl(phenylmethyl)amino]-9-(1-methylethyl)-9H-purin-2-yl]amino]butyl L-valine ester hydrochloride (1:1)	New
24/08/2026	Orphan: EU/3/26/3268 - orphan designation for treatment of gastric cancer sonesitatur vedotin	New
24/08/2026	Orphan: EU/3/26/3261 - orphan designation for treatment of venous malformations serabelisib	New
24/08/2026	Orphan: EU/3/26/3266 - orphan designation for treatment of alpha-1 antitrypsin deficiency guide RNA against the human SERPINA1 gene, mRNA encoding a CRISPR-associated endonuclease Cas9 against the human SERPINA1 gene	New
24/08/2026	Orphan: EU/3/26/3267 - orphan designation for treatment of non-syndromic inherited retinal dystrophies of the cone-dominant phenotype allogeneic human induced pluripotent stem cell-derived photoreceptor precursor cells	New
24/08/2026	Orphan: EU/3/26/3272 - orphan designation for treatment of osteogenesis imperfecta cisatracurium besilate	New
24/08/2026	Orphan: EU/3/26/3263 - orphan designation for treatment of coccidioidomycosis olorofim	New
24/08/2026	Orphan: EU/3/26/3260 - orphan designation for treatment of lymphatic malformations serabelisib	New
24/08/2026	Orphan: EU/3/26/3262 - orphan designation for treatment of myelofibrosis selcodebart	New

NOTICE TO APPLICANTS

No updates since June 24th, 2026.

BFARM - PHARMAKOVIGILANZ (SPECIFIC FOR GERMANY)

Date	Title
28.08.2026	Behördlich beauftragtes Schulungsmaterial - neue Webseitenstruktur Aufgrund der Vielzahl an Informationen rund um die Bereitstellung und den Genehmigungsprozess von behördlich beauftragtem Schulungsmaterial wurde der Aufbau der Seiten zur besseren Auffindbarkeit der Informationen neu strukturiert.

BFARM – MEDIZINPRODUKTE (SPECIFIC FOR GERMANY)

No updates since August 12th, 2026.

PEI - VIGILANZ (SPECIFIC FOR GERMANY)

No updates since August 3rd, 2026.

PHARMEUROPA TEXTS FOR COMMENT

Information on Pharmedropa updates will be presented quarterly.

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