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HEADS OF AGENCIES – CMDh

No updates since July 3rd, 2026.

HEADS OF AGENCIES – PAEDIATRIC REGULATION

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

EUROPEAN MEDICINES AGENCY (EMA)

Date	Content	Status
10/07/2026	Medicine: Venclyxto venetoclax	Updated
10/07/2026	Medicine: Natpar parathyroid hormone	Updated
10/07/2026	Medicine: Fendrix hepatitis B (rDNA) vaccine (adjuvanted, adsorbed)	Updated
10/07/2026	Medicine: Esbriet pirfenidone	Updated
10/07/2026	Medicine: Neofordex dexamethasone	Updated
10/07/2026	Shortage: Azactam aztreonam	New
10/07/2026	Document: Scientific recommendations on classification of advanced therapy medicinal products	Updated
10/07/2026	Document: User manual for the eXtended EudraVigilance Medicinal Product Dictionary (XEVMPD) user interface (XEVMPDweb)	Updated

Date	Content	Status
10/07/2026	Document: Coding of indications in the eXtended EudraVigilance Medicinal Product Dictionary (XEVMPD)	Updated
10/07/2026	Document: HMA-EMA Network Data Steering Group: membership list	Updated
10/07/2026	Medicine: Vaxchora cholera vaccine, oral, live	Updated
10/07/2026	Page: Antimicrobial resistance in veterinary medicine	Updated
10/07/2026	Document: CVMP activities related to antimicrobials - Status report on EMA/CVMP activities (2021–2025) and EMANS 2028 Strategic Overview (Theme 4)	New
10/07/2026	Document: List of clinical evaluation consultation procedure (CECP) opinions issued for medical devices awaiting finalisation of conformity assessment	Updated
10/07/2026	Document: Cardiac valves - Notified Body 0344 - 20/12/2025 - Expert decision and opinion in the context of the clinical evaluation consultation procedure (CECP)	New
10/07/2026	Document: Female contraceptive - Notified Body 0123 - 08/05/2025 - Expert decision and opinion in the context of the clinical evaluation consultation procedure (CECP)	New
10/07/2026	Medicine: Bomyntra denosumab	Updated
10/07/2026	Medicine: Olazax olanzapine	Updated
10/07/2026	Medicine: Nobivac NXT HCPC feline calicivirosis, feline rhinotracheitis, feline panleucopenia and feline chlamydiosis (live) vaccine	Updated
10/07/2026	Medicine: Nobivac NXT HCP felid herpesvirus 1, strain G2620A, live; feline calicivirus, strain F9, live; feline panleucopenia virus, strain MW-1, live	Updated
10/07/2026	Medicine: Desloratadine Actavis desloratadine	Updated
10/07/2026	Medicine: Nobivac NXT HC feline calicivirosis and feline viral rhinotracheitis vaccine (live)	Updated
10/07/2026	Medicine: Desloratadine ratiopharm desloratadine	Updated

Date	Content	Status
10/07/2026	Medicine: Fycompa perampanel	Updated
10/07/2026	Page: Enpr-EMA priority activities	Updated
10/07/2026	Document: Annex to interim measures regarding notification of pharmacovigilance alerts by marketing authorisation holders under Regulation (EU) 2019/6: contact points	Updated
10/07/2026	News: Meeting highlights from the Pharmacovigilance Risk Assessment Committee (PRAC) 6-9 July 2026	New
10/07/2026	Medicine: Ozempic semaglutide	Updated
10/07/2026	Medicine: Cometriq cabozantinib	Updated
10/07/2026	Medicine: Infanrix Hexa diphtheria (D), tetanus (T), pertussis (acellular, component) (Pa), hepatitis B (rDNA) (HBV), poliomyelitis (inactivated) (IPV) and Haemophilus influenzae type-b (Hib) conjugate vaccine (adsorbed)	Updated
10/07/2026	Medicine: Menveo meningococcal group A, C, W-135 and Y conjugate vaccine	Updated
10/07/2026	Document: PWCP 20th anniversary summary	New
10/07/2026	PIP: EMA-002601-PIP01-19 - paediatric investigation plan adeno-associated viral vector serotype 8 containing the human RPGR gene	Updated
10/07/2026	PIP: EMA-002617-PIP01-19 - paediatric investigation plan ravagalimab	Updated
10/07/2026	PIP: EMA-002430-PIP01-18 - paediatric investigation plan timrepigene emparvovec	Updated
10/07/2026	PIP: EMA-001556-PIP01-13 - paediatric investigation plan Human recombinant interleukin-2	Updated
10/07/2026	PIP: EMA-001693-PIP03-21 - paediatric investigation plan reparixin	Updated
10/07/2026	Document: Minutes - Enpr-EMA Coordinating Group meeting, April 2026	New
10/07/2026	Document: Agenda - EnprEMA Coordinating Group meeting, April 2026	New

Date	Content	Status
10/07/2026	Event: Enpr-EMA Coordinating Group meeting April 2026	New
10/07/2026	Document: Article 57 product data	Updated
09/07/2026	Medicine: Zavesca miglustat	Updated
09/07/2026	Medicine: Ztalmy ganaxolone	Updated
09/07/2026	Medicine: Ryzneuta efbemalenograstim alfa	Updated
09/07/2026	Medicine: Adynovi rurioctocog alfa pegol	Updated
09/07/2026	Medicine: Cervarix human papillomavirus vaccine [types 16, 18] (recombinant, adjuvanted, adsorbed)	Updated
09/07/2026	Medicine: Evenity romosozumab	Updated
09/07/2026	Medicine: Mircera methoxy polyethylene glycol-epoetin beta	Updated
09/07/2026	Document: CTIS Simplification Task Force: topics analysed	Updated
09/07/2026	Document: Agenda - Sixteenth industry stakeholder platform on research and development support	Updated
09/07/2026	Medicine: Evkeeza evinacumab	Updated
09/07/2026	Medicine: Pyrukynd mitapivat	Updated
09/07/2026	Document: Dates of 2027 SAWP meetings and submission deadlines Scientific advice, protocol assistance, qualification of biomarkers and parallel HTACG/EMA Joint Scientific Consultation requests	Updated
09/07/2026	Event: Sixteenth meeting of the industry stakeholder platform on the operation of the centralised procedure for human medicines	Updated
09/07/2026	Medicine: Locametz gozetotide	Updated

Date	Content	Status
09/07/2026	Event: Sixteenth industry stakeholder platform on research and development support	Updated
09/07/2026	Document: Presentation - SPOR and XEVMPD status update webinar - Q3 2026	Updated
08/07/2026	Page: International arrangements	Updated
08/07/2026	Page: New Zealand	Updated
08/07/2026	Event: eXtended EudraVigilance Medicinal Product Dictionary (XEVMPD) training course (Bucharest) - October 2026	New
08/07/2026	Medicine: Ebixa memantine	Updated
08/07/2026	Medicine: Trazimera trastuzumab	Updated
08/07/2026	Document: Meeting Summary - PCWP/HCPWP joint meeting	New
08/07/2026	Medicine: Wyost denosumab	Updated
08/07/2026	Medicine: Mepsevii vestronidase alfa	Updated
08/07/2026	Medicine: Altuvoct efanesoctocog alfa	Updated
08/07/2026	Medicine: Tolura telmisartan	Updated
08/07/2026	Medicine: Fruzaqla fruquintinib	Updated
08/07/2026	Document: EMA risk management information day	New
08/07/2026	Document: Clinical Trial Information System (CTIS) - Sponsor handbook	Updated
08/07/2026	Medicine: Ritonavir Viatris (previously Ritonavir Mylan) ritonavir	Updated
08/07/2026	Document: Working arrangement for the collaboration and exchange of information on therapeutic products and medicinal products between DG SANTE/EMA and the New Zealand Ministry of Health	New

Date	Content	Status
08/07/2026	Orphan: EU/3/26/3232 - orphan designation for treatment of Wilson's disease copper metabolism disorder	New
08/07/2026	Orphan: EU/3/26/3231 - orphan designation for treatment of narcolepsy alixorexton	New
08/07/2026	Orphan: EU/3/26/3243 - orphan designation for treatment of syndromic inherited retinal dystrophies of the rod-dominant phenotype allogeneic human induced pluripotent stem cell-derived photoreceptor precursor cells	New
08/07/2026	Orphan: EU/3/26/3233 - orphan designation for treatment of KCNT1-related epilepsy (S)-N-(2-(2-Cyclopropylpyridin-4-yl)-4,5,6,7-tetrahydrobenzo[d]oxazol-4-yl)-1-methyl-3-(trifluoromethyl)-1H-pyrazole-5-carboxamide	New
08/07/2026	Orphan: EU/3/26/3235 - orphan designation for treatment of inherited retinal disease due to dysfunction in the USH2A gene antisense oligonucleotide against USH2A pre-mRNA	New
08/07/2026	Orphan: EU/3/26/3241 - orphan designation for treatment of pancreatic cancer quemliclустat	New
08/07/2026	Orphan: EU/3/26/3240 - orphan designation for treatment of peripheral T-cell lymphoma igermetostat maleate	New
08/07/2026	Orphan: EU/3/26/3239 - orphan designation for treatment of PIK3CA related overgrowth spectrum serabelisib	New
08/07/2026	PIP: EMA/PE/0000235869 - paediatric investigation plan humanised IgG1 monoclonal antibody against SEZ6, conjugated to (2S)-2-(2-bromoacetamido)-N-[(2S)-1-({3-[(7S)-7-ethyl-7-hydroxy-8,11-dioxo-7,8,11,13-tetrahydro-2H,10H-[1,3]dioxolo[4,5-g]pyrano[3',4':6,7]indolizino[1,2-b]quinolin-14-yl]bicyclo[1.1.1]pentan-1-yl}amino)-1-oxopropan-2-yl]-3-methylbutanamide	New
08/07/2026	PIP: EMA/PE/0000239491 - paediatric investigation plan IgG1 trispecific monoclonal antibody against T-cell receptor CD3, B-cell maturation antigen and G protein-coupled receptor class C group 5 member D	New
08/07/2026	PIP: EMA/PE/0000222352 - paediatric investigation plan clostridium botulinum a, strain pm-12759 hall-a, botulin a conjugated to protein ntnh, hemagglutinin ha17, hemagglutinin ha34, hemagglutinin ha23 and hemagglutinin ha48	New
08/07/2026	PIP: EMA/PE/0000240548 - paediatric investigation plan autologous t-cells transduced with a lentiviral vector expressing a chimeric antigen receptor against bcma and gprc5d	New

Date	Content	Status
07/07/2026	Page: Download website data in JSON data format	Updated
07/07/2026	Medicine: Fluenz influenza vaccine (live attenuated, nasal)	Updated
07/07/2026	Medicine: Sarclisa isatuximab	Updated
07/07/2026	Medicine: Ixchiq Chikungunya vaccine (live)	Updated
07/07/2026	Document: List of medicines currently in PRIME scheme	Updated
07/07/2026	Medicine: Onpattro patisiran	Updated
07/07/2026	Medicine: Abevmy bevacizumab	Updated
07/07/2026	PIP: EMA/PE/0000241119 - paediatric investigation plan (12m)-(1s,2s)-n-((63s,4s,z)-1 l-ethyl-12-(2-((s)-1-methoxyethyl)-5-(4-methylpiperazin-1-yl)pyridin-3-yl)-10,10-dimethyl-5,7-dioxo-61,62,63,64,65,66-hexahydro-1 l h-8-oxa-2(4,2)-thiazola-1(5,3)-indola-6(1,3)-pyridazinacycloundecaphane-4-yl)-2-methylcyclopropane-1-carboxamide	New
07/07/2026	PIP: EMA/PE/0000239082 - paediatric investigation plan human (scfv)2-fab fusion protein against cd40l	New
07/07/2026	PIP: EMA/PE/0000241527 - paediatric investigation plan baxdrostat; dapagliflozin propanediol	New
07/07/2026	PIP: EMA/PE/0000241327 - paediatric investigation plan palopegteriparatide	Updated
07/07/2026	PIP: EMA/PE/0000238807 - paediatric investigation plan derivative of azabicycloheptane-carboxamide	Updated
07/07/2026	PIP: EMA/PE/0000232780 - paediatric investigation plan probenecid	New
07/07/2026	PIP: EMA/PE/0000231576 - paediatric investigation plan atrasentan	Updated
07/07/2026	PIP: EMA/PE/0000240469 - paediatric investigation plan levonorgestrel	Updated
07/07/2026	PIP: EMA/PE/0000240232 - paediatric investigation plan Brivaracetam	Updated
07/07/2026	PIP: EMA/PE/0000240971 - paediatric investigation plan rilpivirine hydrochloride; dolutegravir sodium	Updated

Date	Content	Status
07/07/2026	Medicine: Telmisartan Actavis telmisartan	Updated
07/07/2026	Event: EMA workshop on the challenges in drug development, regulation and clinical practice in immune thrombocytopenia	Updated
07/07/2026	News: EMA fast tracks review of a medicine for metastatic pancreatic cancer	New
07/07/2026	PIP: EMA/PE/0000237641 - paediatric investigation plan Difelikefalin	Updated
07/07/2026	PIP: EMA/PE/0000241538 - paediatric investigation plan finerenone	Updated
07/07/2026	Event: 20th anniversary of European Medicines Agency's Patients' and Consumers' Working Party (PCWP)	Updated
07/07/2026	Event: PCWP/HCPWP joint meeting	Updated
07/07/2026	Medicine: Xolremdi mavorixafor	Updated
07/07/2026	Event: SPOR and XEVMPD status update webinar - Q3 2026	Updated
07/07/2026	Event: Mandatory use of ISO/ICH E2B(R3) Individual Case Safety Reporting in the EU: Hands-on training course using the EudraVigilance system	New
07/07/2026	Page: Qualification of novel methodologies for medicine development	Updated
07/07/2026	Document: Qualification of novel methodologies for medicinal product development: guidance to applicants	Updated
06/07/2026	Medicine: Calquence acalabrutinib	Updated
06/07/2026	Medicine: Tysabri natalizumab	Updated
06/07/2026	Document: Agenda of the PRAC meeting 6-9 July 2026	New
06/07/2026	Medicine: Enhertu trastuzumab deruxtecan	Updated

Date	Content	Status
06/07/2026	Document: Agenda of the HMPC meeting 6-8 July 2026	New
06/07/2026	Document: List of signals discussed at PRAC since September 2012	Updated
06/07/2026	Page: Accessibility	Updated
06/07/2026	Document: Start of procedure: Type II Variation - Extension of indication under evaluation by the CHMP (22 May 2026 - 25 June 2026)	New
06/07/2026	Document: Start of procedure: Extension of marketing authorisation (22 May 2026 - 25 June 2026)	New
06/07/2026	Medicine: Alprolix eftrenonacog alfa	Updated
06/07/2026	Event: 17th Industry Standing Group (ISG) meeting	Updated
06/07/2026	Document: New product information wording: extracts from PRAC recommendations on signals adopted at the 8-11 June 2026 PRAC	New
06/07/2026	Document: PRAC recommendations on signals adopted at the 8-11 June 2026 PRAC meeting	New

NOTICE TO APPLICANTS

No updates since June 24th, 2026.

BFARM - PHARMAKOVIGILANZ (SPECIFIC FOR GERMANY)

Date	Title
10.07.2026	Pharmacovigilance Risk Assessment Committee (PRAC) Das Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM) veröffentlicht die neuen Signale, die im Rahmen der PRAC-Sitzung vom 06.07.-09.07.2026 behandelt wurden.
09.07.2026	Informationen zu Einreichung und Genehmigung von Schulungsmaterial Aktualisierung der Hilfestellungsdokumente zur Einreichung und Genehmigung von behördlich genehmigten Schulungsmaterialien.
08.07.2026	Rote-Hand-Brief zu Keppra (Levetiracetam): Risiko eines Medikationsfehlers Wirkstoff: Levetiracetam Risiko eines Medikationsfehlers durch Wechsel der Applikationsspritze für Zubereitungen zum Einnehmen.

BFARM – MEDIZINPRODUKTE (SPECIFIC FOR GERMANY)

No updates since June 23rd, 2026.

PEI - VIGILANZ (SPECIFIC FOR GERMANY)

No updates since July 01st, 2026.

PHARMEUROPA TEXTS FOR COMMENT

Information on Pharmeduropa updates will be presented quarterly.

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