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HEADS OF AGENCIES – CMDh

07 April

[NEW - Ramipril/indapamide PSUR WS SmAR](#)

HEADS OF AGENCIES – PAEDIATRIC REGULATION

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

EUROPEAN MEDICINES AGENCY (EMA)

Date	Content	Status
10/04/2026	Orphan: EU/3/25/3186 - orphan designation for treatment of primary IgA nephropathy N-[5-(2H-1,3-Benzodioxol-5-yl)-6-{2-[(5-bromopyrimidin-2-yl)oxy]ethoxy}pyrimidin-4-yl]-N'-(2-methoxyethyl)sulfuric diamide	New
10/04/2026	Orphan: EU/3/25/3187 - orphan designation for treatment of multiple system atrophy 2-[[[4-Methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1H-benzimidazol-5-ol	New
10/04/2026	Orphan: EU/3/25/3180 - orphan designation for diagnosis of ovarian cancer aminolevulinic acid hydrochloride	New
10/04/2026	Orphan: EU/3/25/3179 - orphan designation for treatment of primary hyperoxaluria lanthanum carbonate octahydrate	New
10/04/2026	Orphan: EU/3/25/3189 - orphan designation for treatment of osteosarcoma sirolimus	New
10/04/2026	PIP: EMEA-001811-PIP03-20 - paediatric investigation plan ligelizumab	Updated

10/04/2026	Medicine: Mysimba naltrexone; bupropion	Updated
10/04/2026	Orphan: EU/3/25/3191 - orphan designation for treatment of BAG3 dilated cardiomyopathy Adeno-associated virus serotype ATC-0187 vector containing the human BAG3 gene	New
10/04/2026	Orphan: EU/3/25/3190 - orphan designation for treatment of osteosarcoma domatinostat	New
10/04/2026	Orphan: EU/3/25/3181 - orphan designation for treatment of Fanconi anaemia autologous human T cells transduced with a lentiviral vector encoding a chimeric antigen receptor against the ERBB family	New
10/04/2026	Orphan: EU/3/25/3193 - orphan designation for treatment of central serous chorioretinopathy spironolactone	New
10/04/2026	Medicine: Equidormin midazolam	New
10/04/2026	Orphan: EU/3/25/3188 - orphan designation for treatment of idiopathic pulmonary fibrosis Phe-Thr-Thr-Phe-Thr-Val-Thr	New
10/04/2026	Orphan: EU/3/25/3192 - orphan designation for treatment of extrapulmonary neuroendocrine carcinoma opantistomig	New
10/04/2026	Medicine: Evrenzo roxadustat	Updated
10/04/2026	Orphan: EU/3/26/3197 - orphan designation for treatment of spinal cord injury (4Z,7R,8E,10E,12Z,14S,16Z,19Z)-7,14-Dihydroxydocosa-4,8,10,12,16,19-hexaenoic acid	New
10/04/2026	Medicine: Mycophenolate mofetil Teva mycophenolate mofetil	Updated
10/04/2026	Orphan: EU/3/26/3203 - orphan designation for treatment of limbal stem cell deficiency spironolactone	New
10/04/2026	Medicine: Olumiant baricitinib	Updated
10/04/2026	Orphan: EU/3/26/3201 - orphan designation for treatment of mesothelioma Measles virus Schwarz strain (live, attenuated)	New
10/04/2026	Orphan: EU/3/26/3196 - orphan designation for treatment of glioma Humanised IgG1 kappa monoclonal antibody against erythropoietin isoform EV-3	New

10/04/2026	Orphan: EU/3/26/3204 - orphan designation for treatment of erythromelalgia N-[(1S)-1-(4-Tert-butylphenyl) ethyl]-2-(6,7-difluoro-1H-benzimidazol-1-yl)acetamide	New
10/04/2026	Orphan: EU/3/25/3146 - orphan designation for treatment of Glb1-related disorders autologous peripheral blood-derived CD34+ haematopoietic stem and progenitor cells transduced with a lentiviral vector containing the murine Glb1 gene	New
10/04/2026	Orphan: EU/3/25/3149 - orphan designation for treatment of KCNT1-related epilepsy and neurodevelopmental disorders (S)-1-(2,2-Difluoroethyl)-3-(difluoromethyl)-N-(1-(3-(2-methoxypyridin-4-yl)-1,2,4-oxadiazol-5-yl)ethyl)-1H-pyrazole-5-carboxamide	New
10/04/2026	Orphan: EU/3/25/3153 - orphan designation for treatment of pancreatic cancer vopimetostat	New
10/04/2026	News: Meeting highlights from the Pharmacovigilance Risk Assessment Committee (PRAC) 7-10 April 2026	New
10/04/2026	Medicine: Myfenax mycophenolate mofetil	Updated
10/04/2026	PIP: EMA-003268-PIP01-22 - paediatric investigation plan 1-(4-(6-chloropyridazin-3-yl)piperazin-1-yl)-2-(4-cyclopropyl-3-fluorophenyl)ethan-1-one (BBP-671)	Updated
10/04/2026	PSUSA: PSUSA/00003170/202508 - periodic safety update report single assessment hexoprenaline sulfate	New
10/04/2026	Orphan: EU/3/25/3103 - orphan designation for treatment of idiopathic pulmonary fibrosis admilparant	New
10/04/2026	Orphan: EU/3/25/3104 - orphan designation for treatment of acute myeloid leukaemia 4-(2-{[2-Amino-6-(3-chloro-2-methylphenyl)pyrimidin-4-yl]amino}ethyl)benzene-1-sulfonamide	New
10/04/2026	Orphan: EU/3/25/3107 - orphan designation for treatment of congenital athymia allogeneic cultured postnatal thymus-derived tissue	New
10/04/2026	Orphan: EU/3/25/3115 - orphan designation for treatment of non-syndromic inherited retinal dystrophies due to defects in the ABCA4 gene gildeuretinol, gildeuretinol acetate	New
10/04/2026	Orphan: EU/3/25/3114 - orphan designation for treatment of alpha-1 antitrypsin deficiency	New

	RNA editing antisense oligonucleotide against the Z mutation of the human SERPINA1 mRNA transcript, sodium salt	
10/04/2026	Orphan: EU/3/25/3133 - orphan designation for treatment of NDP gene-related disorders adeno-associated viral vector serotype ShH10 containing a codon-optimised human NDP gene	New
10/04/2026	Orphan: EU/3/25/3106 - orphan designation for treatment of multiple myeloma 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
10/04/2026	Orphan: EU/3/25/3129 - orphan designation for treatment of syndromic inherited retinal dystrophies of the rod-dominant phenotype sonpiretigene isteparvovec	New
10/04/2026	Orphan: EU/3/25/3122 - orphan designation for treatment of uveal melanoma darovasertib	New
10/04/2026	Orphan: EU/3/25/3113 - orphan designation for treatment of hereditary cerebral amyloid angiopathies acetylcysteine amide	New
10/04/2026	Orphan: EU/3/25/3110 - orphan designation for treatment of spinal muscular atrophy emugrobart	New
10/04/2026	Orphan: EU/3/25/3105 - orphan designation for treatment of dystrophic myotonia RNA, [P-deoxy-P-(dimethylamino)](2',3'-dideoxy-2',3'-imino-2',3'-seco)(2'a->5') (C-A-G-C-A-G-C-A-G-C-A-G-C-A-G-C-A-G-C-A-[2'a-[39-[[1-acetyl-L-prolyl-L-lysyl-L-lysyl-L-lysyl-L-arginyl-L-lysyl-L-valyl-2-[2-(2-aminoethoxy)ethoxy]acetyl-N6-(L-phenylalanyl)glycyl-L-phenylalanyl]glycyl-L-arginyl]glycyl-L-arginyl-L-gamma-glutamyl)-L-lysyl]amino]-1-oxo-4,7,10,13,16,19,22,25,28,31,34,37-dodecaoxanonatriacont-1-yl]]G), (8'>1')-lactam	New
10/04/2026	Orphan: EU/3/25/3120 - orphan designation for treatment of immunoglobulin G4-related disease rilzabrutinib	New
10/04/2026	Orphan: EU/3/25/3109 - orphan designation for treatment of NDP gene-related disorders adeno-associated virus serotype 9 vector containing the human NDP gene	New
10/04/2026	Orphan: EU/3/25/3124 - orphan designation for treatment of immune thrombocytopenia mezagitamab	New
10/04/2026	Orphan: EU/3/25/3128 - orphan designation for treatment of pancreatic cancer 7-ethyl-10-hydroxycamptothecin	New
10/04/2026	Orphan: EU/3/25/3111 - orphan designation for treatment of graft-versus-host disease pegтаразимод	New
10/04/2026	Orphan: EU/3/25/3102 - orphan designation for prevention of bronchopulmonary dysplasia mecasermin rinfabate	New
10/04/2026	Orphan: EU/3/25/3112 - orphan designation for treatment of methylmalonic acidemia lentiviral vector containing the human MMUT transgene	New

10/04/2026	Orphan: EU/3/25/3152 - orphan designation for treatment of MECP2 duplication syndrome 2'-O-(2-Methoxyethyl) modified antisense oligonucleotide against MECP2 pre-mRNA	New
10/04/2026	Orphan: EU/3/25/3123 - orphan designation for treatment of common variable immunodeficiency (CVID) leniolisib	New
10/04/2026	Orphan: EU/3/25/3108 - orphan designation for treatment of acute myeloid leukaemia cladribine	New
10/04/2026	Orphan: EU/3/25/3148 - orphan designation for treatment of amyotrophic lateral sclerosis 2-(3-Chlorophenyl)-N-[6-(trifluoromethyl)-1,3-benzothiazol-2-yl]acetamide	New
10/04/2026	Orphan: EU/3/25/3118 - orphan designation for treatment of primary hyperoxaluria mRNA encoding Cas12HF endonuclease, Single guide RNA against the human HAO1 gene	New
10/04/2026	Orphan: EU/3/25/3117 - orphan designation for treatment of lymphoplasmacytic lymphoma 3-tert-butyl-N-{{(1R)-1-[4-(6-{{6-[4-({1-[4-(2,4-dioxo-1,3-diazinan-1-yl)phenyl]piperidin-4-yl)}methyl)piperazin-1-yl]pyridin-3-yl)}-7H-pyrrolo[2,3-d]pyrimidin-4-yl)-2-methylphenyl]ethyl}-1,2,4-oxadiazole-5-carboxamide	New
10/04/2026	Orphan: EU/3/25/3134 - orphan designation for treatment of non-syndromic macular dystrophy sonpiretigene isteparvovec	New
10/04/2026	Orphan: EU/3/25/3121 - orphan designation for treatment of idiopathic inflammatory myopathy brepocitinib	New
10/04/2026	Orphan: EU/3/25/3154 - orphan designation for treatment of non-syndromic inherited retinal dystrophies due to defects in the ABCA4 gene antisense oligonucleotide against ABCA4 pre-mRNA	New
10/04/2026	Orphan: EU/3/25/3155 - orphan designation for treatment of oesophageal cancer zanidatamab	New
10/04/2026	Orphan: EU/3/25/3125 - orphan designation for treatment of glioma temozolomide	New
10/04/2026	Orphan: EU/3/25/3127 - orphan designation for treatment of soft tissue sarcoma varegacestat	New
10/04/2026	Orphan: EU/3/25/3119 - orphan designation for treatment of fibrodysplasia ossificans progressiva zilurgisertib	New
10/04/2026	Orphan: EU/3/25/3130 - orphan designation for treatment of syndromic inherited retinal dystrophies of the cone-dominant phenotype sonpiretigene isteparvovec	New
10/04/2026	Orphan: EU/3/25/3131 - orphan designation for treatment of non-syndromic inherited retinal dystrophies of the rod-dominant phenotype sonpiretigene isteparvovec	New
10/04/2026	Orphan: EU/3/25/3135 - orphan designation for treatment of primary large B-cell lymphoma of immune-privileged sites methotrexate	New

10/04/2026	Orphan: EU/3/25/3132 - orphan designation for treatment of non-syndromic inherited retinal dystrophies of the cone-dominant phenotype sonpiretigene isteparvovec	New
10/04/2026	PIP: EMA-003071-PIP02-23 - paediatric investigation plan cedazuridine; decitabine	Updated
10/04/2026	Page: CHMP opinions on consultation procedures on ancillary substances incorporated in a medical device	Updated
10/04/2026	Medicine: Mynzepli afibercept	Updated
10/04/2026	Orphan: EU/3/25/3151 - orphan designation for treatment of primary sclerosing cholangitis leuconostoc citreum, strain G511, Live	New
10/04/2026	Medicine: Myclusen mycophenolate mofetil	Updated
10/04/2026	Orphan: EU/3/25/3159 - orphan designation for treatment of idiopathic pulmonary fibrosis orvepitant maleate	New
10/04/2026	Medicine: Abrysvo respiratory syncytial virus vaccine (bivalent, recombinant)	Updated
10/04/2026	Medicine: CellCept mycophenolate mofetil	Updated
10/04/2026	Page: Download medicine data	Updated
10/04/2026	Page: Download website data in JSON data format	Updated
10/04/2026	Medicine: Dupixent dupilumab	Updated
09/04/2026	Medicine: Cabliivi caplacizumab	Updated
09/04/2026	Medicine: Tafinlar dabrafenib	Updated
09/04/2026	Medicine: Iclusig ponatinib	Updated
09/04/2026	Medicine: Sorafenib Accord sorafenib	Updated
09/04/2026	Medicine: Kayshild semaglutide	Updated
09/04/2026	Medicine: Fylrevy estetrol	Updated
09/04/2026	Page: Union Product Database	Updated
09/04/2026	Medicine: Fintepla fenfluramine	Updated
09/04/2026	Medicine: Neofordex dexamethasone	Updated
09/04/2026	Medicine: Copiktra duvelisib	Updated
09/04/2026	Medicine: Ondibta insulin glargine	Updated
09/04/2026	Page: Core summary of product characteristics for human normal immunoglobulin for subcutaneous and intramuscular use - Scientific guideline	Updated

09/04/2026	Page: Clinical investigation of human normal immunoglobulin for subcutaneous and/or intramuscular administration (SCIg/IMIg) - Scientific guideline	Updated
09/04/2026	Document: Template for sharing EMA documents by Industry to support reliance	Updated
09/04/2026	Document: Clinical Trial Information System (CTIS) - Sponsor Frequently Asked Questions (FAQ)	Updated
09/04/2026	Medicine: Theralugand lutetium (177Lu) chloride	Updated
09/04/2026	Page: PRIME: priority medicines	Updated
09/04/2026	Medicine: Sibnaya potassium citrate; potassium hydrogen carbonate	Updated
09/04/2026	Document: List of medicines currently in PRIME scheme	Updated
09/04/2026	Medicine: Darzalex daratumumab	Updated
09/04/2026	Document: List of eligible industry stakeholder organisations	Updated
08/04/2026	Page: Vaccines: concerns, questions and false claims	Updated
08/04/2026	Page: COVID-19 vaccines: key facts	Updated
08/04/2026	Medicine: Supemtek trivalent influenza vaccine (recombinant, prepared in cell culture)	Updated
08/04/2026	Medicine: Comirnaty COVID-19 mRNA vaccine	Updated
08/04/2026	Medicine: Blenrep belantamab mafodotin	Updated
08/04/2026	Medicine: Yellox bromfenac	Updated
08/04/2026	Medicine: Fycompa perampanel	Updated
08/04/2026	Medicine: Agamree vamorolone	Updated
08/04/2026	Medicine: Rebif interferon beta-1a	Updated
08/04/2026	Medicine: Aripiprazole Zentiva aripiprazole	Updated
08/04/2026	Medicine: Poteligeo mogamulizumab	Updated
08/04/2026	Event: Breakthrough medical devices: information session	Updated
08/04/2026	Medicine: Crysvita burosumab	Updated
08/04/2026	Medicine: Rezzayo rezafungin	Updated
08/04/2026	Medicine: Doptelet avatrombopag	Updated
08/04/2026	Referral: Levamisole-containing medicinal products - referral levamisole	Updated

08/04/2026	Event: European Platform for Regulatory Science Research meeting	New
08/04/2026	Page: Maximum residue limits (MRLs): Questions and answers	New
08/04/2026	Page: Substances exempt from maximum residue limit evaluation	New
08/04/2026	Page: Submitting a maximum residue limit application	New
08/04/2026	Page: Establishing maximum residue limits for veterinary medicines	New
08/04/2026	Page: Maximum residue limits (MRL)	Updated
08/04/2026	Page: Animal health practitioners	Updated
08/04/2026	Page: Veterinary medicine safety day	New
08/04/2026	Document: Veterinary medicine safety day 2026: Image carousel	New
08/04/2026	Document: Veterinary medicine safety day 2026: Campaign poster	New
08/04/2026	Document: Veterinary medicine safety day: How to check veterinary medicines are working	New
08/04/2026	Document: Veterinary medicine safety day 2026: Expert presentation	New
08/04/2026	Document: Veterinary medicine safety day: Why read veterinary medicines package leaflet	New
08/04/2026	Document: Veterinary medicine safety day: How to dispose of unused veterinary medicines	New
08/04/2026	Document: CHMP PROM minutes for the meeting on 6 October 2025	Updated
08/04/2026	Document: CHMP PROM minutes for the meeting on 8 September 2025	Updated
08/04/2026	Document: CHMP PROM minutes for the meeting on 14 July 2025	Updated
08/04/2026	Document: CHMP PROM minutes for the meeting on 10 June 2025	Updated
08/04/2026	Document: CHMP PROM minutes for the meeting on 12 May 2025	Updated
07/04/2026	Medicine: Viramune nevirapine	Updated
07/04/2026	PSUSA: PSUSA/00002042/202507 - periodic safety update report single assessment metronidazole / miconazole, chlorquinaldol / metronidazole	Updated
07/04/2026	PSUSA: PSUSA/00002661/202507 - periodic safety update report single assessment ropinirole	New
07/04/2026	Page: Plasma master file certificates	Updated
07/04/2026	Medicine: Imcivree setmelanotide	Updated

07/04/2026	Medicine: Neupro rotigotine	Updated
07/04/2026	Medicine: Kavigale sipavibart	Updated
07/04/2026	Medicine: Aerinaze desloratadine; pseudoephedrine	Updated
07/04/2026	Document: Public engagement highlights 2025	New
07/04/2026	Medicine: Zokinvy lonafarnib	Updated
07/04/2026	Medicine: Rezurock belumosudil	Updated
07/04/2026	Event: Pharmacovigilance Risk Assessment Committee (PRAC): 7-10 April 2026	Updated
07/04/2026	Medicine: Opdualag relatlimab; nivolumab	Updated
07/04/2026	Medicine: Adtralza tralokinumab	Updated
07/04/2026	Medicine: Eurneffy epinephrine	Updated
07/04/2026	Page: Data protection and privacy at EMA	Updated
07/04/2026	Document: European Medicines Agency's data protection notice for the implementation of the Instrument for Pre-accession Assistance (IPA) programme	New
07/04/2026	Event: SPOR and XEVMPD status update webinar - Q2 2026	Updated
07/04/2026	Page: Industry Standing Group	Updated
07/04/2026	Document: Highlights - EMA - European Alliance of Associations for Rheumatology (EULAR) bilateral meeting - March 2026	New
07/04/2026	Event: European Medicines Regulatory Network (EMRN) workshop on Geographic Atrophy endpoints	Updated
07/04/2026	Event: Electronic application form (eAF) Q&A clinic	Updated
07/04/2026	Document: Notices and alerts per role - CTIS Training Programme - Module 07	Updated
07/04/2026	DHPC: Avtozma - direct healthcare professional communication (DHPC) tocilizumab	New
07/04/2026	Page: PRAC recommendations on safety signals	Updated
07/04/2026	Document: New product information wording - Extracts from PRAC recommendations on signals adopted at the 9-12 March 2026 PRAC	New
07/04/2026	Document: PRAC recommendations on signals adopted at the 9-12 March 2026 PRAC meeting	New
07/04/2026	Document: List of signals discussed at PRAC since September 2012	Updated

NOTICE TO APPLICANTS

No updates since October 30th, 2025.

BFARM - PHARMAKOVIGILANZ (SPECIFIC FOR GERMANY)

Date	Title
10.04.2026	Pharmacovigilance Risk Assessment Committee (PRAC) Das Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM) veröffentlicht die neuen Signale, die im Rahmen der PRAC-Sitzung vom 07.04.-10.04.2026 behandelt wurden.
10.04.2026	Informationen zu Einreichung und Genehmigung von Schulungsmaterial Aktualisierung der Hilfestellungsdokumente zur Einreichung und Genehmigung von behördlich genehmigten Schulungsmaterialien.
09.04.2026	Rote-Hand-Brief zu Mysimba (Naltrexon/Bupropion): Langfristiges kardiovaskuläres Risiko und neue Empfehlungen für die jährliche Bewertung Wirkstoff: Naltrexon, Bupropion Der Zulassungsinhaber von naltrexonhydrochlorid- und bupropionhydrochloridhaltigen Arzneimitteln informiert über den aktuellen Sachstand bezüglich langfristiger kardiovaskulärer Risiken von Mysimba.

BFARM – MEDIZINPRODUKTE (SPECIFIC FOR GERMANY)

No updates since April 02nd, 2026.

PEI - VIGILANZ (SPECIFIC FOR GERMANY)

No updates since April 01st 2026.

PHARMEUROPA TEXTS FOR COMMENT

Information on Pharmedeuropa updates will be presented quarterly.

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