TABLE OF CONTENTS

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
21/08/2026	**Medicine**: Ondibta insulin glargine	Updated
21/08/2026	**Medicine**: Rimmyrah ranibizumab	Updated
21/08/2026	**Medicine**: Cenrifki tolebrutinib	Updated
21/08/2026	**Medicine**: Imaavy nipocalimab	Updated
21/08/2026	**Medicine**: Veoza fezolinetant	Updated
21/08/2026	**Medicine**: Zolgensma onasemnogene abeparvovec	Updated
21/08/2026	**Medicine**: Tuyory tocilizumab	Updated
21/08/2026	**Medicine**: Enspryng satralizumab	Updated
21/08/2026	**Medicine**: Eylea aflibercept	Updated

Date	Content	Status
21/08/2026	**Medicine**: Rystiggo rozanolixizumab	Updated
21/08/2026	**Medicine**: Isembyld apitegromab	New
21/08/2026	**Orphan**: EU/3/18/2115 - orphan designation for treatment of spinal muscular atrophy human anti-promyostatin monoclonal antibody (apitegromab)	Updated
21/08/2026	**Orphan**: EU/3/15/1598 - orphan designation for treatment of Charcot-Marie-Tooth disease 2-(2-Chlorobenzylidene)hydrazinecarboximidamide acetate	Updated
21/08/2026	**Orphan**: EU/3/22/2618 - orphan designation for treatment of amyotrophic lateral sclerosis Icerguastat acetate	Updated
21/08/2026	**Orphan**: EU/3/14/1406 - orphan designation for treatment of inborn errors in primary bile acid synthesis chenodeoxycholic acid	Updated
21/08/2026	**Orphan**: EU/3/23/2850 - orphan designation for treatment of Alport syndrome setanaxib	Updated
21/08/2026	**Orphan**: EU/3/15/1559 - orphan designation for treatment of systemic sclerosis 2-(2-chlorophenyl)-4-[3-(dimethylamino)phenyl]-5-methyl-1H-pyrazolo[4,3-C]pyridine-3,6(2H,5H)-dione	Updated
21/08/2026	**Orphan**: EU/3/20/2387 - orphan designation for treatment of primary biliary cholangitis setanaxib	Updated
21/08/2026	**Orphan**: EU/3/23/2881 - orphan designation for treatment of acute myeloid leukaemia ziftomenib	Updated
21/08/2026	**Orphan**: EU/3/26/3227 - orphan designation for treatment of pancreatic cancer daraxonrasib	Updated
21/08/2026	**Orphan**: EU/3/15/1510 - orphan designation for treatment of amyotrophic lateral sclerosis edaravone	Updated
21/08/2026	**Orphan**: EU/3/21/2571 - orphan designation for treatment of Leber's hereditary optic neuropathy	Updated
21/08/2026	**Orphan**: EU/3/10/802 - orphan designation for treatment of idiopathic pulmonary fibrosis	Updated

Date	Content	Status
	2-(2-chlorophenyl)-4-[3-(dimethylamino)phenyl]-5-methyl-1H-pyrazolo[4,3-C]pyridine-3,6(2H,5H)-dione	
21/08/2026	**Orphan**: EU/3/24/2923 - orphan designation for treatment of small cell lung cancer 7-ethyl-10-hydroxy-camptothecin; irinotecan hydrochloride trihydrate	Updated
21/08/2026	**Orphan**: EU/3/24/2933 - orphan designation for treatment of hepatitis D virus infection human IgG1 monoclonal antibody against hepatitis B virus, surface antigen	Updated
21/08/2026	**Orphan**: EU/3/14/1278 - orphan designation for treatment of choroideraemia adeno-associated viral vector serotype 2 containing the human CHM gene encoding human Rab escort protein 1	Updated
21/08/2026	**Orphan**: EU/3/23/2764 - orphan designation for treatment of vanishing white matter disease guanabenz acetate	Updated
21/08/2026	**Orphan**: EU/3/17/1847 - orphan designation for treatment of soft tissue sarcoma milademetan tosilate monohydrate	Updated
21/08/2026	**Orphan**: EU/3/21/2478 - orphan designation for treatment of frontotemporal dementia adeno-associated virus vector serotype 1 containing the human GRN gene	Updated
21/08/2026	**Orphan**: EU/3/12/997 - orphan designation for treatment of schwannoma N-Hydroxy-4-(3-methyl-2-(S)-phenyl-butyrylamino) benzamide	Updated
21/08/2026	**Orphan**: EU/3/12/999 - orphan designation for treatment of cytomegalovirus disease in patients with impaired cell-mediated immunity Letermovir	Updated
21/08/2026	**Medicine**: Taltz ixekizumab	Updated
21/08/2026	**Orphan**: EU/3/12/996 - orphan designation for treatment of meningioma N-Hydroxy-4-(3-methyl-2-(S)-phenyl-butyrylamino) benzamide	Updated
21/08/2026	**Orphan**: EU/3/22/2589 - orphan designation for treatment of sickle cell disease (S)-12-fluoro-4-(2-methylpyridin-3-yl)-7a,8,13,14-tetrahydro-7H-[1,2,4]triazolo[4',3':1,6]pyrido[3,2-b]benzofuro[4,3-fg][1,4]oxazonine	Updated
21/08/2026	**Orphan**: EU/3/12/975 - orphan designation for treatment of Prader-Willi syndrome carbetocin	Updated
21/08/2026	**Orphan**: EU/3/14/1343 - orphan designation for treatment of pancreatic cancer Immunoglobulin G1, anti-(human tumour-associated calcium signal transducer 2)(human-Mus musculus monoclonal hRS7 heavy chain),	Updated

Date	Content	Status
	disulfide with human-Mus musculus monoclonal hRS7 κ-chain, dimer, hexakis(thioether) with (4S)-4-[[[[4-[[(2S)-2-(4-aminobutyl)-2-[[2-[2-[[26-[4-[[[[4-[(3-mercapto-2,5-dioxo-1-pyrrolidinyl)methyl]cyclohexyl]carbonyl]amino]methyl]-1H-1,2,3-triazol-1-yl]-3,6,9,12,15,18,21,24-octaoxahexacos-1-yl]amino]-2-oxoethoxy]acetyl]amino]-1-oxoethyl]amino]phenyl]methoxy]carbonyl]oxy]-4,11-diethyl-9-hydroxy-1H-pyrano[3',4':6,7]indolizino[1,2-b]quinoline-3,14(4H,12H)-dione (sacituzumab govitecan)	
21/08/2026	**Orphan**: EU/3/21/2416 - orphan designation for treatment of glioma 5-fluoro-4-(7'-fluoro-2'-methylspiro[cyclopentane-1,3'-indol]-5'-yl)-N-(5-(1-methylpiperidin-4-yl)pyridin-2-yl)pyrimidin-2-amine; crozbaciclib	Updated
21/08/2026	**Orphan**: EU/3/22/2707 - orphan designation for treatment of Guillain-Barré syndrome Eculizumab	Updated
21/08/2026	**Orphan**: EU/3/17/1902 - orphan designation for treatment of hepatocellular carcinoma N-{2-[(6-{[(2,6-dichloro-3,5-dimethoxyphenyl)carbamoyl](methyl)amino}pyrimidin-4-yl)amino]-5-(4-ethylpiperazin-1-yl)phenyl}prop-2-enamide	Updated
21/08/2026	**Medicine**: Krazati adagrasib	Updated
21/08/2026	**Orphan**: EU/3/13/1222 - orphan designation for treatment of malignant mesothelioma amatuximab	Updated
21/08/2026	**Orphan**: EU/3/08/535 - orphan designation for treatment of ovarian cancer Humanised monoclonal antibody to the folate receptor alpha	Updated
21/08/2026	**Orphan**: EU/3/24/2915 - orphan designation for treatment of idiopathic hypersomnia serdexmethylphenidate	Updated
21/08/2026	**PSUSA**: PSUSA/00000633/202504 - periodic safety update report single assessment cetrorelix	New
21/08/2026	**Orphan**: EU/3/09/696 - orphan designation for treatment of ovarian cancer human MHC non-restricted cytotoxic T-cell line	Updated
21/08/2026	**Medicine**: Vabysmo faricimab	Updated
21/08/2026	**Orphan**: EU/3/20/2268 - orphan designation for diagnosis of AL amyloidosis florbetaben (18F)	Updated

Date	Content	Status
21/08/2026	**Orphan**: EU/3/20/2313 - orphan designation for diagnosis of progressive supranuclear palsy 2-(2-(18F)fluoropyridin-4-yl)-9H-pyrrolo[2,3-b:4,5-c']dipyridine	Updated
21/08/2026	**Orphan**: EU/3/20/2340 - orphan designation for diagnosis of corticobasal degeneration 2-(2-(18F)fluoropyridin-4-yl)-9H-pyrrolo[2,3-b:4,5-c']dipyridine	Updated
21/08/2026	**Orphan**: EU/3/25/3055 - orphan designation for diagnosis of ATTR amyloidosis florbetaben (18F)	Updated
21/08/2026	**Orphan**: EU/3/22/2661 - orphan designation for treatment of glioma 2,4,6,7,8,9-hexahydro-4-((2-methylphenyl)methyl)-7-(phenylmethyl)imidazo(1,2-a)pyrido(3,4-e)pyrimidin-5(1H)-one	Updated
21/08/2026	**Medicine**: Aripiprazole Sandoz aripiprazole	Updated
21/08/2026	**Medicine**: Ngenla somatrogon	Updated
21/08/2026	**Document**: Report - Quality Innovation Group (QIG): Listen and learn focus group meeting on sustainability	New
21/08/2026	**Medicine**: Tavneos avacopan	Updated
21/08/2026	**Medicine**: Oxbryta voxelotor	Updated
21/08/2026	**Medicine**: Artesunate Amivas artesunate	Updated
21/08/2026	**Medicine**: Zilbrysq zilucoplan	Updated
21/08/2026	**Event**: EMA risk management information day	Updated
20/08/2026	**Medicine**: Lacosamide UCB lacosamide	Updated
20/08/2026	**Medicine**: Junod denosumab	Updated
20/08/2026	**Medicine**: Xolremdi mavorixafor	Updated
20/08/2026	**Medicine**: Vimpat lacosamide	Updated
20/08/2026	**Medicine**: Epidyolex cannabidiol	Updated

Date	Content	Status
20/08/2026	**Medicine**: MabThera rituximab	Updated
20/08/2026	**Medicine**: Instanyl fentanyl	Updated
20/08/2026	**Medicine**: Epivir lamivudine	Updated
20/08/2026	**Medicine**: Ocrevus ocrelizumab	Updated
20/08/2026	**Document**: Timetable: Post-authorisation measure (PAM) assessed by PRAC	Updated
20/08/2026	**Document**: Timetable: Post-authorisation measures (PAMs) assessed by PRAC - ATMP	Updated
20/08/2026	**Medicine**: Rivastigmine 1 A Pharma rivastigmine	Updated
20/08/2026	**Medicine**: Rivastigmine Hexal rivastigmine	Updated
20/08/2026	**Medicine**: Rivastigmine Sandoz rivastigmine	Updated
20/08/2026	**Document**: Guidance and template for industry on implementing Shortage Prevention Plans (SPP)	Updated
20/08/2026	**Document**: Timetable: Companion diagnostic follow-up consultation	Updated
20/08/2026	**Document**: Timetable: Companion diagnostic follow-up consultation - ATMP	Updated
20/08/2026	**Document**: Timetable: Companion diagnostic initial consultation	Updated
20/08/2026	**Document**: Timetable: Companion diagnostic initial consultation - ATMP	Updated
20/08/2026	**Document**: Timetable: Type II variation and worksharing application monthly assessment	Updated
20/08/2026	**Medicine**: Arexvy Respiratory Syncytial Virus (RSV) vaccine (recombinant, adjuvanted)	Updated
20/08/2026	**Medicine**: Kesimpta ofatumumab	Updated

Date	Content	Status
20/08/2026	**Medicine**: Ryeqo relugolix; estradiol; norethisterone acetate	Updated
20/08/2026	**DHPC**: Jentadueto - direct healthcare professional communication (DHPC) linagliptin; metformin hydrochloride	New
20/08/2026	**Medicine**: Samsca tolvaptan	Updated
19/08/2026	**Document**: International Pharmaceutical Abstracts (IPA) journals	Updated
19/08/2026	**Document**: Monitoring of medical literature and the entry of relevant information into the EudraVigilance database by the European Medicines Agency - Description of the Journal/Reference databases used	Updated
19/08/2026	**Medicine**: Tyenne tocilizumab	Updated
19/08/2026	**Medicine**: Rubraca rucaparib	Updated
19/08/2026	**Medicine**: Kisqali ribociclib	Updated
19/08/2026	**Medicine**: Vanflyta quizartinib	Updated
19/08/2026	**Medicine**: Skyclarys omaveloxolone	Updated
19/08/2026	**Medicine**: Andembry garadacimab	Updated
19/08/2026	**Medicine**: Nivestim filgrastim	Updated
19/08/2026	**Medicine**: Nucala mepolizumab	Updated
19/08/2026	**Medicine**: Opdivo nivolumab	Updated
19/08/2026	**Event**: EMA multi-stakeholder workshop on supporting innovation in cardiovascular medicines and medical devices in the EU	Updated
19/08/2026	**Document**: Product Management Service (PMS) public API - Frequently asked questions (FAQs)	Updated
19/08/2026	**Medicine**: Kaftrio ivacaftor; tezacaftor; elexacaftor	Updated

Date	Content	Status
19/08/2026	**Medicine**: Alyftrek deutivacaftor / tezacaftor / vanzacaftor	Updated
19/08/2026	**Medicine**: Jinarc tolvaptan	Updated
19/08/2026	**Medicine**: Ryzneuta efbemalenograstim alfa	Updated
19/08/2026	**EU-M4all**: Dengue Tetravalent Vaccine (Live, Attenuated) Takeda - opinion on medicine for use outside EU dengue tetravalent vaccine (live, attenuated)	Updated
19/08/2026	**Medicine**: Febuxostat Viatris (previously Febuxostat Mylan) febuxostat	Updated
19/08/2026	**Medicine**: Qdenga dengue tetravalent vaccine (live, attenuated)	Updated
19/08/2026	**Page**: Pre-authorisation guidance	Updated
19/08/2026	**Medicine**: Inrebic fedratinib	Updated
19/08/2026	**Medicine**: Xeljanz tofacitinib	Updated
19/08/2026	**Document**: Questions and answers - Practical arrangements on the companion diagnostics consultation procedure to the European Medicines Agency by notified bodies	Updated
19/08/2026	**Document**: Template for submission of comments for the Veterinary Dictionary for Drug Regulatory Activities (VeDDRA) standard list for EudraVigilance Veterinary (EVVet)	Updated
19/08/2026	**Document**: EMA procedural advice for medicinal products intended exclusively for markets outside the European Union in the context of co-operation with the World Health Organisation (WHO)	Updated
19/08/2026	**Document**: Questions and answers - Practical arrangements on the companion diagnostics consultation procedure to the European Medicines Agency by notified bodies - tracked changes	Updated
19/08/2026	**Document**: Questions and answers on the consultation procedure to the European Medicines Agency by notified bodies on an ancillary medicinal substance or an ancillary human blood derivative incorporated in a medical device	Updated

Date	Content	Status
19/08/2026	**Page**: Pre-authorisation guidance under the Veterinary Medicinal Products Regulation (Regulation (EU) 2019/6)	Updated
19/08/2026	**Document**: European Medicines Agency pre-authorisation procedural advice for users of the centralised procedure	Updated
19/08/2026	**Document**: European Medicines Agency pre-authorisation procedural advice for users of the centralised procedure: document with tracked changes	Updated
19/08/2026	**Page**: Marketing authorisation (veterinary medicines)	Updated
19/08/2026	**Document**: Veterinary medicines marketing authorisation application pre-submission interaction request form	Updated
19/08/2026	**Medicine**: Prolia denosumab	Updated
18/08/2026	**Page**: Accessibility	Updated
18/08/2026	**Medicine**: Herwenda trastuzumab	Updated
18/08/2026	**Medicine**: Tagrisso osimertinib	Updated
18/08/2026	**Medicine**: Arixtra fondaparinux sodium	Updated
18/08/2026	**Medicine**: Alimta pemetrexed	Updated
18/08/2026	**Medicine**: Parsabiv etelcalcetide	Updated
18/08/2026	**Document**: Medicinal products for human use: monthly figures - July 2026	New
18/08/2026	**Document**: Timetable: Post-authorisation measure (PAM) Paediatric art. 46 submission	Updated
18/08/2026	**Event**: Webinar on new approach methodologies (NAMs) in ecotoxicology: QSARs to predict aquatic toxicity	New

Date	Content	Status
18/08/2026	**Document**: Timetable: Post-authorisation measure (PAM) assessed by CHMP	Updated
18/08/2026	**Document**: Timetable: Post-authorisation measure (PAM) assessed by CAT	Updated
18/08/2026	**Medicine**: Mounjaro tirzepatide	Updated
18/08/2026	**Document**: Timetable: Post-authorisation measure (PAM) Paediatric art. 46 submission - ATMP	Updated
18/08/2026	**Medicine**: Stelara ustekinumab	Updated
18/08/2026	**Medicine**: Brilique ticagrelor	Updated
18/08/2026	**Medicine**: Tuznue trastuzumab	Updated
18/08/2026	**Medicine**: Amgevita adalimumab	Updated
18/08/2026	**Medicine**: Yaxwer denosumab	Updated
18/08/2026	**PSUSA**: PSUSA/00000548/202510 - periodic safety update report single assessment carbidopa / levodopa	New
18/08/2026	**Medicine**: Dupixent dupilumab	Updated
18/08/2026	**Medicine**: Conexxence denosumab	Updated
18/08/2026	**Post-authorisation**: Dupixent - withdrawal of application for variation to marketing authorisation dupilumab	Updated
18/08/2026	**Medicine**: Temodal temozolomide	Updated
18/08/2026	**Medicine**: Akeega niraparib; abiraterone acetate	Updated
18/08/2026	**Medicine**: MenQuadfi meningococcal group A, C, W-135 and Y conjugate vaccine	Updated
18/08/2026	**Medicine**: Vislyfa ranibizumab	Updated

Date	Content	Status
18/08/2026	**Page**: International Coalition of Medicines Regulatory Authorities (ICMRA)	Updated
17/08/2026	**Medicine**: Rinvoq upadacitinib	Updated
17/08/2026	**Event**: Shortage prevention plan (SPP) workshop	Updated
17/08/2026	**Document**: Draft data standards framework	New
17/08/2026	**Medicine**: Pheburane sodium phenylbutyrate	Updated
17/08/2026	**Document**: Minutes of the Management Board meeting: 10-11 June 2026	New
17/08/2026	**Document**: Shortage prevention plan (SPP) workshop report	New

NOTICE TO APPLICANTS

No updates since June 24th, 2026.

BFARM - PHARMAKOVIGILANZ (SPECIFIC FOR GERMANY)

Date	Title
19.08.2026	**Umsetzung des einstimmigen Beschlusses der Koordinierungsgruppe vom 25.06.2026 betreffend die Zulassungen für Humanarzneimittel mit der Wirkstoffkombination Bisoprolol/Perindopril** Das BfArM veröffentlicht den Umsetzungsbescheid für die Wirkstoffkombination Bisoprolol/Perindopril Bisoprolol infolge des Europäischen PSUR Single Assessment Verfahrens nach Artikel 107d) bis g) der Richtlinie 2001/83/EG.
19.08.2026	**Umsetzung des einstimmigen Beschlusses der Koordinierungsgruppe vom 25.06.2026 betreffend die Zulassungen für Humanarzneimittel mit dem Wirkstoff Bisoprolol** Das BfArM veröffentlicht den Umsetzungsbescheid für den Wirkstoff Bisoprolol infolge des Europäischen PSUR Single Assessment Verfahrens nach Artikel 107d) bis g) der Richtlinie 2001/83/EG.

BFARM – MEDIZINPRODUKTE (SPECIFIC FOR GERMANY)

Date	Title
12.08.2026	**Prüfbogen für wesentliche Veränderungen und geringfügige Änderungen nach § 18 der Digitale Gesundheitsanwendungen-Verordnung (DiGAV)** Prüfbogen für wesentliche Veränderungen und geringfügige Änderungen nach § 18 der Digitale Gesundheitsanwendungen-Verordnung (DiGAV)

PEI - VIGILANZ (SPECIFIC FOR GERMANY)

No updates since August 3rd, 2026.

PHARMEUROPA TEXTS FOR COMMENT

Information on Pharmeuropa updates will be presented quarterly.