

TABLE OF CONTENTS

HEADS OF AGENCIES – CMDH.....	1
HEADS OF AGENCIES – PAEDIATRIC REGULATION	1
EUROPEAN MEDICINES AGENCY (EMA)	1
NOTICE TO APPLICANTS.....	8
BFARM - PHARMAKOVIGILANZ (SPECIFIC FOR GERMANY).....	8
BFARM – MEDIZINPRODUKTE (SPECIFIC FOR GERMANY)	9
PEI - VIGILANZ (SPECIFIC FOR GERMANY)	9
PHARMEUROPA TEXTS FOR COMMENT.....	9

HEADS OF AGENCIES – CMDh

20 April

[NEW - 21-22 April CMDh agenda](#)

HEADS OF AGENCIES – PAEDIATRIC REGULATION

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

EUROPEAN MEDICINES AGENCY (EMA)

Date	Content	Status
24/04/2026	Shortage: Methotrexate methotrexate	Updated
24/04/2026	Shortage: Hycamtin topotecan	Updated
24/04/2026	Document: Minutes - Executive steering group on shortages and safety of medicinal products (MSSG) - 23 March 2026	New
24/04/2026	Shortage: Menopur menotropin	Updated
24/04/2026	Shortage: Perfusion solutions	Updated
24/04/2026	Document: Minutes of the CVMP meeting 10-12 February 2026	New
24/04/2026	Medicine: Ranluspec ranibizumab	Updated
24/04/2026	Event: 20th anniversary of European Medicines Agency's Patients' and Consumers' Working Party (PCWP)	Updated

Date	Content	Status
24/04/2026	Medicine: Besremi ropeginterferon alfa-2b	Updated
24/04/2026	Medicine: Beyfortus nirsevimab	Updated
24/04/2026	Medicine: Epidyolex cannabidiol	Updated
24/04/2026	Document: Orientation guide for patient representatives and healthcare professionals - EMA building	Updated
24/04/2026	Document: Orientation guide for delegates - EMA building	Updated
24/04/2026	Medicine: Advate octocog alfa	Updated
24/04/2026	Medicine: Caelyx pegylated liposomal doxorubicin	Updated
24/04/2026	Medicine: Stelara ustekinumab	Updated
24/04/2026	Medicine: Striascan ioflupane (1231)	Updated
24/04/2026	Medicine: Ondibta insulin glargine	Updated
24/04/2026	News: Meeting highlights from the Committee for Medicinal Products for Human Use (CHMP) 20-23 April 2026	New
24/04/2026	Medicine: Cenrifki tolebrutinib	New
24/04/2026	Medicine: Palbociclib Viartis palbociclib	New
24/04/2026	Medicine: Itvisma onasemnogene abeparvovec	New
24/04/2026	Medicine: Redemplo plozasiran	New
24/04/2026	Medicine: Rexatilux ranibizumab	New
24/04/2026	Medicine: Viokat diazoxide choline	New
24/04/2026	Post-authorisation: Privigen - opinion on variation to marketing authorisation human normal immunoglobulin (IVIg)	New

Date	Content	Status
24/04/2026	Post-authorisation: Inaqovi - opinion on variation to marketing authorisation cedazuridine; decitabine	New
24/04/2026	Post-authorisation: Opdivo - opinion on variation to marketing authorisation nivolumab	New
24/04/2026	Post-authorisation: Aquipta - opinion on variation to marketing authorisation atogepant	New
24/04/2026	Post-authorisation: Crysvita - opinion on variation to marketing authorisation burosumab	New
24/04/2026	Post-authorisation: Skyrizi - opinion on variation to marketing authorisation risankizumab	New
24/04/2026	Post-authorisation: Comirnaty - opinion on variation to marketing authorisation COVID-19 mRNA vaccine	New
24/04/2026	Post-authorisation: Venclxyto - opinion on variation to marketing authorisation venetoclax	New
24/04/2026	Post-authorisation: Venclxyto - opinion on variation to marketing authorisation venetoclax	New
24/04/2026	Document: Draft concept paper on the development for guidance on demonstration of biosimilarity of biological veterinary medicinal products	New
24/04/2026	Page: Demonstration of biosimilarity of biological veterinary medicinal products - Scientific guideline	New
24/04/2026	Event: ACT EU webinar on contractual agreements	Updated
24/04/2026	Event: EnprEMA & ACT EU workshop on paediatric clinical trials	Updated
24/04/2026	Orphan: EU/3/17/1941 - orphan designation for treatment of Prader-Willi syndrome diazoxide choline	Updated
24/04/2026	Event: Clinical Trials Information System (CTIS): Walk-in clinic April 2026	Updated
24/04/2026	Event: European Platform for Regulatory Science Research meeting	Updated
24/04/2026	Page: Expert panel support for breakthrough medical devices: pilot programme	Updated

Date	Content	Status
24/04/2026	Document: Breakthrough status request: Template for applicants for breakthrough medical devices pilot	New
24/04/2026	Event: CVMP Interested Parties' meeting 2026	New
24/04/2026	Document: Advice request: Template for applicants for breakthrough medical devices pilot	New
24/04/2026	Post-authorisation: Pluvicto - withdrawal of application for variation to marketing authorisation lutetium (177Lu) vipivotide tetraxetan	New
24/04/2026	Document: Draft reflection paper on the use of macrolides, lincosamides and streptogramins (MLS) in animals in the European Union: development of resistance and impact on public and animal health - Revision 1	New
24/04/2026	Page: Use of macrolides, lincosamides and streptogramins (MLS) in animals in the European Union - Scientific guideline	Updated
24/04/2026	Medicine: Vysribli (previously Denosumab Intas) Vysribli	Updated
24/04/2026	Orphan: EU/3/21/2459 - orphan designation for treatment of familial chylomicronaemia syndrome synthetic double-stranded siRNA oligonucleotide directed against apolipoprotein C-III mRNA and covalently linked to a ligand containing three N-acetylgalactosamine residues	Updated
24/04/2026	News: New medicine to reduce triglycerides in adults with familial chylomicronaemia syndrome	New
23/04/2026	PIP: EMEA-001776-PIP01-15-M01 - paediatric investigation plan risankizumab	Updated
23/04/2026	Medicine: Terrosa teriparatide	Updated
23/04/2026	Medicine: Kinpeygo budesonide	Updated
23/04/2026	Medicine: Jayempi azathioprine	Updated
23/04/2026	Medicine: Aptivus tipranavir	Updated
23/04/2026	Medicine: Praxbind idarucizumab	Updated
23/04/2026	Medicine: Jemperli dostarlimab	Updated
23/04/2026	Medicine: Zilbrysq zilucoplan	Updated
23/04/2026	DHPC: Savene - direct healthcare professional communication (DHPC) dexrazoxane	New
23/04/2026	Medicine: Opsumit macitentan	Updated
23/04/2026	Medicine: Nulojix belatacept	Updated
23/04/2026	Medicine: Taltz ixekizumab	Updated

Date	Content	Status
23/04/2026	Medicine: Remsima infliximab	Updated
23/04/2026	Medicine: Amgevita adalimumab	Updated
23/04/2026	News: EMA business hours over King's Day and Labour Day, 27 April and 1 May	New
23/04/2026	Document: Product Management Service (PMS) – Frequently Asked Questions (FAQs)	Updated
23/04/2026	Page: Podcast: Inside EMA	Updated
23/04/2026	Page: Referentials Management Service (RMS)	Updated
22/04/2026	Medicine: Movymia teriparatide	Updated
22/04/2026	Orphan: EU/3/26/3225 - orphan designation for prevention of corneal graft rejection aganirsen	New
22/04/2026	Orphan: EU/3/26/3224 - orphan designation for treatment of large B-cell lymphoma surovatamig	New
22/04/2026	Orphan: EU/3/26/3222 - orphan designation for treatment of myelofibrosis 3-(4-((7-Cyano-1-methyl-2-((1-methyl-2-oxo-5-(trifluoromethyl)-1,2-dihydropyridin-3-yl)amino)-1H-imidazo[4,5-b]pyridin-6-yl)oxy)pyridin-2-yl)-1,1-dimethylurea	New
22/04/2026	Orphan: EU/3/26/3226 - orphan designation for treatment of Duchenne muscular dystrophy adeno-associated virus serotype SLB101 containing the human microdystrophin gene	New
22/04/2026	Orphan: EU/3/26/3229 - orphan designation for treatment of SYNGAP1-related disorder antisense oligonucleotide against SYNGAP1 regulatory RNA	New
22/04/2026	Medicine: Vyndaqel tafamidis	Updated
22/04/2026	Orphan: EU/3/26/3220 - orphan designation for treatment of systemic sclerosis upadacitinib	New
22/04/2026	Orphan: EU/3/26/3228 - orphan designation for treatment of congenital factor V deficiency coagulation factor V	New
22/04/2026	Page: Procurement and grants	Updated
22/04/2026	Orphan: EU/3/26/3223 - orphan designation for treatment of VEXAS syndrome Momelotinib dihydrochloride monohydrate	New
22/04/2026	Orphan: EU/3/26/3227 - orphan designation for treatment of pancreatic cancer daraxonrasib	New
22/04/2026	Medicine: Volibris ambrisentan	Updated

Date	Content	Status
22/04/2026	Orphan: EU/3/26/3221 - orphan designation for treatment of spinal cord injury oremepemin alfa	New
22/04/2026	Orphan: EU/3/26/3218 - orphan designation for treatment of myelodysplastic syndromes lisaftoclax	New
22/04/2026	Orphan: EU/3/26/3214 - orphan designation for treatment of CACNA1A disorders acetylleucine	New
22/04/2026	Medicine: Dabigatran Etxilate Accord dabigatran etexilate	Updated
22/04/2026	Orphan: EU/3/26/3216 - orphan designation for treatment of Alport syndrome exaluren sulfate	New
22/04/2026	Orphan: EU/3/26/3210 - orphan designation for treatment of vernal keratoconjunctivitis tacrolimus monohydrate	New
22/04/2026	Medicine: Forxiga dapagliflozin	Updated
22/04/2026	Medicine: Erleada apalutamide	Updated
22/04/2026	Medicine: Ozempic semaglutide	Updated
22/04/2026	Medicine: Rybelsus semaglutide	Updated
22/04/2026	Medicine: Noxafil posaconazole	Updated
22/04/2026	Medicine: Loqtorzi toripalimab	Updated
22/04/2026	Medicine: Rotarix rotavirus vaccine, live	Updated
22/04/2026	Medicine: Irbesartan Zentiva (previously Irbesartan Winthrop) irbesartan	Updated
22/04/2026	Medicine: Keytruda pembrolizumab	Updated
22/04/2026	Medicine: Enflonsia clesrovimab	Updated
22/04/2026	Orphan: EU/3/26/3215 - orphan designation for treatment of pulmonary neuroendocrine carcinoma atigotatug; nivolumab	New
22/04/2026	Orphan: EU/3/26/3217 - orphan designation for treatment of hepatocellular carcinoma irpagratinib tosilate monohydrate	New
22/04/2026	Orphan: EU/3/26/3213 - orphan designation for treatment of pancreatic cancer telisotuzumab adizutecan	New
22/04/2026	Orphan: EU/3/26/3211 - orphan designation for treatment of homocystinuria and/or methylmalonic acidaemia due to genetic defects of intracellular cobalamin processing hydroxocobalamin acetate	New
22/04/2026	Orphan: EU/3/26/3209 - orphan designation for treatment of pulmonary neuroendocrine carcinoma humanised IgG1 monoclonal antibody against SEZ6, conjugated to (2S)-2-	New

Date	Content	Status
	(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	
21/04/2026	Medicine: Pyrukynd mitapivat	Updated
21/04/2026	Medicine: Verquvo vericiguat	Updated
21/04/2026	Document: Clinical Data Publication (CDP) - Questions and Answers (Q&As) on the European Medicines Agency policy on the publication of clinical data for medicinal products for human use (Policy 0070) work-share initiative with Health Canada (HC)	New
21/04/2026	Medicine: Veoza fezolinetant	Updated
21/04/2026	Document: Agenda - PDCO agenda of the 21-24 April 2026 meeting	New
21/04/2026	Medicine: Ezmekly mirdametinib	Updated
21/04/2026	Medicine: Arsenic trioxide medac arsenic trioxide	Updated
21/04/2026	Herbal: Centaurii herba - herbal medicinal product Centaury	Updated
21/04/2026	Medicine: Evrysdi risdiplam	Updated
21/04/2026	Medicine: Orphacol cholic acid	Updated
21/04/2026	Medicine: Ferriprox deferiprone	Updated
21/04/2026	Document: Process for the electronic submission of medicinal product information - Chapter 3	Updated
21/04/2026	Document: Process for submitting existing data on medicinal products authorised for human use – SIAMED II & XEVMPD to PMS deltas - Chapter 9	Updated
21/04/2026	Event: Q&A clinic on eXtended EudraVigilance Medicinal Product Dictionary (XEVMPD) service - March 2026	Updated
21/04/2026	Event: Q&A clinic on Substance, Organisation, Referentials Management Services - March 2026	Updated
21/04/2026	Shortage: Moventig	Updated
21/04/2026	Document: Opinion of the CVMP on the establishment of maximum residue limits: Lidocaine (EMA/V/MRL/003649/MODF/0004)	Updated
20/04/2026	Document: Guidance on the electronic submission of information on investigational medicinal products for human use in the Extended EudraVigilance medicinal product dictionary (XEVMPD)	Updated

Date	Content	Status
20/04/2026	Orphan: EU/3/26/3212 - orphan designation for treatment of large granular lymphocytic leukaemia dibotatug	New
20/04/2026	Event: Committee for Medicinal Products for Human Use (CHMP): 20-23 April 2026	Updated
20/04/2026	Document: Annex to agenda of the CHMP meeting 20-23 April 2026	New
20/04/2026	Document: Agenda of the CHMP meeting 20-23 April 2026	New
20/04/2026	Orphan: EU/3/26/3219 - orphan designation for treatment of Behçet's Disease dusquetide	New
20/04/2026	Medicine: Roteas edoxaban	Updated
20/04/2026	Medicine: Lixiana edoxaban	Updated
20/04/2026	Event: European Shortages Monitoring Platform (ESMP) training on readable IDs and general updates for industry	Updated
20/04/2026	Medicine: Aclasta zoledronic acid	Updated
20/04/2026	Page: Submission dates	Updated
20/04/2026	Page: Respiratory syncytial virus (RSV)	New
20/04/2026	Medicine: Dupixent dupilumab	Updated
20/04/2026	Document: Validation checklist for initial marketing authorisation applications - biologicals other than immunologicals (applicable to submissions under Regulation (EU) 2019/6)	Updated
20/04/2026	Document: Focus group on submission predictability: 2025 final report	New

NOTICE TO APPLICANTS

No updates since October 30th, 2025.

BFARM - PHARMAKOVIGILANZ (SPECIFIC FOR GERMANY)

Date	Title
23.04.2026	<p>Umsetzung des Durchführungsbeschlusses der Europäischen Kommission vom 30.03.2026 zum PSUR Single Assessment betreffend die Zulassungen für Humanarzneimittel mit dem Wirkstoff Mycophenolatmofetil, Mycophenolsäure</p> <p>Das BfArM veröffentlicht den Umsetzungsbescheid für den Wirkstoff Mycophenolatmofetil, Mycophenolsäure infolge des Europäischen PSUR Single Assessment Verfahrens nach Artikel 107d) bis g) der Richtlinie 2001/83/EG.</p>

Date	Title
22.04.2026	<p>Umsetzung des Durchführungsbeschlusses der Europäischen Kommission vom 07.04.2026 zum PSUR Single Assessment betreffend die Zulassungen für Humanarzneimittel mit der Wirkstoffkombination Hydrochlorothiazid/Telmisartan und dem Wirkstoff Telmisartan</p> <p>Das BfArM veröffentlicht den Umsetzungsbescheid für die Wirkstoffkombination Hydrochlorothiazid/Telmisartan und den Wirkstoff Telmisartan infolge des Europäischen PSUR Single Assessment Verfahrens nach Artikel 107d) bis g) der Richtlinie 2001/83/EG.</p>
20.04.2026	<p>Umsetzung des einstimmigen Beschlusses der Koordinierungsgruppe vom 29.01.2026 betreffend die Zulassungen für Humanarzneimittel mit dem Wirkstoff Methadon</p> <p>Das BfArM veröffentlicht den Umsetzungsbescheid für den Wirkstoff Methadon infolge des Europäischen PSUR Single Assessment Verfahrens nach Artikel 107d) bis g) der Richtlinie 2001/83/EG.</p>
20.04.2026	<p>Umsetzung des einstimmigen Beschlusses der Koordinierungsgruppe vom 29.01.2026 betreffend die Zulassungen für Humanarzneimittel mit dem Wirkstoff Ioversol</p> <p>Das BfArM veröffentlicht den Umsetzungsbescheid für den Wirkstoff Ioversol infolge des Europäischen PSUR Single Assessment Verfahrens nach Artikel 107d) bis g) der Richtlinie 2001/83/EG.</p>

BFARM – MEDIZINPRODUKTE (SPECIFIC FOR GERMANY)

No updates since April 17th 2026.

PEI - VIGILANZ (SPECIFIC FOR GERMANY)

Date	Title
22.04.2026	Sicherheitsbewertung von Aluminium in Therapieallergenen

PHARMEUROPA TEXTS FOR COMMENT

Information on Pharmeuropa updates will be presented quarterly.

Trotz regelmäßiger Aktualisierung und sorgfältiger Überwachung der Veröffentlichungen können wir keine Haftung oder Garantie für die Aktualität, Richtigkeit und Vollständigkeit der hier bereitgestellten Informationen übernehmen. Dieser Newsletter enthält Links zu anderen Websites. Trotz sorgfältiger inhaltlicher Kontrolle übernehmen wir keine Haftung für die Inhalte externer Links. Für den Inhalt der verlinkten Seiten sind ausschließlich deren Betreiber verantwortlich.

Despite regular updating and careful monitoring of the publications, we cannot take any responsibility or guarantee for the topicality, correctness and completeness of the information provided here. This Newsletter contains links to other websites. Despite careful control of the content we would like to point out that we are not liable for the contents of external web links. The editors of the respective websites are fully responsible for their contents.