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HEADS OF AGENCIES – CMDh

No updates since May 07th, 2026.

HEADS OF AGENCIES – PAEDIATRIC REGULATION

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

EUROPEAN MEDICINES AGENCY (EMA)

Date	Content	Status
13/05/2026	Referral: Levamisole-containing medicinal products - referral levamisole	Updated
13/05/2026	Medicine: Lucentis ranibizumab	Updated
13/05/2026	DHPC: Tecovirimat SIGA - direct healthcare professional communication (DHPC) tecovirimat monohydrate	Updated
13/05/2026	DHPC: Ontozry - direct healthcare professional communication (DHPC) cenobamate	New
13/05/2026	Medicine: Iclusig ponatinib	Updated
13/05/2026	Medicine: Aspaveli pegcetacoplan	Updated
13/05/2026	Medicine: EndolucinBeta lutetium (177Lu) chloride	Updated
13/05/2026	Document: Timetable: Initial (full) marketing authorisation application accelerated assessment timetables - Advanced therapy medicinal product (ATMP)	Updated

Date	Content	Status
13/05/2026	Document: Timetable: Initial (full) marketing authorisation application accelerated assessment timetables	Updated
13/05/2026	Document: Timetable: Initial (Full) marketing authorisation application - ATMP	Updated
13/05/2026	Document: Timetable: Informed consent and multiple application	Updated
13/05/2026	Document: Timetable: Extension application	Updated
13/05/2026	Document: Timetable: Accelerated assessment request for initial marketing authorisations - ATMP	Updated
13/05/2026	Document: Timetable accelerated assessment request for initial marketing authorisation applications	Updated
13/05/2026	Orphan: EU/3/17/1971 - orphan designation for treatment of RARS2 syndrome vatiquinone	Updated
13/05/2026	Orphan: EU/3/21/2536 - orphan designation for treatment of Alpers-Huttenlocher syndrome vatiquinone	Updated
13/05/2026	Orphan: EU/3/22/2573 - orphan designation for treatment of mitochondrial encephalomyopathy, lactic acidosis, and stroke-like episodes vatiquinone	Updated
13/05/2026	Orphan: EU/3/20/2383 - orphan designation for treatment of respiratory distress syndrome perflubron	Updated
13/05/2026	Orphan: EU/3/18/2114 - orphan designation for treatment in solid organ transplantation C1 esterase inhibitor (human)	Updated
13/05/2026	Orphan: EU/3/13/1184 - orphan designation for treatment of sickle cell disease	Updated
13/05/2026	Document: Timetable: Extension application - ATMP	Updated
13/05/2026	Medicine: Hetrionfly serplulimab	Updated
13/05/2026	Document: HMPC meetings in 2025 and 2026	Updated

Date	Content	Status
13/05/2026	Document: HMPC: overview of assessment work - priority list	Updated
13/05/2026	Medicine: Rivastigmine Hexal rivastigmine	Updated
12/05/2026	Herbal: Fragariae folium - herbal medicinal product Wild Strawberry Leaf	Updated
12/05/2026	Medicine: Sotyktu deucravacitinib	Updated
12/05/2026	Page: Development and manufacture of synthetic peptides - Scientific guideline	Updated
12/05/2026	Page: Parallel scientific advice and special development aspects or product types	Updated
12/05/2026	Medicine: Ezmekly mirdametinib	Updated
12/05/2026	Page: Other fees and charges for medicinal products for human use, veterinary medicinal products and consultations on medical devices	Updated
12/05/2026	Medicine: Xbonzy denosumab	Updated
12/05/2026	Medicine: Evrenzo roxadustat	Updated
12/05/2026	Medicine: Olazax Disperzi olanzapine	Updated
12/05/2026	Medicine: Zoledronic acid Actavis zoledronic acid	Updated
12/05/2026	News: EMA actively monitoring cruise ship Hantavirus outbreak	New
12/05/2026	Medicine: Zoledronic Acid Hospira zoledronic acid	Updated
12/05/2026	News: EMA business hours over Ascension Day holidays, 14 and 15 May	New
12/05/2026	Document: Article 57 product data	Updated
12/05/2026	Event: Workshop on Vulnerability Assessment	Updated
12/05/2026	Medicine: Emepax maropitant	Updated
12/05/2026	Medicine: Xolremdi mavoxifafor	Updated

Date	Content	Status
12/05/2026	PSUSA: PSUSA/00002540/202509 - periodic safety update report single assessment progesterone	New
12/05/2026	Medicine: AviGate S. Infantis Salmonella Infantis vaccine (live)	Updated
12/05/2026	Medicine: VeroBlue-3 bluetongue virus vaccine (inactivated)	Updated
12/05/2026	News: EMA welcomes political agreement on Critical Medicines Act	New
12/05/2026	Document: Template for response to list of questions/list of outstanding issues: Quality / Non-clinical / Clinical	Updated
11/05/2026	Medicine: Lenalidomide Mylan lenalidomide	Updated
11/05/2026	Medicine: Olazax olanzapine	Updated
11/05/2026	Medicine: Tobi Podhaler tobramycin	Updated
11/05/2026	Medicine: Camcevi leuprorelin	Updated
11/05/2026	Medicine: Imuldosa ustekinumab	Updated
11/05/2026	PSUSA: PSUSA/00002702/202509 - periodic safety update report single assessment silver sulfadiazine	New
11/05/2026	PSUSA: PSUSA/00002904/202509 - periodic safety update report single assessment terizidone	New
11/05/2026	PSUSA: PSUSA/00010582/202509 - periodic safety update report single assessment allergen for therapy: dermatophagoides pteronyssinus / dermatophagoides farina (oromucosal use, products authorised via mutually recognition procedure and decentralised procedure)	New
11/05/2026	Medicine: Omlyclo omalizumab	Updated
11/05/2026	Medicine: Exdensur depemokimab	Updated
11/05/2026	Medicine: Qalsody tofersen	Updated
11/05/2026	Medicine: Amglidia glibenclamide	Updated
11/05/2026	Medicine: Giotrif afatinib	Updated
11/05/2026	Medicine: Orencia abatacept	Updated
11/05/2026	Medicine: Denbrayce denosumab	Updated
11/05/2026	Document: Agenda of the CAT meeting 11-13 May 2026	New
11/05/2026	Document: Applications for new human medicines under evaluation: May 2026	New

Date	Content	Status
11/05/2026	Herbal: Hamamelidis cortex - herbal medicinal product Hamamelis Bark	Updated
11/05/2026	Herbal: Hamamelidis folium - herbal medicinal product Hamamelis Leaf	Updated
11/05/2026	Herbal: Hamamelidis folium et cortex aut ramunculus destillatum - herbal medicinal product Hamamelis Distillate	Updated
11/05/2026	Document: Antimicrobial Sales and Use (ASU) Platform: Release notes	Updated
11/05/2026	Document: Olazax : EPAR - Procedural steps taken and scientific information after authorisation (archive)	Updated
11/05/2026	Document: Agenda - EnprEMA & ACT EU workshop on paediatric clinical trials	Updated
11/05/2026	Medicine: Ojemda tovorafenib	Updated
11/05/2026	Orphan: EU/3/21/2477 - orphan designation for treatment of otoferlin gene-mediated hearing loss Adeno-associated viral vector serotype Anc80 containing the 3' portion of human OTOF gene, adeno-associated viral vector serotype Anc80 containing the 5' portion of human OTOF gene	Updated
11/05/2026	Orphan: EU/3/23/2779 - orphan designation for treatment of neurofibromatosis type 1 2-((2-fluoro-4-iodophenyl)amino)-N-(2-hydroxyethoxy)-1-methyl-1H-pyrrolo[2,3-b]pyridine-3-carboxamide	Updated
11/05/2026	Orphan: EU/3/21/2510 - orphan designation for treatment of hypoparathyroidism encaleret	Updated
11/05/2026	Orphan: EU/3/22/2641 - orphan designation for treatment of myelodysplastic syndromes eltanexor	Updated
11/05/2026	Orphan: EU/3/14/1317 - orphan designation for treatment of diffuse large B-cell lymphoma (Z)-3-(3-(3,5-bis(trifluoromethyl)phenyl)-1H-1,2,4-triazol-1-yl)-N'-(pyrazin-2-yl)acrylohydrazide	Updated
11/05/2026	Orphan: EU/3/14/1354 - orphan designation for treatment of chronic lymphocytic leukaemia / small lymphocytic lymphoma selinexor	Updated
11/05/2026	Orphan: EU/3/22/2705 - orphan designation for treatment of myelofibrosis selinexor	Updated
11/05/2026	Orphan: EU/3/21/2509 - orphan designation for treatment of glioma selinexor	Updated
11/05/2026	Orphan: EU/3/14/1313 - orphan designation for treatment of acute myeloid leukaemia (Z)-3-(3-(3,5-bis(trifluoromethyl)phenyl)-1H-1,2,4-triazol-1-yl)-N'-(pyrazin-2-yl)acrylohydrazide	Updated
11/05/2026	Orphan: EU/3/25/3071 - orphan designation for treatment of primary sclerosing cholangitis beta-lapachone	Updated

Date	Content	Status
11/05/2026	Orphan: EU/3/21/2470 - orphan designation for treatment of amyotrophic lateral sclerosis pridopidine hydrochloride	Updated
11/05/2026	Orphan: EU/3/05/288 - orphan designation for treatment of Huntington's disease 4-[3-(Methylsulfonyl)phenyl]-1-propylpiperidine x HCl (pridopidine hydrochloride)	Updated
11/05/2026	Event: Breakthrough medical devices: information session	Updated
11/05/2026	Document: Agenda of the COMP Meeting 11-12 May 2026	New

NOTICE TO APPLICANTS

No updates since October 30th, 2025.

BFARM - PHARMAKOVIGILANZ (SPECIFIC FOR GERMANY)

Date	Title
13.05.2026	Informationen zu Einreichung und Genehmigung von Schulungsmaterial Aktualisierung der Hilfestellungsdokumente zur Einreichung und Genehmigung von behördlich genehmigten Schulungsmaterialien.
12.05.2026	Rote-Hand-Brief zu Ontozry (Cenobamat): Risiko für schweren Leberschaden und neue Empfehlungen zur Überwachung der Leberfunktion Wirkstoff: Cenobamat Das BfArM informiert darüber, dass bei mit Ontozry behandelten Patienten Fälle von schwerem Leberschaden einschließlich Lebersversagen berichtet wurde.
11.05.2026	Tecovirimat SIGA: Überprüfung der Wirksamkeit bei der Behandlung von Mpx Wirkstoff: Tecovirimat Der Ausschuss für Humanarzneimittel (CHMP) der EMA hat empfohlen, Tecovirimat SIGA nicht länger zur Behandlung von Mpx anzuwenden.
11.05.2026	Rote-Hand-Brief zu Tecovirimat SIGA (Tecovirimat-Monohydrat): Einschränkung der Indikation aufgrund mangelnder Wirksamkeit bei Patienten mit Mpx Wirkstoff: Tecovirimat Die Firma SIGA Technologies Netherlands B.V. informiert darüber, dass Tecovirimat SIGA (Tecovirimat-Monohydrat) bei Patienten mit Mpx eine mangelnde Wirksamkeit aufweist.
11.05.2026	Studien bei Synapse Labs, Indien: Überprüfung in Bezug auf die Durchführung Wirkstoff: Verschiedene Für Arzneimittel, für die Studien von Synapse Labs, einem Auftragsforschungsinstitut (CRO) mit Sitz in Indien, durchgeführt wurden, ist das Ruhen der Zulassungen bis zum 25.05.2028 verlängert worden.
11.05.2026	93. Sitzung (21. Juli 2026 per Videokonferenz) – Tagesordnung Sachverständigen-Ausschuss für Verschreibungspflicht nach § 53 Absatz 2 AMG

BFARM – MEDIZINPRODUKTE (SPECIFIC FOR GERMANY)

No updates since April 17th, 2026.

PEI - VIGILANZ (SPECIFIC FOR GERMANY)

Date	Title
12.05.2026	Informationsschreiben von Biotest Pharma GmbH: Yimmugo

PHARMEUROPA TEXTS FOR COMMENT

Information on Pharmedeuropa updates will be presented quarterly.

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