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HEADS OF AGENCIES – CMDh

No updates since April 7th, 2026.

HEADS OF AGENCIES – PAEDIATRIC REGULATION

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

EUROPEAN MEDICINES AGENCY (EMA)

Date	Content	Status
17/04/2026	Herbal: Rusci rhizoma - herbal medicinal product Butcher's Broom	Updated
17/04/2026	Medicine: Evrysdi risdiplam	Updated
17/04/2026	Medicine: Micardis telmisartan	Updated
17/04/2026	Medicine: Tepmetko tepotinib	Updated
17/04/2026	Post-authorisation: Startvac - opinion on variation to marketing authorisation adjuvanted inactivated vaccine for cattle against Staphylococcus aureus, coliforms and coagulase-negative staphylococci	New
17/04/2026	Medicine: Nobivac NXT HCPChFeLV feline calicivirosis, feline rhinotracheitis, feline panleucopenia, feline chlamydiosis (live) and feline leukemia (RNA replicon particle) vaccine	New
17/04/2026	News: Meeting highlights from the Committee for Veterinary Medicinal Products (CVMP) 14-16 April 2026	New

17/04/2026	News: EMA recommends authorisation of first veterinary vaccine using RNA technology	New
17/04/2026	Medicine: Rezurock belumosudil	Updated
17/04/2026	Medicine: Teizeild teplizumab	Updated
17/04/2026	Medicine: Livmarli maralixibat chloride	Updated
16/04/2026	Medicine: Atriance nelarabine	Updated
16/04/2026	Medicine: Steqeyma ustekinumab	Updated
16/04/2026	Page: Recommendations on medication errors	Updated
16/04/2026	Document: Minutes - HMA-EMA joint Network Data Steering Group meeting - 9 March 2026	New
16/04/2026	Event: Q&A clinic on eXtended EudraVigilance Medicinal Product Dictionary (XEVMPD) service - October 2026	New
16/04/2026	Event: Q&A clinic on eXtended EudraVigilance Medicinal Product Dictionary (XEVMPD) service - July 2026	New
16/04/2026	Event: Q&A clinic on eXtended EudraVigilance Medicinal Product Dictionary (XEVMPD) service - June 2026	New
16/04/2026	Event: Q&A clinic on eXtended EudraVigilance Medicinal Product Dictionary (XEVMPD) service - November 2026	New
16/04/2026	Event: Q&A clinic on eXtended EudraVigilance Medicinal Product Dictionary (XEVMPD) service - December 2026	New
16/04/2026	Event: Q&A clinic on eXtended EudraVigilance Medicinal Product Dictionary (XEVMPD) service - September 2026	New
16/04/2026	Page: Human papillomavirus (HPV)	Updated
16/04/2026	Page: Applying for orphan designation	Updated

16/04/2026	Medicine: Qoyvolma ustekinumab	Updated
16/04/2026	Document: Procedural advice for orphan medicinal product designation: Guidance for sponsors	Updated
16/04/2026	Event: ACT EU webinar on draft guidance on the conduct of clinical trials during public health emergencies	Updated
16/04/2026	Document: Regulatory Procedure Management in IRIS roadmap	Updated
16/04/2026	Document: Chapter 3.II: XEVPRM detailed user guidance on the electronic submission of information on medicinal products for human use by marketing authorisation holders to the EMA	Updated
16/04/2026	Medicine: Zolsketil pegylated liposomal doxorubicin	Updated
16/04/2026	DHPC: Levamisole - direct healthcare professional communication (DHPC) levamisole	New
16/04/2026	Medicine: Emtricitabine / Tenofovir alafenamide Viartis emtricitabine; tenofovir alafenamide	Updated
16/04/2026	Event: Q&A clinic on Substance, Organisation, Referentials Management Services - September 2026	New
16/04/2026	Event: Q&A clinic on Substance, Organisation, Referentials Management Services - November 2026	New
16/04/2026	Event: Q&A clinic on Substance, Organisation, Referentials Management Services - December 2026	New
16/04/2026	Event: Q&A clinic on Substance, Organisation, Referentials Management Services - October 2026	New
16/04/2026	Event: Q&A clinic on Substance, Organisation, Referentials Management Services - July 2026	New
16/04/2026	Event: Q&A clinic on Substance, Organisation, Referentials Management Services - June 2026	New
16/04/2026	Page: CHMP opinions on consultation procedures on ancillary substances incorporated in a medical device	Updated

16/04/2026	Document: IVF Media G5 - Procedural steps and scientific information after initial consultation	Updated
16/04/2026	PSUSA: PSUSA/00002475/202509 - periodic safety update report single assessment povidone, polyvinyl alcohol / povidone	New
16/04/2026	Medicine: Ocrevus ocrelizumab	Updated
16/04/2026	Medicine: Icatibant Accord icatibant	Updated
16/04/2026	Medicine: Myqorzo aficamten	Updated
16/04/2026	Medicine: Enwylma denosumab	Updated
16/04/2026	Document: Procedural advice on paediatric applications	Updated
16/04/2026	Document: Template for scientific document for paediatric investigation plan or product-specific waiver	Updated
16/04/2026	Document: Paediatric investigation plan (PIP) - Key elements form	Updated
15/04/2026	PSUSA: PSUSA/00001392/202508 - periodic safety update report single assessment finasteride	New
15/04/2026	EU-M4all: Acoziborole Winthrop - opinion on medicine for use outside EU acoziborole	Updated
15/04/2026	Medicine: Jelrix autologous cartilage-derived articular chondrocytes, in-vitro expanded	Updated
15/04/2026	Medicine: Kygevvi doxocitine; doxribtimine	Updated
15/04/2026	Medicine: Teduglutide Viatrix teduglutide	Updated
15/04/2026	Medicine: Prialt ziconotide	Updated
15/04/2026	Page: EU Innovation Network (EU-IN)	Updated
15/04/2026	Document: Radiopharmaceuticals EU-IN Horizon Scanning Report	New
15/04/2026	PSUSA: PSUSA/00000073/202507 - periodic safety update report single assessment albendazole	New
15/04/2026	Medicine: Lorviqua lorlatinib	Updated
15/04/2026	Medicine: Jorveza budesonide	Updated
15/04/2026	Medicine: Bortezomib Hospira bortezomib	Updated
15/04/2026	Event: Meeting of the Medicine Shortages Single Point of Contact (SPOC) Working Party	Updated
14/04/2026	Orphan: EU/3/25/3140 - orphan designation for treatment of pulmonary neuroendocrine carcinoma risvutatug rezetecan	New

14/04/2026	Orphan: EU/3/25/3144 - orphan designation for treatment of Rett syndrome fenfluramine hydrochloride	New
14/04/2026	Page: Paediatric investigation plans: questions and answers	Updated
14/04/2026	Orphan: EU/3/25/3141 - orphan designation for treatment of Hirschsprung's disease glial cell line-derived neurotrophic factor; sodium butyrate	New
14/04/2026	Orphan: EU/3/25/3137 - orphan designation for treatment of amyotrophic lateral sclerosis Unasnemab	New
14/04/2026	PSUSA: PSUSA/00001912/202509 - periodic safety update report single assessment losartan	New
14/04/2026	Orphan: EU/3/25/3138 - orphan designation for treatment of Glanzmann thrombasthenia sutacimig	New
14/04/2026	Orphan: EU/3/25/3142 - orphan designation for treatment of primary IgA nephropathy mezagitamab	New
14/04/2026	Orphan: EU/3/25/3136 - orphan designation for treatment of Glanzmann thrombasthenia ozisiran	New
14/04/2026	Orphan: EU/3/25/3143 - orphan designation for treatment of congenital aceruloplasminemia ceruloplasmin	New
14/04/2026	Document: List of industry subject matter experts and list of planned calls for industry subject matter experts	Updated
14/04/2026	Event: European Medicines Agency meeting with senior representatives of pharmaceutical companies	New
14/04/2026	Orphan: EU/3/25/3156 - orphan designation for treatment of primary membranous nephropathy Felzartamab	New
14/04/2026	Orphan: EU/3/25/3158 - orphan designation for treatment of systemic sclerosis resecabtagene autoleucel	New
14/04/2026	Orphan: EU/3/25/3147 - orphan designation for treatment of sickle cell disease nangibotide	New
14/04/2026	Orphan: EU/3/25/3139 - orphan designation for treatment of Huntington's disease bevantolol hydrochloride	New
14/04/2026	Orphan: EU/3/25/3157 - orphan designation for treatment of hypochondroplasia Infigratinib	New
14/04/2026	Orphan: EU/3/25/3145 - orphan designation for treatment of peripheral T-cell lymphoma soquelitinib	New
14/04/2026	Orphan: EU/3/26/3207 - orphan designation for treatment of inherited retinal dystrophy due to biallelic autosomal recessive mutations in the human guanylate cyclase 1 (GUCY2D) gene	New

	non-replicating adeno-associated virus serotype 5 containing the human retinal guanylate cyclase 1 gene	
14/04/2026	Orphan: EU/3/26/3198 - orphan designation for treatment of intestinal failure-associated liver disease orziloben	New
14/04/2026	Orphan: EU/3/26/3200 - orphan designation for treatment of acute respiratory distress syndrome (ARDS) aviptadil	New
14/04/2026	Shortage: Creon pancreas powder; pancrelipase	Updated
14/04/2026	Orphan: EU/3/26/3202 - orphan designation for treatment of palmoplantar pustulosis 1- {[2-(3,6-Diazabicyclo[3.1.1]heptan-3-yl)-7-(1,3-thiazol-2-yl)-1,3-benzoxazol-4-yl]oxy}-1,1-difluoro-2-methylpropan-2-ol	New
14/04/2026	PSUSA: PSUSA/00000415/202508 - periodic safety update report single assessment biperiden	New
14/04/2026	PSUSA: PSUSA/00000813/202508 - periodic safety update report single assessment clonidine	New
14/04/2026	Medicine: Bluevac BTV (previously Bluevac BTV8)	Updated
14/04/2026	Medicine: Spevigo spesolimab	Updated
14/04/2026	Medicine: Pavblu afibercept	Updated
14/04/2026	Medicine: Vfend voriconazole	Updated
14/04/2026	Orphan: EU/3/26/3206 - orphan designation for treatment of ovarian cancer rinatabart sesutecan	New
14/04/2026	Orphan: EU/3/26/3208 - orphan designation for treatment of inherited retinal dystrophy due to dysfunction in the human retinoschisin (RS1) gene adeno-associated viral vector serotype 44.9 containing the human HRS1 gene	New
14/04/2026	Orphan: EU/3/26/3195 - orphan designation for treatment of primary IgA nephropathy sefaxersen	New
14/04/2026	Document: Article 57 product data	Updated
14/04/2026	Document: Applications for new human medicines under evaluation: April 2026	New
14/04/2026	Event: Committee for Medicinal Products for Veterinary Use (CVMP): 14-16 April 2026	Updated
13/04/2026	PSUSA: PSUSA/00002156/202508 - periodic safety update report single assessment nifedipine	New
13/04/2026	PSUSA: PSUSA/00001945/202508 - periodic safety update report single assessment meclozine	New

13/04/2026	PSUSA: PSUSA/00010224/202508 - periodic safety update report single assessment fluocinolone acetonide (intravitreal implant in applicator)	New
13/04/2026	Medicine: Aripiprazole Sandoz aripiprazole	Updated
13/04/2026	PSUSA: PSUSA/00002605/202509 - periodic safety update report single assessment raltitrexed	New
13/04/2026	Orphan: EU/3/26/3205 - orphan designation for treatment of primary membranous nephropathy povetacicept	New
13/04/2026	Document: Records of data processing activity for the EudraVigilance Signal and Safety Analytics (EV SSA) platform	New
13/04/2026	Document: PDCO minutes of the 24-27 February 2026 meeting	New

NOTICE TO APPLICANTS

No updates since October 30th, 2025.

BFARM - PHARMAKOVIGILANZ (SPECIFIC FOR GERMANY)

Date	Title
16.04.2026	Umsetzung des einstimmigen Beschlusses der Koordinierungsgruppe vom 29.01.2026 betreffend die Zulassungen für Humanarzneimittel mit dem Wirkstoff Tamoxifen Das BfArM veröffentlicht den Umsetzungsbescheid für den Wirkstoff Tamoxifen infolge des Europäischen PSUR Single Assessment Verfahrens nach Artikel 107d) bis g) der Richtlinie 2001/83/EG.
16.04.2026	Umsetzung des einstimmigen Beschlusses der Koordinierungsgruppe vom 29.01.2026 betreffend die Zulassungen für Humanarzneimittel mit dem Wirkstoff Levomethadon Das BfArM veröffentlicht den Umsetzungsbescheid für den Wirkstoff Levomethadon infolge des Europäischen PSUR Single Assessment Verfahrens nach Artikel 107d) bis g) der Richtlinie 2001/83/EG.
16.04.2026	Informationen zu Einreichung und Genehmigung von Schulungsmaterial Aktualisierung der Hilfestellungsdokumente zur Einreichung und Genehmigung von behördlich genehmigten Schulungsmaterialien.
15.04.2026	Venöse Thromboembolien und kombinierte hormonale Kontrazeptiva Im Januar 2024 wurde das bisher unbekannte Risiko für eine venöse Thromboembolie für die Kombination aus Chlormadinon und Ethinylestradiol auf Grundlage der Ergebnisse einer retrospektiven Kohortenstudie bestimmt und ergänzt.
13.04.2026	Informationen zu Rote-Hand-Briefen und Informationsbriefen Das Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM) veröffentlicht neue Hinweise zu anstehenden Rote-Hand-Briefen und Informationsbriefen.

BFARM – MEDIZINPRODUKTE (SPECIFIC FOR GERMANY)

Date	Title
17.04.2026	Registrierung von Medizinprodukten: Übergang vom DMIDS zu EUDAMED Die EU-Kommission bietet im April und Mai drei Webinare zu den Modulen Actors, UDI/Devices und Notified Bodies & Certificates an.

PEI - VIGILANZ (SPECIFIC FOR GERMANY)

No updates since April 01st 2026.

PHARMEUROPA TEXTS FOR COMMENT

Information on Pharmedropa updates will be presented quarterly.

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