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HEADS OF AGENCIES – CMDh

No updates since May 27th, 2026.

HEADS OF AGENCIES – PAEDIATRIC REGULATION

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

EUROPEAN MEDICINES AGENCY (EMA)

Date	Content	Status
19/06/2026	Medicine: Winrevair sotatercept	Updated
19/06/2026	Medicine: Nobivac NXT HCPFeLV feline calicivirosis, feline rhinotracheitis, feline panleucopenia (live) and feline leukemia (RNA replicon particle) vaccine	New
19/06/2026	Medicine: Nobivac NXT HCPChFeLV feline calicivirosis, feline rhinotracheitis, feline panleucopenia, feline chlamydiosis (live) and feline leukemia (RNA replicon particle) vaccine	Updated
19/06/2026	Medicine: Scovella velagliflozin	New
19/06/2026	News: Meeting highlights from the Committee for Veterinary Medicinal Products (CVMP) 16-18 June 2026	New
19/06/2026	Medicine: Nobivac NXT FeLV feline leukemia (RNA particle) vaccine	New
19/06/2026	Event: EMA workshop on the challenges in drug development, regulation and clinical practice in immune thrombocytopenia	Updated
19/06/2026	PIP: EMA/PE/0000231366 - paediatric investigation plan efgartigimod alfa	New

Date	Content	Status
19/06/2026	PIP: EMA/PE/0000228536 - paediatric investigation plan enlicitide (decanoate)	New
19/06/2026	PIP: EMA/PE/0000228081 - paediatric investigation plan voclosporin	New
19/06/2026	PIP: EMA/PE/0000189672 - paediatric investigation plan obefazimod	New
19/06/2026	PIP: EMA/PE/0000233797 - paediatric investigation plan delandistrogene moxeparvovec	New
19/06/2026	Medicine: Leqembi lecanemab	Updated
19/06/2026	Medicine: Semglee insulin glargine	Updated
18/06/2026	PIP: EMA/PE/0000227963 - paediatric investigation plan catequentinib (dihydrochloride)	New
18/06/2026	PIP: EMA/PE/0000232680 - paediatric investigation plan ustekinumab	New
18/06/2026	PIP: EMA/PE/0000233803 - paediatric investigation plan chikungunya virus virus-like particle (CHIKV VLP)	New
18/06/2026	Orphan: EU/3/06/368 - orphan designation for treatment of Fabry disease 1-Deoxygalactonojirimycin hydrochloride	Updated
18/06/2026	PIP: EMA/PE/0000229144 - paediatric investigation plan Respiratory Syncytial Virus stabilised prefusion f subunit vaccine (RSVpreF)	New
18/06/2026	PIP: EMA/PE/0000232890 - paediatric investigation plan clevidipine	New
18/06/2026	PIP: EMA/PE/0000228305 - paediatric investigation plan	New
18/06/2026	Page: How to recognise scams and phishing using EMA credentials	Updated
17/06/2026	Page: One Health approach	Updated
17/06/2026	Document: EU Implementation Guide (IG) on veterinary medicines product data in the Union Product Database - Chapter 7: Submission of other post-authorisation data	Updated
17/06/2026	Document: Timetable: Type II variation and worksharing application monthly assessment	Updated

Date	Content	Status
17/06/2026	Document: Timetable: Type II variation and worksharing application assessment - ATMP	Updated
17/06/2026	Document: Medicinal products for human use: monthly figures - May 2026	New
17/06/2026	Document: Darwin EU: Making health data count	Updated
17/06/2026	Document: DARWIN EU data partners onboarded in Year I, II, III and IV	Updated
17/06/2026	PIP: EMEA-003553-PIP01-23 - paediatric investigation plan oreporexton	New
17/06/2026	PIP: EMEA-002568-PIP02-23 - paediatric investigation plan sonelokimab	New
17/06/2026	PIP: EMA/PE/0000239927 - paediatric investigation plan [2-Chloro-3-(trifluoromethyl)phenyl][(4R)-1-(5-fluoro-2-pyrimidinyl)-4-methyl-1,4,6,7-tetrahydro-5H-[1,2,3]triazolo[4,5-c]pyridin-5-yl]methanone	New
17/06/2026	PIP: EMA/PE/0000233807 - paediatric investigation plan visugromab	New
17/06/2026	PIP: EMA/PE/0000233717 - paediatric investigation plan benzoyl peroxide (hydrous)	New
17/06/2026	PIP: EMA/PE/0000233446 - paediatric investigation plan Ifinatamab deruxtecan	New
17/06/2026	PIP: EMA/PE/0000232939 - paediatric investigation plan surabgene lomparvovec	New
17/06/2026	PIP: EMA/PE/0000232936 - paediatric investigation plan atigotatug; nivolumab	New
17/06/2026	Event: Committee for Advanced Therapies (CAT): 17-19 June 2026	Updated
16/06/2026	Event: Sixteenth meeting of the industry stakeholder platform on the operation of the centralised procedure for human medicines	Updated
16/06/2026	Event: Meeting of the Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG) - May 2026	Updated
16/06/2026	Document: Timetable: Type II variation and worksharing application weekly assessment	Updated
16/06/2026	Document: Timetable: Type II variation and worksharing application alternative monthly assessment	Updated
16/06/2026	Page: Languages on this website	Updated

Date	Content	Status
16/06/2026	Page: Data recommendations for herbal medicinal products and traditional herbal medicinal products used in paediatric patients - Scientific guideline	New
16/06/2026	PSUSA: PSUSA/00001104/202509 - periodic safety update report single assessment dinoprostone	New
16/06/2026	Document: Regulatory Procedure Management in IRIS roadmap	Updated
16/06/2026	PSUSA: PSUSA/00010155/202509 - periodic safety update report single assessment felbamate	New
16/06/2026	Page: Frequently asked questions	Updated
16/06/2026	Event: Meeting of the Medicine Shortages Single Point of Contact (SPOC) Working Party	Updated
16/06/2026	PSUSA: PSUSA/00002305/202511 - periodic safety update report single assessment ascorbic acid / caffeine / paracetamol / phenylephrine hydrochloride / terpine	New
16/06/2026	PSUSA: PSUSA/00000767/202511 - periodic safety update report single assessment cinnarizine / dimenhydrinate	New
16/06/2026	PSUSA: PSUSA/00000694/202511 - periodic safety update report single assessment acetylsalicylic acid / chlorphenamine / phenylephrine	New
16/06/2026	Event: First Advisory group on vaccine confidence meeting	New
16/06/2026	PSUSA: PSUSA/00002564/202510 - periodic safety update report single assessment prothipendyl	Updated
16/06/2026	Medicine: Eydenzelt aflibercept	Updated
16/06/2026	Medicine: Kefdensis denosumab	Updated
16/06/2026	Document: Process for the electronic submission of medicinal product information - Chapter 3	Updated
16/06/2026	Event: Joint Heads of Medicines Agencies (HMA)/European Medicines Agency (EMA) multistakeholder workshop on Patient Registries for Alzheimer's disease	Updated
16/06/2026	Document: Committee for Advanced Therapies (CAT) rules of procedure	Updated
16/06/2026	PSUSA: PSUSA/00000967/202509 - periodic safety update report single assessment desogestrel / ethinylestradiol	New
16/06/2026	PSUSA: PSUSA/00001786/202510 - periodic safety update report single assessment isoflurane	New
16/06/2026	PSUSA: PSUSA/00010735/202510 - periodic safety update report single assessment valsartan / rosuvastatin	New

Date	Content	Status
16/06/2026	PSUSA: PSUSA/00000236/202510 - periodic safety update report single assessment artemether / lumefantrin (apart from the dispersible tablet)	New
16/06/2026	PSUSA: PSUSA/00000165/202510 - periodic safety update report single assessment aminosalicylic acid	New
16/06/2026	PSUSA: PSUSA/00000437/202509 - periodic safety update report single assessment bromhexine	New
16/06/2026	PSUSA: PSUSA/00000794/202509 - periodic safety update report single assessment clenbuterol	New
16/06/2026	PSUSA: PSUSA/00002681/202510 - periodic safety update report single assessment salmeterol	New
16/06/2026	PSUSA: PSUSA/00002066/202510 - periodic safety update report single assessment minoxidil (non topical formulations)	New
16/06/2026	Medicine: Kadcyla trastuzumab emtansine	Updated
16/06/2026	Medicine: Nucala mepolizumab	Updated
16/06/2026	Medicine: Ziihera zanidatamab	Updated
15/06/2026	Medicine: Startvac adjuvanted inactivated vaccine for cattle against Staphylococcus aureus, coliforms and coagulase-negative staphylococci	Updated
15/06/2026	Medicine: Lonquex lipegfilgrastim	Updated
15/06/2026	Medicine: Opzelura ruxolitinib	Updated
15/06/2026	Medicine: Palsonify paltusotine	Updated
15/06/2026	Medicine: Entyvio vedolizumab	Updated
15/06/2026	Medicine: Rimmyrah ranibizumab	Updated
15/06/2026	Medicine: Rezzayo rezafungin	Updated
15/06/2026	Medicine: Zolgensma onasemnogene abeparvovec	Updated
15/06/2026	Medicine: Grasustek pegfilgrastim	Updated
15/06/2026	Page: Contacting EMA: post-authorisation	Updated
15/06/2026	Page: Notifying EMA of changes to contact persons (veterinary medicines)	Updated
15/06/2026	Document: IRIS guide for applicants - How to create, submit and manage IRIS applications, for industry and individual applicants	Updated
15/06/2026	Document: IRIS guide to registration and RPIs	Updated

Date	Content	Status
15/06/2026	Referral: Tecovirimat SIGA - referral tecovirimat	Updated
15/06/2026	Medicine: Tecovirimat SIGA tecovirimat monohydrate	Updated
15/06/2026	Event: Webinar on the use of platform approaches in the non-clinical and clinical domains	Updated
15/06/2026	Event: Committee for Medicinal Products for Veterinary Use (CVMP): 10-12 March 2026	Updated
15/06/2026	News: EMA Management Board: highlights of June 2026 meeting	New
15/06/2026	Medicine: Sitagliptin / Metformin hydrochloride Mylan sitagliptin hydrochloride monohydrate; metformin hydrochloride	Updated
15/06/2026	Medicine: Tadalafil Mylan tadalafil	Updated
15/06/2026	Medicine: Tuyory tocilizumab	Updated

NOTICE TO APPLICANTS

No updates since October 30th, 2025.

BFARM - PHARMAKOVIGILANZ (SPECIFIC FOR GERMANY)

Date	Title
15.06.2026	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
18.06.2026	SAE- und DD-Meldung im Rahmen einer klinischen Prüfung SAE- und DD-Meldung im Rahmen einer klinischen Prüfung

PEI - VIGILANZ (SPECIFIC FOR GERMANY)

No updates since May 12th, 2026.

PHARMEUROPA TEXTS FOR COMMENT

Information on Pharmedeuropa updates will be presented quarterly.

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