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HEADS OF AGENCIES – CMDh

No updates since March 04th, 2026.

HEADS OF AGENCIES – PAEDIATRIC REGULATION

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

EUROPEAN MEDICINES AGENCY (EMA)

Date	Content	Status
20/03/2026	Event: EMA traineeship programme informative session	New
20/03/2026	Medicine: Apremilast Accord apremilast	Updated
20/03/2026	Medicine: Cunitraxx fenbendazole	New
20/03/2026	PSUSA: PSUSA/00000402/202506 - periodic safety update report single assessment bethanechol	New
20/03/2026	Medicine: Ebglyss lebrikizumab	Updated
20/03/2026	PIP: EMA/PE/0000232315 - paediatric investigation plan spesolimab	Updated
20/03/2026	Medicine: Adcetris brentuximab vedotin	Updated
20/03/2026	Medicine: Evfraxy denosumab	Updated
20/03/2026	Document: MedDRA important medical event terms list - version 29.0	Updated

Date	Content	Status
20/03/2026	Document: EMA's biennial report on stakeholder engagement activities 2024-2025	New
20/03/2026	Medicine: Xofluza baloxavir marboxil	Updated
20/03/2026	Page: Plant testing strategy in the risk assessment for veterinary medicinal products - Scientific guideline	Updated
20/03/2026	Page: Guidance and template on the risk management plan (RMP) for novel therapy veterinary medicinal products - Scientific guideline	New
20/03/2026	Page: EU Innovation Network (EU-IN)	Updated
20/03/2026	Page: Chemistry of active substances (chemistry of new active substances) - Scientific guideline	Updated
20/03/2026	Event: EMA workshop on the challenges in drug development, regulation and clinical practice in immune thrombocytopenia	New
20/03/2026	Event: Meeting of the Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG) - April 2026	New
20/03/2026	Document: Innovation Task Force (ITF) briefing meeting report	Updated
20/03/2026	Event: European Shortages Monitoring Platform (ESMP) training on readable IDs and general updates for industry	New
20/03/2026	Event: Meeting of the Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG) - March 2026	Updated
20/03/2026	Document: Introductory cover note to the list of European Union reference dates and frequency of submission of periodic safety update reports	Updated
20/03/2026	Document: Overview of comments received on the draft Qualification opinion for Molecule-independent device bridging approach (MIDBA)	New
20/03/2026	Document: Qualification opinion for Molecule-independent device bridging approach (MIDBA)	New

Date	Content	Status
20/03/2026	Medicine: Icatibant Accord icatibant	Updated
20/03/2026	Page: Electronic product information (ePI)	Updated
20/03/2026	Document: Electronic product information (ePI) roadmap	New
20/03/2026	Medicine: SonoVue sulphur hexafluoride	Updated
19/03/2026	Medicine: Xgeva denosumab	Updated
19/03/2026	Medicine: Vargatef nintedanib	Updated
19/03/2026	Medicine: Osenvelt denosumab	Updated
19/03/2026	Medicine: Libmyris adalimumab	Updated
19/03/2026	Medicine: Aerius desloratadine	Updated
19/03/2026	Medicine: Neoclarityn desloratadine	Updated
19/03/2026	Medicine: Kaftrio ivacaftor; tezacaftor; elexacaftor	Updated
19/03/2026	Medicine: Hympavzi marstacimab	Updated
19/03/2026	Medicine: Imfinzi durvalumab	Updated
19/03/2026	Medicine: Lynparza olaparib	Updated
19/03/2026	Document: Article 57 product data	Updated
19/03/2026	Document: IRIS guide for applicants - How to create, submit and manage IRIS applications, for industry and individual applicants	Updated
19/03/2026	Document: QRD veterinary Appendix I - Adverse event (PhV) MSs reporting details	Updated
19/03/2026	Document: Innovation Task Force (ITF) briefing meeting request form	Updated

Date	Content	Status
19/03/2026	Document: 2025 Annual Report on EudraVigilance for the European Parliament, the Council and the Commission	New
19/03/2026	Document: Timetable: Safety signal - Assessment of responses to request for supplementary information (RSI) - ATMP	Updated
19/03/2026	Document: Timetable: Safety signal - Assessment of responses to request for supplementary information (RSI)	Updated
19/03/2026	Event: ACT EU webinar on contractual agreements	Updated
19/03/2026	Document: EU Implementation Guide (IG) on veterinary medicines product data in the Union Product Database - Chapter 5: Technical specifications	Updated
19/03/2026	Medicine: Kostaive zapomeran	Updated
19/03/2026	Document: List of withdrawn medicinal products in accordance with Art. 123(4) of the Directive (1 January - 31 December 2025)	Updated
19/03/2026	PSUSA: PSUSA/00001324/202505 - periodic safety update report single assessment etodolac	New
19/03/2026	PSUSA: PSUSA/00001040/202507 - periodic safety update report single assessment diclofenac / misoprostol	New
18/03/2026	PSUSA: PSUSA/00001672/202508 - periodic safety update report single assessment hydrocortisone / natamycin / neomycine sulphate	New
18/03/2026	PSUSA: PSUSA/00002149/202505 - periodic safety update report single assessment nicardipine	New
18/03/2026	Medicine: Voranigo vorasidenib	Updated
18/03/2026	Medicine: Deltyba delamanid	Updated
18/03/2026	Medicine: Keytruda pembrolizumab	Updated
18/03/2026	Medicine: Strensiq asfotase alfa	Updated

Date	Content	Status
18/03/2026	Medicine: Akynzeo netupitant; palonosetron	Updated
18/03/2026	Medicine: Opdivo nivolumab	Updated
18/03/2026	PSUSA: PSUSA/00003146/202507 - periodic safety update report single assessment ziprasidone	New
18/03/2026	PSUSA: PSUSA/00001476/202508 - periodic safety update report single assessment fosphenytoin	New
18/03/2026	Medicine: Zynyz retifanlimab	Updated
18/03/2026	Page: PRIME: priority medicines	Updated
18/03/2026	News: New PRIME tools to accelerate development of medicines in the EU	New
18/03/2026	Page: Website outages and upgrades	Updated
18/03/2026	EU-M4all: Mosquirix - opinion on medicine for use outside EU Plasmodium falciparum and hepatitis B vaccine (recombinant, adjuvanted)	Updated
18/03/2026	Medicine: Vaborem meropenem; vaborbactam	Updated
18/03/2026	Document: Network Portfolio Roadmap	Updated
18/03/2026	Medicine: Veoza fezolinetant	Updated
18/03/2026	Medicine: Cegfila (previously Pegfilgrastim Mundipharma) pegfilgrastim	Updated
18/03/2026	Medicine: Pelmeg pegfilgrastim	Updated
18/03/2026	Page: Quality Innovation Group	Updated
17/03/2026	Event: EMA Veterinary Medicines Info Day 2026	Updated
17/03/2026	Medicine: Gohibic vilobelimab	Updated
17/03/2026	Document: Standard operating procedure for processing of requests for fee reduction falling under paragraph 5 of Article 6 of Regulation (EU)	Updated

Date	Content	Status
	2024/568	
17/03/2026	Medicine: Elfabrio pegunigalsidase alfa	Updated
17/03/2026	Referral: Melatomed and associated names - referral melatonin	Updated
17/03/2026	Medicine: Gazyvaro obinutuzumab	Updated
17/03/2026	Document: Questions and answers on the refusal of a change to the marketing authorisation for Hetlioz (tasimelteon) (X-39)	Updated
17/03/2026	Document: Questions and answers on the refusal of a change to the marketing authorisation for Hetlioz (tasimelteon) (II-40)	Updated
17/03/2026	Medicine: Daybu trofinetide	Updated
17/03/2026	Medicine: Plegridy peginterferon beta-1a	Updated
17/03/2026	Referral: Quarter-based selective dry cow therapy - referral	Updated
17/03/2026	PSUSA: PSUSA/00000777/202507 - periodic safety update report single assessment cisatracurium	New
17/03/2026	PSUSA: PSUSA/00010502/202507 - periodic safety update report single assessment pitavastatin	New
17/03/2026	Medicine: Pemazyre pemigatinib	Updated
17/03/2026	Medicine: Bimzelx bimekizumab	Updated
17/03/2026	Medicine: Comirnaty COVID-19 mRNA vaccine	Updated
17/03/2026	Medicine: Akeega niraparib; abiraterone acetate	Updated
17/03/2026	Medicine: Trydonis beclometasone; formoterol; glycopyrronium bromide	Updated
17/03/2026	Medicine: Trimbow beclometasone; formoterol; glycopyrronium bromide	Updated

Date	Content	Status
17/03/2026	PSUSA: PSUSA/00001763/202508 - periodic safety update report single assessment iodine (123i) iobenguane	New
17/03/2026	PSUSA: PSUSA/00001775/202506 - periodic safety update report single assessment ioversol	New
17/03/2026	PSUSA: PSUSA/00001552/202507 - periodic safety update report single assessment glyceryl trinitrate	New
17/03/2026	PSUSA: PSUSA/00010068/202507 - periodic safety update report single assessment beclometasone / formoterol	New
17/03/2026	Document: Template for a request for amendments of or addition of active substances or combinations of active substances to the European Union reference-date list	Updated
17/03/2026	PSUSA: PSUSA/00000210/202508 - periodic safety update report single assessment anastrozole	New
17/03/2026	PSUSA: PSUSA/00001824/202507 - periodic safety update report single assessment lamivudine	New
17/03/2026	PSUSA: PSUSA/00000640/202508 - periodic safety update report single assessment cetylpyridinium / lysozyme, lysozyme / pyridoxine	New
17/03/2026	PSUSA: PSUSA/00002286/202508 - periodic safety update report single assessment amoxicillin / clarithromycin / pantoprazole	New
17/03/2026	PSUSA: PSUSA/00010748/202507 - periodic safety update report single assessment octenidine	New
17/03/2026	Page: Clinical pharmacology and pharmacokinetics: questions and answers	Updated
17/03/2026	Event: Meeting of the Medicine Shortages Single Point of Contact (SPOC) Working Party	Updated
17/03/2026	Document: Agenda - Medicine Shortages SPOC Working Party meeting 16-17 March 2026	New
17/03/2026	Medicine: Ozempic semaglutide	Updated

Date	Content	Status
17/03/2026	Document: Antimicrobial Sales and Use (ASU) Power BI application user guide	Updated
17/03/2026	Document: Antimicrobial Sales and Use (ASU) platform user guide	Updated
17/03/2026	Document: Agenda - Management Board meeting: 12 March 2026	Updated
17/03/2026	Document: Records of data processing activity for women leadership development and mentoring activities	New
17/03/2026	Event: Committee for Orphan Medicinal Products (COMP): 17-19 March 2026	Updated
16/03/2026	Event: Quarterly System Demo - Q1 2026	Updated
16/03/2026	Page: Stakeholders and Communication	Updated
16/03/2026	Document: HMPC: overview of assessment work - priority list	Updated
16/03/2026	Event: Paediatric Committee (PDCO): 27-30 January 2026	Updated
16/03/2026	Page: Procedures for monograph and list entry establishment	Updated
16/03/2026	Herbal: Tormentillae rhizoma - herbal medicinal product Tormentil	Updated
16/03/2026	Herbal: Leonuri cardiaca herba - herbal medicinal product Motherwort	Updated
16/03/2026	Herbal: Thymi aetheroleum - herbal medicinal product Thyme oil	Updated
16/03/2026	Herbal: Taraxaci radix cum herba - herbal medicinal product Dandelion Root with Herb	Updated
16/03/2026	Herbal: Taraxaci folium - herbal medicinal product Dandelion Leaf	Updated
16/03/2026	Herbal: Tanacetii parthenii herba - herbal medicinal product Feverfew	Updated
16/03/2026	Herbal: Quercus cortex - herbal medicinal product Oak Bark	Updated
16/03/2026	Herbal: Phaseoli fructus (sine semine) - herbal medicinal product Green bean pod	Updated

Date	Content	Status
16/03/2026	Herbal: Millefolii herba - herbal medicinal product Yarrow	Updated
16/03/2026	Event: Extraordinary meeting of the Committee for Medicinal Products for Human Use (CHMP): 16 March 2026	New
16/03/2026	Herbal: Millefolii flos - herbal medicinal product Yarrow Flower	Updated
16/03/2026	Herbal: Menthae piperitae folium - herbal medicinal product peppermint leaf	Updated
16/03/2026	Herbal: Menthae piperitae aetheroleum - herbal medicinal product Peppermint oil	Updated
16/03/2026	Herbal: Herniariae herba - herbal medicinal product Rupturewort	Updated
16/03/2026	Herbal: Filipendulae ulmariae herba - herbal medicinal product Meadowsweet	Updated
16/03/2026	Herbal: Filipendulae ulmariae flos - herbal medicinal product Meadowsweet Flower	Updated
16/03/2026	Herbal: Chamomillae romanae flos - herbal medicinal product Roman Chamomile Flower	Updated
16/03/2026	Herbal: Arctii radix - herbal medicinal product Burdock Root	Updated
16/03/2026	Herbal: Absinthii herba - herbal medicinal product Wormwood	Updated
16/03/2026	PSUSA: PSUSA/00010801/202507 - periodic safety update report single assessment poliovirus type 1 / poliovirus type 2 / poliovirus type 3 vaccine (oral, live, attenuated), poliovirus type 1 / poliovirus type 3 vaccine (oral, live, attenuated), poliovirus type 1 (oral, live, attenuated) vaccine, poliovirus type 2 (oral, live, attenuated) vaccine, poliovirus type 3 (oral, live, attenuated) vaccine	New
16/03/2026	Event: Workshop on Vulnerability Assessment	New
16/03/2026	Event: EMA - Alzheimer Europe (AE) bilateral meeting	New
16/03/2026	PIP: EMA-001272-PIP02-13-M01 - paediatric investigation plan azacitidine	Updated
16/03/2026	PIP: EMA-002741-PIP01-20-M02 - paediatric investigation plan fordadistrogene movaparvovec	Updated

NOTICE TO APPLICANTS

No updates since October 30th, 2025.

BFARM - PHARMAKOVIGILANZ (SPECIFIC FOR GERMANY)

Date	Title
19.03.2026	<p>Schriftliche Information zur 98. Routinesitzung nach § 63 AMG am 19. März 2026 Das BfArM veröffentlicht die schriftliche Information zur 98. Routinesitzung nach § 63 AMG am 19. März 2026.</p>
19.03.2026	<p>Aktualisierung des Rote-Hand-Brief zu Phenhydan Injektionslösung: Risiko sichtbarer Partikel, Verwendung eines Partikelfilters Wirkstoff: Phenytoin-Natrium Die Firma Desitin Arzneimittel GmbH informiert über einen möglichen Qualitätsmangel des Arzneimittels Phenhydan Injektionslösung.</p>
18.03.2026	<p>Colecalciferol (Vitamin D3) / Fluorid – sichere Anwendung von Tabletten zur Rachitis- und/oder Kariesprophylaxe bei Säuglingen und Kleinkindern Wirkstoff: Colecalciferol, Vitamin D3, Fluorid Das BfArM weist auf das Risiko für eine versehentlichen Aspiration hin, wenn die Gabe der Tablette bei Säuglingen und Kleinkindern in unaufgelöster Form erfolgt.</p>
17.03.2026	<p>Umsetzung des einstimmigen Beschlusses der Koordinierungsgruppe vom 15.10.2026 betreffend die Zulassungen für Humanarzneimittel mit dem Wirkstoff Gabapentin Das BfArM veröffentlicht den Umsetzungsbescheid für den Wirkstoff Gabapentin infolge des Europäischen PSUR Single Assessment Verfahrens nach Artikel 107d) bis g) der Richtlinie 2001/83/EG.</p>
17.03.2026	<p>Umsetzung des einstimmigen Beschlusses der Koordinierungsgruppe vom 11.12.2025 betreffend die Zulassungen für Humanarzneimittel mit dem Wirkstoff Piritramid Das BfArM veröffentlicht den Umsetzungsbescheid für den Wirkstoff Piritramid 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 March 05th, 2026.

PEI - VIGILANZ (SPECIFIC FOR GERMANY)

No updates since March 12th, 2026.

PHARMEUROPA TEXTS FOR COMMENT

Information on Pharmedeuropa updates will be presented quarterly.

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