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HEADS OF AGENCIES – CMDh

No updates since January 8th, 2026.

HEADS OF AGENCIES – PAEDIATRIC REGULATION

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

EUROPEAN MEDICINES AGENCY (EMA)

Date	Content	Status
19/01/2026	Document: Agenda of the HMPC meeting 19-21 January 2026	New
16/01/2026	Page: European Shortages Monitoring Platform (ESMP)	Updated
16/01/2026	Medicine: Rystiggo rozanolixizumab	Updated
16/01/2026	Medicine: Namuscla mexiletine hcl	Updated
16/01/2026	PSUSA: PSUSA/00000411/202505 - periodic safety update report single assessment bifonazole	New
16/01/2026	PSUSA: PSUSA/00010226/202505 - periodic safety update report single assessment fusidic acid (systemic use)	New
16/01/2026	PSUSA: PSUSA/00001128/202505 - periodic safety update report single assessment diphtheria / tetanus vaccines (adsorbed), diphtheria vaccines (adsorbed)	New

Date	Content	Status
16/01/2026	PSUSA: PSUSA/00010651/202505 - periodic safety update report single assessment ozenoxacin	New
16/01/2026	PSUSA: PSUSA/00002642/202505 - periodic safety update report single assessment rifaximin	New
16/01/2026	PSUSA: PSUSA/00001939/202505 - periodic safety update report single assessment mebendazole	New
16/01/2026	PSUSA: PSUSA/00001371/202506 - periodic safety update report single assessment fenticonazole	New
16/01/2026	PSUSA: PSUSA/00001898/202506 - periodic safety update report single assessment lodoxamide	New
16/01/2026	Medicine: Kerendia finerenone	Updated
16/01/2026	Medicine: Sugammadex Adroiq sugammadex	Updated
16/01/2026	Medicine: Ervebo Ebola Zaire vaccine (rVSVΔG-ZEBOV-GP, live)	Updated
16/01/2026	Medicine: Elrexio elranatamab	Updated
16/01/2026	Medicine: Aripiprazole Zentiva aripiprazole	Updated
16/01/2026	Medicine: Intuniv guanfacine	Updated
16/01/2026	Medicine: Alimta pemetrexed	Updated
16/01/2026	Medicine: Irbesartan Hydrochlorothiazide Zentiva (previously Irbesartan Hydrochlorothiazide Winthrop) irbesartan; hydrochlorothiazide	Updated
16/01/2026	Medicine: Xospata gilteritinib	Updated

Date	Content	Status
16/01/2026	DHPC: Mysimba - direct healthcare professional communication (DHPC) bupropion hydrochloride; naltrexone hydrochloride	New
16/01/2026	Medicine: Terrosa teriparatide	Updated
16/01/2026	Medicine: Karvea irbesartan	Updated
16/01/2026	Medicine: Tauvid flortaucipir (18F)	Updated
16/01/2026	Document: Guidance for rapporteurs and members of drafting groups of documents developed by the GMP/GDP Inspectors Working Group	Updated
16/01/2026	Medicine: Cynamza ramucirumab	Updated
16/01/2026	Medicine: Amyvid florbetapir (18F)	Updated
16/01/2026	Medicine: Abiraterone Krka abiraterone acetate	Updated
16/01/2026	News: Meeting highlights from the Committee for Veterinary Medicinal Products (CVMP) 13-14 January 2026	New
16/01/2026	Medicine: Lotilaner / Milbemycin Elanco lotilaner; milbemycin oxime	New
16/01/2026	Referral: Oxbryta - referral voxelotor	Updated
16/01/2026	Medicine: Victoza liraglutide	Updated
16/01/2026	Medicine: Ifirmacombi irbesartan; hydrochlorothiazide	Updated
16/01/2026	Medicine: Irbesartan/Hydrochlorothiazide Teva irbesartan; hydrochlorothiazide	Updated
16/01/2026	Medicine: Rivastigmine 1 A Pharma rivastigmine	Updated
16/01/2026	Medicine: Rivastigmine Hexal rivastigmine	Updated
16/01/2026	Medicine: Rivastigmine Sandoz rivastigmine	Updated

Date	Content	Status
16/01/2026	News: Meeting highlights from the Pharmacovigilance Risk Assessment Committee (PRAC) 12 - 15 January 2026	New
16/01/2026	Medicine: Entecavir Viatriis (previously Entecavir Mylan) entecavir	Updated
16/01/2026	Event: Meeting of the CTTI/FDA Patient Engagement Collaborative (PEC) and EMA Patients and Consumers Working Party (PCWP)	New
16/01/2026	Event: Meeting of the CTTI/FDA Patient Engagement Collaborative (PEC) and EMA Patients and Consumers Working Party (PCWP)	New
16/01/2026	Event: Meeting of the CTTI/FDA Patient Engagement Collaborative (PEC) and EMA Patients and Consumers Working Party (PCWP)	New
16/01/2026	Referral: Levamisole-containing medicinal products - referral levamisole	Updated
15/01/2026	Document: Briefing Document for Quality Innovation Group (QIG) 1-to-1 meeting	New
15/01/2026	Event: Webinar on the use of platform technologies in the non-clinical and clinical domains	New
15/01/2026	Event: Paediatric Committee (PDCO): 11-14 November 2025	Updated
15/01/2026	Document: Minutes - PDCO minutes of the 11-14 November 2025 meeting	New
15/01/2026	PSUSA: PSUSA/00010353/202505 - periodic safety update report single assessment misoprostol (gynaecological indication - labour induction)	New
15/01/2026	PSUSA: PSUSA/00000827/202505 - periodic safety update report single assessment clotiazepam	New
15/01/2026	PSUSA: PSUSA/00010012/202504 - periodic safety update report single assessment ciprofloxacin / dexamethasone (ear drops, suspension)	New

Date	Content	Status
15/01/2026	PSUSA: PSUSA/00000614/202505 - periodic safety update report single assessment ceftriaxone sodium / lidocaine hydrochloride	New
15/01/2026	PSUSA: PSUSA/00000562/202506 - periodic safety update report single assessment carmellose (eye preparation)	New
15/01/2026	PSUSA: PSUSA/00001294/202506 - periodic safety update report single assessment etamsylate	New
15/01/2026	PSUSA: PSUSA/00000492/202506 - periodic safety update report single assessment calcipotriol	New
15/01/2026	PSUSA: PSUSA/00000592/202503 - periodic safety update report single assessment cefditoren	New
15/01/2026	PIP: EMEA-003402-PIP01-23 - paediatric investigation plan fibroblast growth factor 21 analogue (NNC194-0499) / semaglutide	Updated
15/01/2026	Medicine: Pemetrexed Pfizer (previously Pemetrexed Hospira) pemetrexed	Updated
15/01/2026	Event: Q&A Clinic - New Variation Classification in eAF	Updated
15/01/2026	Medicine: Verkazia ciclosporin	Updated
15/01/2026	Medicine: Ikervis ciclosporin	Updated
15/01/2026	Medicine: Rhokiinsa netarsudil	Updated
15/01/2026	Medicine: Bekemv eculizumab	Updated
15/01/2026	Medicine: Roclanda latanoprost / netarsudil	Updated
15/01/2026	Document: Minutes of the COMP meeting 4-6 November 2025	New

Date	Content	Status
15/01/2026	Document: 3-year rolling work plan for the Quality Innovation Group (QIG) 2026-2028	New
15/01/2026	Page: Medicine evaluation figures	Updated
15/01/2026	Medicine: Ebglyss lebrikizumab	Updated
15/01/2026	Medicine: Vyvgart efgartigimod alfa	Updated
15/01/2026	Page: Clinical investigation of medicinal products in the treatment of peripheral-arterial occlusive disease - Scientific guideline	Updated
15/01/2026	Medicine: Blincyto blinatumomab	Updated
15/01/2026	News: Human medicines in 2025	New
15/01/2026	Page: Classification of changes: questions and answers	Updated
15/01/2026	Document: European Medicines Agency post-authorisation procedural advice for users of the centralised procedure	Updated
15/01/2026	Document: European Medicines Agency post-authorisation procedural advice for users of the centralised procedure: document with tracked changes	Updated
14/01/2026	PSUSA: PSUSA/00000851/202503 - periodic safety update report single assessment codeine / paracetamol	New
14/01/2026	Medicine: Roctavian valoctocogene roxaparvovec	Updated
14/01/2026	Medicine: Triumeq abacavir; dolutegravir; lamivudine	Updated
14/01/2026	News: EMA and FDA set common principles for AI in medicine development	New
14/01/2026	Medicine: Otezla apremilast	Updated
14/01/2026	Document: Guiding principles of good AI practice in drug development	New
14/01/2026	Event: New variations guidelines: webinar for marketing authorisation holders (human)	Updated
14/01/2026	Medicine: Yesafili afibercept	Updated

Date	Content	Status
14/01/2026	Medicine: Zvogra denosumab	Updated
14/01/2026	Medicine: Abiraterone Accord abiraterone	Updated
14/01/2026	Medicine: Stoboclo denosumab	Updated
14/01/2026	Medicine: Abevmy bevacizumab	Updated
14/01/2026	Medicine: Nemluvio nemolizumab	Updated
14/01/2026	Medicine: Rydapt midostaurin	Updated
14/01/2026	Page: International Coalition of Medicines Regulatory Authorities (ICMRA)	Updated
14/01/2026	Document: List of clinical evaluation consultation procedure (CECP) opinions issued for medical devices awaiting finalisation of conformity assessment	Updated
14/01/2026	Event: EMA/HMA annual data forum	Updated
13/01/2026	Medicine: Aranesp darbepoetin alfa	Updated
13/01/2026	Medicine: Welireg belzutifan	Updated
13/01/2026	Medicine: Mavenclad cladribine	Updated
13/01/2026	Medicine: Kisunla donanemab	Updated
13/01/2026	Medicine: Yesintek ustekinumab	Updated
13/01/2026	Medicine: Besremi ropeginterferon alfa-2b	Updated
13/01/2026	Medicine: Inrebic fedratinib	Updated
13/01/2026	Medicine: GalenVita germanium (68Ge) chloride; gallium (68Ga) chloride	Updated
13/01/2026	Document: Dates of 2026 Scientific Advice Working Party - Human (SAWP-H) meetings and submission deadlines for	Updated

Date	Content	Status
	scientific advice, protocol assistance, qualification of novel methodologies and HTACG/EMA parallel Joint Scientific Consultation (JSC) requests	
13/01/2026	Medicine: Winlevi clascoterone	Updated
13/01/2026	Medicine: Voydeya danicopan	Updated
13/01/2026	Document: Article 57 product data	Updated
13/01/2026	Event: Joint Heads of Medicines Agencies (HMA)/European Medicines Agency (EMA) multistakeholder workshop on Patient Registries for Alzheimer's disease	Updated
13/01/2026	Medicine: Neparvis sacubitril; valsartan	Updated
13/01/2026	Medicine: Entresto sacubitril; valsartan	Updated
12/01/2026	PIP: EMA/PE/0000232896 - paediatric investigation plan antisense oligonucleotide against patatin like phospholipase domain containing protein 3 gene (PNPLA3), conjugated to N-acetylgalactosamine (AZD2693), sodium salt	Updated
12/01/2026	PIP: EMA-000976-PIP01-10 - paediatric investigation plan Grass pollen allergen extract from Dactylis glomerata L., Anthoxanthum odoratum L., Lolium perenne L., Poa pratensis L. and Phleum pratense L.	Updated
12/01/2026	PIP: EMA-001710-PIP04-17-M03 - paediatric investigation plan Ozanimod (hydrochloride)	Updated
12/01/2026	Medicine: Celsentri maraviroc	Updated
12/01/2026	Medicine: Hetronify serplulimab	Updated
12/01/2026	Document: Agenda of the CVMP meeting 13-15 January 2026	New
12/01/2026	Medicine: Latuda lurasidone	Updated

Date	Content	Status
12/01/2026	Event: Pharmacovigilance Risk Assessment Committee (PRAC): 12 - 15 January 2026	Updated
12/01/2026	Document: Agenda of the PRAC meeting 12 - 15 January 2026	New
12/01/2026	Event: Product Management Service (PMS) information day 2026	New
12/01/2026	Event: Q&A clinic on Substance, Organisation, Referentials Management Services	Updated
12/01/2026	Event: Questions and answers clinic on Product Management Service (PMS) Product User Interface (PUI) and Application Programming Interface (API) - December 2025	Updated
12/01/2026	Event: Q&A clinic on eXtended EudraVigilance Medicinal Product Dictionary (XEVMPD) service	Updated
12/01/2026	Page: Medical devices	Updated
12/01/2026	Medicine: Libmyris adalimumab	Updated
12/01/2026	Medicine: Bosulif bosutinib	Updated
12/01/2026	Medicine: Abilify aripiprazole	Updated
12/01/2026	Medicine: Xeljanz tofacitinib	Updated
12/01/2026	Page: Substance and product data management services	Updated
12/01/2026	Medicine: Tremfya guselkumab	Updated
12/01/2026	Medicine: Hepcludex bulevirtide	Updated

NOTICE TO APPLICANTS

No updates since October 30th, 2025.

BFARM - PHARMAKOVIGILANZ (SPECIFIC FOR GERMANY)

Date	Title
16.01.2026	Pharmacovigilance Risk Assessment Committee (PRAC) Das Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM) veröffentlicht die neuen Signale, die im Rahmen der PRAC-Sitzung vom 12.01.-15.01.2026 behandelt wurden.
13.01.2026	Informationen zu Einreichung und Genehmigung von Schulungsmaterial Aktualisierung der Hilfestellungsdokumente zur Einreichung und Genehmigung von behördlich genehmigten Schulungsmaterialien
13.01.2026	Umsetzung des einstimmigen Beschlusses der Koordinierungsgruppe vom 13.11.2025 betreffend die Zulassungen für Humanarzneimittel mit dem Wirkstoff Metoprolol Das BfArM veröffentlicht den Umsetzungsbescheid für den Wirkstoff Metoprolol infolge des Europäischen PSUR Single Assessment Verfahrens nach Artikel 107d) bis g) der Richtlinie 2001/83/EG.
13.01.2026	Umsetzung des einstimmigen Beschlusses der Koordinierungsgruppe vom 13.11.2025 betreffend die Zulassungen für Humanarzneimittel mit dem Wirkstoff Rifampicin Das BfArM veröffentlicht den Umsetzungsbescheid für den Wirkstoff Rifampicin infolge des Europäischen PSUR Single Assessment Verfahrens nach Artikel 107d) bis g) der Richtlinie 2001/83/EG.
13.01.2026	Umsetzung des einstimmigen Beschlusses der Koordinierungsgruppe vom 13.11.2025 betreffend die Zulassungen für Humanarzneimittel mit dem Wirkstoff Selegilin Das BfArM veröffentlicht den Umsetzungsbescheid für den Wirkstoff Selegilin infolge des Europäischen PSUR Single Assessment Verfahrens nach Artikel 107d) bis g) der Richtlinie 2001/83/EG.

Date	Title
13.01.2026	Umsetzung des einstimmigen Beschlusses der Koordinierungsgruppe vom 13.11.2025 betreffend die Zulassungen für Humanarzneimittel mit dem Wirkstoff Rocuronium Das BfArM veröffentlicht den Umsetzungsbescheid für den Wirkstoff Rocuronium infolge des Europäischen PSUR Single Assessment Verfahrens nach Artikel 107d) bis g) der Richtlinie 2001/83/EG.

BFARM – MEDIZINPRODUKTE (SPECIFIC FOR GERMANY)

No updates since December 16th, 2025.

PEI - VIGILANZ (SPECIFIC FOR GERMANY)

Date	Title
14.01.2026	Influenza-Impfstoff Eflueda mit italienischer Beschriftung in Deutschland verfügbar

PHARMEUROPA TEXTS FOR COMMENT

Information on Pharmedeuropa updates will be presented quarterly.

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