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HEADS OF AGENCIES – CMDh

19 January

[UPDATE - National recommendations for requests to act as RMS](#)

HEADS OF AGENCIES – PAEDIATRIC REGULATION

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

EUROPEAN MEDICINES AGENCY (EMA)

Date	Content	Status
23/01/2026	Medicine: Ronapreve casirivimab; imdevimab	Updated
23/01/2026	Medicine: Austedo deutetrabenazine	Updated
23/01/2026	Medicine: Nexviadyme avalglucosidase alfa	Updated
23/01/2026	Medicine: Travatan travoprost	Updated
23/01/2026	Document: European Medicines Agency's data protection notice for EudraVigilance Human (EV)	Updated
23/01/2026	Document: Joint controllership arrangement with regard to EudraVigilance Human (EV)	Updated
23/01/2026	Document: SMS guidance for external users	Updated

Date	Content	Status
23/01/2026	Document: PRAC work plan 2026	New
23/01/2026	Medicine: Simbrinza brinzolamide; brimonidine tartrate	Updated
23/01/2026	Medicine: Nevanac nepafenac	Updated
23/01/2026	Medicine: Elahere mirvetuximab soravtansine	Updated
23/01/2026	Medicine: Bimzelx bimekizumab	Updated
23/01/2026	PIP: EMA-002828-PIP01-20 - paediatric investigation plan firsocostat; cilofexor	New
23/01/2026	Document: PDCO work plan 2026	New
23/01/2026	Medicine: Aripiprazole Mylan Pharma (previously Aripiprazole Pharmathen) aripiprazole	Updated
23/01/2026	Medicine: Enzalutamide Viatriis enzalutamide	Updated
23/01/2026	Medicine: Vyvgart efgartigimod alfa	Updated
23/01/2026	Medicine: Ontruzant trastuzumab	Updated
23/01/2026	News: Ilona Reischl re-elected as chair of Committee for Advanced Therapies	New
23/01/2026	Document: Concept paper on the development of a guideline for using owner assessment as efficacy parameter	New
23/01/2026	Page: Owner assessment as efficacy parameter - Scientific guideline	New
23/01/2026	Page: Veterinary medicinal products controlling Varroa destructor parasitosis in bees - Scientific guideline	Updated
23/01/2026	Document: Draft guideline on veterinary medicinal products controlling Varroa	New

Date	Content	Status
	destructor parasitosis in bees - Revision 2	
23/01/2026	Page: Testing and evaluation of the efficacy of antiparasitic substances for the treatment and prevention of tick and flea infestations in dogs and cats - Scientific guideline	Updated
23/01/2026	Document: Draft guideline for the evaluation of efficacy of ectoparasitocides - general requirements	New
23/01/2026	Page: Environmental risk assessment for immunological veterinary medicinal products - Scientific guideline	Updated
23/01/2026	Page: Design of studies to evaluate the safety and efficacy of fish vaccines - Scientific guideline	Updated
23/01/2026	Medicine: Inluriyo imlunestrant	Updated
23/01/2026	Page: User safety for immunological veterinary medicinal products - Scientific guideline	Updated
23/01/2026	Document: Draft guideline on the requirements for combined vaccines and associations of immunological veterinary medicinal products (IVMPs) - Revision 1	New
23/01/2026	Page: Requirements for combined vaccines and associations of immunological veterinary medicinal products (IVMPs) - Scientific guideline	Updated
23/01/2026	Medicine: Steqeyma ustekinumab	Updated
23/01/2026	Medicine: Byooviz ranibizumab	Updated
23/01/2026	Document: Scientific advice and protocol assistance adopted during the CHMP	New

Date	Content	Status
	meeting 8-11 December 2025	
23/01/2026	Page: Investigation and assessment of cardiovascular safety of anticancer medicinal products	Updated
23/01/2026	Document: Reflection paper on investigation and assessment of cardiovascular safety of anticancer medicinal products	New
22/01/2026	PIP: EMA/PE/0000239079 - paediatric investigation plan cangrelor (tetrasodium)	Updated
22/01/2026	Medicine: Opatanol olopatadine	Updated
22/01/2026	Event: Eighth European Medicines Agency (EMA) and Medicines for Europe bilateral meeting	Updated
22/01/2026	Shortage: Fludarabine fludarabine	Updated
22/01/2026	Medicine: Erivedge vismodegib	Updated
22/01/2026	Medicine: Nuvaxovid COVID-19 Vaccine (recombinant, adjuvanted)	Updated
22/01/2026	Medicine: Bavencio avelumab	Updated
22/01/2026	Page: Podcast: Inside EMA	Updated
22/01/2026	Document: New product information wording: extracts from PRAC recommendations on signals adopted at the 7-10 July 2025 PRAC	Updated
21/01/2026	Event: First EMA/HMA multi-stakeholder forum on EudraVigilance and signal detection	Updated
21/01/2026	Event: Meeting of the Medicine Shortages Single Point of Contact (SPOC)	Updated

Date	Content	Status
	Working Party	
21/01/2026	Medicine: Lacosamide Adroiq lacosamide	Updated
21/01/2026	Document: European Union example instances - E2B(R3) testing files	Updated
21/01/2026	Medicine: Simponi golimumab	Updated
21/01/2026	Document: EU reference instances (EDQM revision)	Updated
21/01/2026	Medicine: Lyumjev (previously Liumjev) insulin lispro	Updated
21/01/2026	Medicine: Liprolog insulin lispro	Updated
21/01/2026	Medicine: Humalog insulin lispro	Updated
21/01/2026	Medicine: Opdivo nivolumab	Updated
21/01/2026	Medicine: Abasaglar (previously Abasria) insulin glargine	Updated
21/01/2026	Document: Consolidated 3-year rolling work plan for the Methodology Working Party 2026-2028	Updated
21/01/2026	Document: Consolidated 3-year rolling work plan for the Non-clinical domain 2026-2028	Updated
21/01/2026	Medicine: Finlee dabrafenib	Updated
21/01/2026	Medicine: Abraxane paclitaxel	Updated
21/01/2026	Medicine: Epidyolex cannabidiol	Updated
21/01/2026	Event: Clinical Trials Information System (CTIS): Walk-in clinic February 2026	New

Date	Content	Status
21/01/2026	Medicine: VacPertagen pertussis vaccine (recombinant, acellular, component, adsorbed)	Updated
21/01/2026	Document: Product Management Service (PMS) – Frequently Asked Questions (FAQs)	Updated
21/01/2026	PSUSA: PSUSA/00001736/202505 - periodic safety update report single assessment indobufen	New
21/01/2026	PSUSA: PSUSA/00002150/202505 - periodic safety update report single assessment nicergoline	New
21/01/2026	PSUSA: PSUSA/00010827/202505 - periodic safety update report single assessment levonorgestrel	New
21/01/2026	PSUSA: PSUSA/00010484/202505 - periodic safety update report single assessment methoxyflurane	New
21/01/2026	PSUSA: PSUSA/00010881/202506 - periodic safety update report single assessment levofloxacin/dexamethasone (ocular use)	New
21/01/2026	PSUSA: PSUSA/00000276/202506 - periodic safety update report single assessment azelaic acid	New
21/01/2026	PSUSA: PSUSA/00002769/202506 - periodic safety update report single assessment solifenacin	New
21/01/2026	PSUSA: PSUSA/00000796/202505 - periodic safety update report single assessment benzoyl peroxide clindamycin phosphate	New
21/01/2026	PSUSA: PSUSA/00001505/202504 - periodic safety update report single assessment gadoteric acid	New

Date	Content	Status
21/01/2026	PSUSA: PSUSA/00001477/202506 - periodic safety update report single assessment fotemustine	New
21/01/2026	PSUSA: PSUSA/00002952/202505 - periodic safety update report single assessment ticlopidine	New
21/01/2026	PSUSA: PSUSA/00010041/202506 - periodic safety update report single assessment magnesium pidolate	New
21/01/2026	PSUSA: PSUSA/00002694/202506 - periodic safety update report single assessment sertaconazole	New
21/01/2026	News: Carmen Purdel elected as new chair of the Committee for Herbal Medicinal Products	New
21/01/2026	Document: Questions and answers about the clinical study data proof-of-concept pilot for industry	Updated
20/01/2026	Document: Questions and Answers on the 'OPEN' Framework	Updated
20/01/2026	Medicine: Agamree vamorolone	Updated
20/01/2026	Medicine: Ponlimsi denosumab	Updated
20/01/2026	Medicine: Spikevax (previously COVID-19 Vaccine Moderna) COVID-19 mRNA vaccine	Updated
20/01/2026	Medicine: Veyvondi vonicog alfa	Updated
20/01/2026	Medicine: HyQvia human normal immunoglobulin	Updated
20/01/2026	Medicine: Nyvepria pegfilgrastim	Updated

Date	Content	Status
20/01/2026	Medicine: Kostaive zapomera	Updated
20/01/2026	Medicine: Libtayo cemiplimab	Updated
20/01/2026	Medicine: Imnovid (previously Pomalidomide Celgene) pomalidomide	Updated
20/01/2026	Medicine: Hycamtin topotecan	Updated
20/01/2026	PSUSA: PSUSA/00001506/202504 - periodic safety update report single assessment gadoteric acid (IV and intravascular formulations)	New
20/01/2026	Event: EMA Veterinary Medicines Info Day 2026	New
20/01/2026	Document: Agenda of the CAT meeting 21-23 January 2026	New
20/01/2026	Event: Committee for Advanced Therapies (CAT): 21-23 January 2026	Updated
20/01/2026	Medicine: Odomzo sonidegib	Updated
20/01/2026	News: Use of paracetamol during pregnancy unchanged in the EU	Updated
20/01/2026	Document: Data access to medicinal products for human use - Chapter 5 Annex A: Product data elements accessible by stakeholder group	Updated
20/01/2026	Medicine: Poteligeo mogamulizumab	Updated
20/01/2026	Medicine: Elfabrio pegunigalsidase alfa	Updated
20/01/2026	Page: Good Clinical Practice Inspectors Working Group	Updated

Date	Content	Status
20/01/2026	Document: Annual report of the Good Clinical Practice Inspectors Working Group 2024	New
20/01/2026	Medicine: Aflunov zoonotic influenza vaccine (H5N1) (surface antigen, inactivated, adjuvanted)	Updated
20/01/2026	Medicine: Daptomycin Hospira daptomycin	Updated
20/01/2026	Medicine: Evrysdi risdiplam	Updated
20/01/2026	Page: Website outages and upgrades	Updated
20/01/2026	Page: Download website data in JSON data format	Updated
20/01/2026	Document: Data access to medicinal products for human use - Chapter 5	Updated
20/01/2026	Medicine: Tocilizumab STADA (previously Tofidence) tocilizumab	Updated
20/01/2026	Document: Standard operating procedure for procedure to be followed when the incident management plan for medicines for veterinary use is triggered	Updated
20/01/2026	Medicine: Degevma denosumab	Updated
20/01/2026	Event: Fourth European Medicines Agency (EMA) and European Confederation of Pharmaceutical Entrepreneurs (EUCOPE) bilateral meeting	Updated
20/01/2026	Document: New product information wording: extracts from PRAC recommendations on signals adopted at the 27-30 October 2025 PRAC	Updated

Date	Content	Status
20/01/2026	Document: Applications for new human medicines under evaluation: January 2026	New
20/01/2026	Document: Questions and answers on signal management	Updated
20/01/2026	Event: New variations guidelines: webinar for marketing authorisation holders (human)	Updated
20/01/2026	Document: Agenda of the COMP meeting 20-22 January 2026	New
19/01/2026	Medicine: Abiraterone Mylan abiraterone acetate	Updated
19/01/2026	Medicine: Xenpozyme olipudase alfa	Updated
19/01/2026	Medicine: Effentora fentanyl	Updated
19/01/2026	Medicine: Brintellix vortioxetine	Updated
19/01/2026	Medicine: Wegovy semaglutide	Updated
19/01/2026	Page: Submission deadlines for orphan designations	Updated
19/01/2026	News: Veterinary medicines in 2025	New
19/01/2026	Event: HMA/EMA multi-stakeholder workshop on artificial intelligence (AI)	Updated
19/01/2026	Medicine: Opuviz aflibercept	Updated
19/01/2026	Medicine: Rybelsus semaglutide	Updated
19/01/2026	Document: Deadlines for submission of applications for orphan medicinal product designation to the EMA and corresponding COMP timetable for valid	New

Date	Content	Status
	applications 2026-2027	
19/01/2026	Medicine: Darzalex daratumumab	Updated
19/01/2026	Medicine: Imuldosa ustekinumab	Updated
19/01/2026	PIP: EMA-002036-PIP01-16 - paediatric investigation plan fosmetpantotenate	Updated
19/01/2026	Medicine: Relistor methyl naltrexone bromide	Updated
19/01/2026	Medicine: Zercepac trastuzumab	Updated
19/01/2026	Document: Fosmetpantotenate : Notification of discontinuation of a paediatric development which is covered by an agreed PIP Decision	New
19/01/2026	Medicine: Skyrizi risankizumab	Updated
19/01/2026	Medicine: Tagrisso osimertinib	Updated
19/01/2026	Medicine: Ziagen abacavir	Updated
19/01/2026	Medicine: Trizivir abacavir; lamivudine; zidovudine	Updated
19/01/2026	Medicine: Kivexa abacavir; lamivudine	Updated
19/01/2026	Medicine: Teduglutide Viatrix teduglutide	Updated
19/01/2026	Page: Union list of critical medicines	Updated
19/01/2026	Document: Union list of critical medicines - version 2.1 (revision 1)	Updated
19/01/2026	Document: Methodology for the annual review of the Union list of critical medicines	New

Date	Content	Status
19/01/2026	PSUSA: PSUSA/00002771/202506 - periodic safety update report single assessment somatostatin	New
19/01/2026	Page: One Health approach	Updated
19/01/2026	Medicine: Aprovel irbesartan	Updated
19/01/2026	Document: Agenda of the HMPC meeting 19-21 January 2026	New

NOTICE TO APPLICANTS

No updates since October 30th, 2025.

BFARM - PHARMAKOVIGILANZ (SPECIFIC FOR GERMANY)

Date	Title
21.01.2026	Umsetzung des einstimmigen Beschlusses der Koordinierungsgruppe vom 13.11.2025 betreffend die Zulassungen für Humanarzneimittel mit dem Wirkstoff Prazepam Das BfArM veröffentlicht den Beschluss der Koordinierungsgruppe (CMDh) für den Wirkstoff Prazepam infolge des Europäischen PSUR Single Assessment Verfahrens nach Artikel 107d) bis g) der Richtlinie 2001/83/EG.
21.01.2026	Umsetzung des einstimmigen Beschlusses der Koordinierungsgruppe vom 13.11.2025 betreffend die Zulassungen für Humanarzneimittel mit der Wirkstoffkombination Codein/Paracetamol Das BfArM veröffentlicht den Umsetzungsbescheid für die Wirkstoffkombination Codein/Paracetamol infolge des Europäischen PSUR Single Assessment Verfahrens nach Artikel 107d) bis g) der Richtlinie 2001/83/EG.
20.01.2026	92. Sitzung (20. Januar 2026 per Videokonferenz) – Kurzprotokoll Sachverständigen-Ausschuss für Verschreibungspflicht nach § 53 Absatz 2 AMG

Date	Title
20.01.2026	Umsetzung des einstimmigen Beschlusses der Koordinierungsgruppe vom 13.11.2025 betreffend die Zulassungen für Humanarzneimittel mit dem Wirkstoff Clomipramin Das BfArM veröffentlicht den Umsetzungsbescheid für den Wirkstoff Clomipramin infolge des Europäischen PSUR Single Assessment Verfahrens nach Artikel 107d) bis g) der Richtlinie 2001/83/EG.
20.01.2026	Umsetzung des einstimmigen Beschlusses der Koordinierungsgruppe vom 13.11.2025 betreffend die Zulassungen für Humanarzneimittel mit dem Wirkstoff Clozapin Das BfArM veröffentlicht den Umsetzungsbescheid für den Wirkstoff Clozapin infolge des Europäischen PSUR Single Assessment Verfahrens nach Artikel 107d) bis g) der Richtlinie 2001/83/EG.
19.01.2026	Sitzung (8. Dezember 2025 per Videokonferenz) – Ergebnisprotokoll Sachverständigen-Ausschuss für Apothekenpflicht nach § 53 Absatz 1 AMG

BFARM – MEDIZINPRODUKTE (SPECIFIC FOR GERMANY)

No updates since December 16th, 2025.

PEI - VIGILANZ (SPECIFIC FOR GERMANY)

Date	Title
21.01.2026	Rote-Hand-Brief: Remsima (Infliximab)

PHARMEUROPA TEXTS FOR COMMENT

Information on Pharmedeuropa updates will be presented quarterly.

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