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HEADS OF AGENCIES – CMDh

Date	Title
12.10.2026	NEW - 13-14 October CMDh agenda

HEADS OF AGENCIES – PAEDIATRIC REGULATION

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

EUROPEAN MEDICINES AGENCY (EMA)

Date	Content	Status
16/10/2026	Medicine: Padcev enfortumab vedotin	Updated
16/10/2026	Medicine: Cibinqo abrocitinib	Updated
16/10/2026	Medicine: Idefrix imlifidase	Updated
16/10/2026	Medicine: Plegridy peginterferon beta-1a	Updated
16/10/2026	Medicine: HyQvia human normal immunoglobulin	Updated
16/10/2026	Medicine: Ocrevus ocrelizumab	Updated
16/10/2026	Document: Agenda - Medicine Shortages SPOC Working Party meeting 13-14 October 2026	Updated
16/10/2026	Medicine: Saphnelo anifrolumab	Updated
16/10/2026	Document: Timetable: Safety signal - Assessment of responses to request for supplementary information (RSI)	Updated
16/10/2026	Document: Timetable: Safety signal - Assessment of responses to request for supplementary information (RSI) - ATMP	Updated
16/10/2026	Medicine: Afstyla lonococog alfa	Updated
16/10/2026	Document: CHMP PROM minutes for the meeting on 1 December 2025	New

16/10/2026	Medicine: Stelara ustekinumab	Updated
16/10/2026	Medicine: Idelvion albutrepenonacog alfa	Updated
16/10/2026	Medicine: Remicade infliximab	Updated
16/10/2026	Medicine: Deferasirox Mylan deferasirox	Updated
16/10/2026	Medicine: Foundayo Orforglipron	New
16/10/2026	Medicine: Fovlussea ranibizumab	New
16/10/2026	Medicine: Yuviwel Navepegritide	New
16/10/2026	Medicine: Neuzafy filgrastim	New
16/10/2026	Medicine: Kizfizo temozolomide	New
16/10/2026	Medicine: Mylotarg gemtuzumab ozogamicin	Updated
16/10/2026	News: Meeting highlights from the Committee for Medicinal Products for Human Use (CHMP) 12-15 October 2026	New
16/10/2026	News: New oral GLP-1 medicine for weight management and type 2 diabetes	New
16/10/2026	Post-authorisation: Pandemic influenza vaccine H5N1 AstraZeneca (previously Pandemic influenza vaccine H5N1 Medimmune) - opinion on variation to marketing authorisation pandemic influenza vaccine (H5N1) (live attenuated, nasal)	New
16/10/2026	Post-authorisation: Talvey - opinion on variation to marketing authorisation talquetamab	New
16/10/2026	Post-authorisation: Ibrance - withdrawal of application for variation to marketing authorisation palbociclib	New
16/10/2026	Post-authorisation: Kyinsu - opinion on variation to marketing authorisation insulin icodec; semaglutide	New
16/10/2026	Post-authorisation: Tukysa - opinion on variation to marketing authorisation tucatinib	New
16/10/2026	Document: Overview of (invented) names reviewed in September 2026 by the Name Review Group (NRG) - Adopted at the CHMP meeting of 15 October 2026	New
16/10/2026	Page: Cancer Medicines Pathfinder	Updated
16/10/2026	Medicine: Strimvelis autologous CD34+ enriched cell fraction that contains CD34+ cells transduced with retroviral vector that encodes for the human ADA cDNA sequence	Updated
16/10/2026	Page: Combination Products Operational Group: agendas and highlight reports	Updated
16/10/2026	Document: Agenda - Combination Products Operational Group (COMBO) - In vitro Diagnostics - 21 October 2026	New
16/10/2026	Document: Annex to 23-26 March 2026 CHMP minutes	New
16/10/2026	Document: Minutes of the CHMP meeting 23-26 March 2026	New

16/10/2026	Scientific guideline: Clinical investigation of immunosuppressants for solid organ transplantation - Scientific guideline	Updated
16/10/2026	Document: Concept paper on clinical trials in recipients of kidney transplantation	New
15/10/2026	Event: Seventeenth meeting of the industry stakeholder platform on the operation of the centralised procedure for human medicines	Updated
15/10/2026	Medicine: Optruma raloxifene	Updated
15/10/2026	PSUSA: PSUSA/00001694/202603 - periodic safety update report single assessment hydroxyethyl starch, hydroxyethyl starch combinations	New
15/10/2026	Referral: Rifadin oral suspension and syrup and associated names - referral rifampicin	Updated
15/10/2026	Medicine: Ratiograstim filgrastim	Updated
15/10/2026	Medicine: Tevagrastim filgrastim	Updated
15/10/2026	Medicine: Elaprase idursulfase	Updated
15/10/2026	Medicine: Mirvaso brimonidine	Updated
15/10/2026	Medicine: Rasonque Daraxonrasib	New
15/10/2026	News: EMA recommends authorisation of Rasonque for metastatic pancreatic cancer	New
15/10/2026	Event: EMA paediatric investigation plans in-person training course	New
15/10/2026	Medicine: Cabometyx cabozantinib	Updated
15/10/2026	Medicine: Nexviadyme avalglucosidase alfa	Updated
15/10/2026	Document: Draft reflection paper on the investigation of drug interactions of herbal medicinal products	New
15/10/2026	Medicine: Koselugo selumetinib	Updated
15/10/2026	Medicine: Opuviz afibercept	Updated
15/10/2026	Page: Academia	Updated
14/10/2026	PIP: EMEA-002727-PIP03-23 - paediatric investigation plan nivolumab; relatlimab	Updated
14/10/2026	Medicine: Dovprela (previously Pretomanid FGK) pretomanid	Updated
14/10/2026	Medicine: Fymiskina ustekinumab	Updated
14/10/2026	Medicine: Vyndaqel tafamidis	Updated
14/10/2026	Medicine: Welireg belzutifan	Updated
14/10/2026	Medicine: Tenofovir disoproxil Viatris (previously Tenofovir disoproxil Mylan) tenofovir disoproxil	Updated
14/10/2026	Medicine: Poherdy pertuzumab	Updated

14/10/2026	Document: Outcome of written procedures finalised during the period from 04 June 2026 to 22 September 2026	New
14/10/2026	Medicine: lasibon ibandronic acid	Updated
14/10/2026	PIP: EMA/PE/0000243861 - paediatric investigation plan venglustat	Updated
14/10/2026	PIP: EMA/PE/0000258095 - paediatric investigation plan levodopa; carbidopa monohydrate	New
14/10/2026	PIP: EMA/PE/0000244980 - paediatric investigation plan mirabegron; solifenacin	New
14/10/2026	PIP: EMA/PE/0000240600 - paediatric investigation plan mirabegron; solifenacin	New
14/10/2026	PIP: EMA/PE/0000243891 - paediatric investigation plan azacitidine; cedazuridine	New
14/10/2026	Medicine: Humira adalimumab	Updated
14/10/2026	PIP: EMA/PE/0000245064 - paediatric investigation plan avutometinib; defactinib	New
14/10/2026	Page: Women's health	Updated
14/10/2026	Medicine: Pritor telmisartan	Updated
14/10/2026	Event: Regulatory perspectives on herbal medicinal / botanical drug product development: Joint FDA / EMA workshop	Updated
14/10/2026	Medicine: Spikevax (previously COVID-19 Vaccine Moderna) COVID-19 mRNA vaccine	Updated
14/10/2026	Medicine: Nemluvio nemolizumab	Updated
14/10/2026	Medicine: mResvia respiratory syncytial virus mRNA vaccine	Updated
14/10/2026	Event: Meeting of the HMA-EMA group focused on AI with industry stakeholders - October 2026	New
14/10/2026	PIP: EMA/PE/0000245149 - paediatric investigation plan mifepristone; misoprostol	New
14/10/2026	PIP: EMA/PE/0000241632 - paediatric investigation plan linaprazan glurate	New
14/10/2026	PIP: EMA/PE/0000245628 - paediatric investigation plan ivonescimab	New
14/10/2026	PIP: EMA/PE/0000245862 - paediatric investigation plan ivonescimab	New
14/10/2026	PIP: EMA/PE/0000235505 - paediatric investigation plan tislelizumab	New
14/10/2026	PIP: EMA/PE/0000234649 - paediatric investigation plan pasritamig	New
14/10/2026	PIP: EMEA-003313-PIP02-23 - paediatric investigation plan povorcitinib	New
14/10/2026	PIP: EMA/PE/0000223258 - paediatric investigation plan afimkibart	New
14/10/2026	PIP: EMA/PE/0000223040 - paediatric investigation plan iloperidone	New
14/10/2026	PIP: EMA/PE/0000183462 - paediatric investigation plan autologous regulatory T lymphocytes CD3+ CD4+ CD25+ CD127- FoxP3+, ex-vivo expanded (PolTreg-T1D)	New
14/10/2026	Scientific guideline: Investigation of bioequivalence - Scientific guideline	Updated

14/10/2026	Medicine: Denosumab Ascend denosumab	Updated
13/10/2026	Page: Qualification of novel methodologies for medicine development: CHMP qualification opinions	New
13/10/2026	Page: Qualification of novel methodologies for medicine development: Letters of support	New
13/10/2026	Medicine: Revatio sildenafil	Updated
13/10/2026	Medicine: Lyrica pregabalin	Updated
13/10/2026	Medicine: Viagra sildenafil	Updated
13/10/2026	Medicine: Olumiant baricitinib	Updated
13/10/2026	Medicine: Jemperli dostarlimab	Updated
13/10/2026	Medicine: Fingolimod Accord fingolimod	Updated
13/10/2026	Medicine: Cometriq cabozantinib	Updated
13/10/2026	Medicine: Imfinzi durvalumab	Updated
13/10/2026	Medicine: Rinvoq upadacitinib	Updated
13/10/2026	EU-M4all: Mosquirix - opinion on medicine for use outside EU Plasmodium falciparum and hepatitis B vaccine (recombinant, adjuvanted)	Updated
13/10/2026	Medicine: Bemfola follitropin alfa	Updated
13/10/2026	Document: Agenda - PDCO agenda of the 13-16 October 2026 meeting	New
13/10/2026	Medicine: Nexium Control esomeprazole	Updated
13/10/2026	Document: Business process description for medical devices	Updated
13/10/2026	Medicine: Intuniv guanfacine	Updated
13/10/2026	Document: Voluntary data submission (VDS) pilot application form	Updated
13/10/2026	Medicine: Qalsody tofersen	Updated
13/10/2026	Document: Article 57 product data	Updated
13/10/2026	Event: IncreaseNET and EU-Innovation Network 2026 Innovation & Competitiveness Summit: Strengthening Europe's Ecosystem	New
13/10/2026	Document: HMPC: overview of assessment work - priority list	Updated
13/10/2026	Page: Qualification of novel methodologies for medicine development (QoNM)	Updated
13/10/2026	Page: Qualification of novel methodologies for medicine development: High-level information on CHMP qualification advice	New
13/10/2026	Event: Risk management information day 2022	Updated
13/10/2026	Document: Appendix 1: Acceptable intakes established for N-nitrosamines	Updated
12/10/2026	Medicine: Casgevy exagamglogene autotemcel	Updated
12/10/2026	Medicine: Rhokiinsa netarsudil	Updated
12/10/2026	Medicine: Roclanda latanoprost / netarsudil	Updated

12/10/2026	Medicine: Duvyzat givinostat	Updated
12/10/2026	Medicine: Lazcluze lazertinib	Updated
12/10/2026	Medicine: Altuvoct efanesoctocog alfa	Updated
12/10/2026	Medicine: Ofev nintedanib	Updated
12/10/2026	Page: New Approach Methodologies Operational Expert Group	New
12/10/2026	Event: Committee for Medicinal Products for Human Use (CHMP): 12-15 October 2026	Updated
12/10/2026	Document: Annex to agenda of the CHMP meeting 12-15 October 2026	New
12/10/2026	Document: Agenda of the CHMP meeting 12-15 October 2026	New
12/10/2026	Medicine: Sunitinib Accord sunitinib	Updated
12/10/2026	Medicine: Daybu trofinetide	Updated
12/10/2026	Scientific guideline: Concept paper on the need for the guideline on the clinical investigation of medicinal products for the treatment of inherited retinal dystrophies - Scientific guideline	New

NOTICE TO APPLICANTS

No updates since July 10th, 2026.

BFARM - PHARMAKOVIGILANZ (SPECIFIC FOR GERMANY)

No updates since October 9th, 2026.

BFARM – MEDIZINPRODUKTE (SPECIFIC FOR GERMANY)

No updates since September 25th, 2026.

PEI - VIGILANZ (SPECIFIC FOR GERMANY)

Date	Title
15.10.2026	Chikungunya-Impfstoff Vimkungya mit französischer und schwedischer/finnischer Beschriftung in Deutschland verfügbar

PHARMEUROPA TEXTS FOR COMMENT

Information on Pharmeduropa updates will be presented quarterly.

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