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HEADS OF AGENCIES – CMDh

No updates since September 27th, 2026

HEADS OF AGENCIES – PAEDIATRIC REGULATION

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

EUROPEAN MEDICINES AGENCY (EMA)

Date	Content	Status
09/10/2026	Medicine: Etcamah camizestrant	Updated
09/10/2026	PIP: EMA/PE/0000183092 - paediatric investigation plan polypeptide consisting of a glucagon-like peptide-1 receptor agonist and an amylin receptor agonist, connected by a linker with 4 glycine residues, and connected to a C18 fatty acid side chain (NNC0487-0111)	New
09/10/2026	PIP: EMA/PE/0000180736 - paediatric investigation plan brogidirsen	New
09/10/2026	Document: Medicinal products for human use: monthly figures - September 2026	New
09/10/2026	Document: Annual report of the Pharmacovigilance Inspectors Working Group for 2025	New
09/10/2026	Medicine: Pylclari piflufolastat (18F)	Updated
09/10/2026	Page: Paediatric investigation plans	Updated
09/10/2026	Page: Paediatric investigation plans: questions and answers	Updated
09/10/2026	Post-authorisation: Kalydeco - withdrawal of application for variation to marketing authorisation ivacaftor	Updated
09/10/2026	Document: Questions and answers on the PIP compliance verification procedure at EMA, and on paediatric rewards	Updated
09/10/2026	Document: European Medicines Agency policy on changes in scope of paediatric investigation plan (PIP) decisions	Updated
09/10/2026	DHPC: Ocrevus - direct healthcare professional communication (DHPC) ocrelizumab	New

09/10/2026	Medicine: Stemyca equine umbilical cord-derived mesenchymal stem cells	New
09/10/2026	Medicine: Bovilis Lumpyvax Lumpy skin disease vaccine (live)	New
09/10/2026	News: Meeting highlights from the Committee for Veterinary Medicinal Products (CVMP) 6-8 October 2026	New
09/10/2026	News: EMA recommends authorisation of veterinary vaccine for lumpy skin disease in cattle	New
09/10/2026	Medicine: Giapreza angiotensin II	Updated
09/10/2026	Event: 21st industry stakeholder platform - operation of European Union (EU) pharmacovigilance	New
09/10/2026	Document: Decision of the Management Board amending budget No. 01, amending appropriations in budget 2026 and transfer of appropriations	New
09/10/2026	Document: Applications for new human medicines under evaluation: October 2026	New
09/10/2026	Medicine: Svariya (previously Rivaroxaban Koanaa) rivaroxaban	Updated
09/10/2026	Document: Agenda - European Medicines Agency workshop on bacteriophage therapy	Updated
09/10/2026	PIP: EMA/PE/0000245485 - paediatric investigation plan ustekinumab	Updated
09/10/2026	PIP: EMA/PE/0000247846 - paediatric investigation plan arimoclomol citrate	Updated
09/10/2026	PIP: EMA/PE/0000245644 - paediatric investigation plan navenibart	Updated
09/10/2026	PIP: EMA/PE/0000245980 - paediatric investigation plan sepoparsen	Updated
09/10/2026	PIP: EMA/PE/0000245997 - paediatric investigation plan ketamine; sufentanil	Updated
09/10/2026	PIP: EMA/PE/0000245698 - paediatric investigation plan tolebrutinib	Updated
09/10/2026	PIP: EMA/PE/0000245423 - paediatric investigation plan human immunoglobulin G1 constant region - human ectodysplasin-A1 receptor-binding domain fusion protein	Updated
09/10/2026	PIP: EMA/PE/0000245173 - paediatric investigation plan iptacopan	Updated
09/10/2026	PIP: EMA/PE/0000246985 - paediatric investigation plan cedazuridine; decitabine	Updated
09/10/2026	PIP: EMA/PE/0000245146 - paediatric investigation plan Insulin lispro (BC222)	Updated
09/10/2026	PIP: EMA/PE/0000244420 - paediatric investigation plan vamorolone	Updated
09/10/2026	PIP: EMA/PE/0000242381 - paediatric investigation plan mRNA encoding for the linked NTD and RBD domains of the spike glycoprotein of SARS-CoV-2 (mRNA-1283)	Updated
09/10/2026	PIP: EMA/PE/0000227737 - paediatric investigation plan Galcanzumab	Updated
09/10/2026	PIP: EMA/PE/0000238109 - paediatric investigation plan bempedoic acid (ETC-1002)	Updated
09/10/2026	PIP: EMA/PE/0000241641 - paediatric investigation plan Live, attenuated, dengue virus, serotype 1 (DENV1); live, attenuated, chimeric dengue virus, serotype 2 (DENV2); Live, attenuated, dengue	Updated

	virus, serotype 3 (DENV3); Live, attenuated, dengue virus, serotype 4 (DENV4)	
09/10/2026	PIP: EMA/PE/0000242151 - paediatric investigation plan erenumab	Updated
09/10/2026	PIP: EMA/PE/0000243984 - paediatric investigation plan disitamab vedotin	Updated
09/10/2026	PIP: EMA/PE/0000242247 - paediatric investigation plan fitusiran	Updated
09/10/2026	PIP: EMA/PE/0000244179 - paediatric investigation plan Indacaterol (acetate); mometasone (furoate); glycopyrronium bromide	Updated
09/10/2026	Document: Timetable: Extension application - ATMP	Updated
09/10/2026	Document: Timetable: Extension application	Updated
08/10/2026	Scientific guideline: Download website data in JSON data format - Scientific guideline	Updated
08/10/2026	Medicine: Hetronifly serplulimab	Updated
08/10/2026	News: Clinical trial applications advice pilot becomes permanent	New
08/10/2026	Scientific guideline: Demonstration of therapeutic equivalence for nasal products - Scientific guideline	Updated
08/10/2026	Document: Draft guideline on the requirements for demonstrating therapeutic equivalence for nasal products	New
08/10/2026	PIP: EMA/PE/0000261512 - paediatric investigation plan Dexamethasone sodium phosphate encapsulated in human autologous erythrocytes	Updated
08/10/2026	Event: Clinical Trials Information System (CTIS): Walk-in clinic October 2026	Updated
08/10/2026	Medicine: Mvasi bevacizumab	Updated
08/10/2026	Document: Agenda - Combination products operational group, MD stream, 8 October 2026	New
08/10/2026	Medicine: Mounjaro tirzepatide	Updated
08/10/2026	Document: Final programming document 2026-28	Updated
08/10/2026	Event: Committee for Medicinal Products for Human Use (CHMP): 15-18 September 2025	Updated
08/10/2026	Document: Annex to 15-18 September 2025 CHMP Minutes	New
08/10/2026	Event: Committee for Medicinal Products for Human Use (CHMP): 20-23 July 2026	Updated
08/10/2026	Document: Annex to 20-23 July 2026 CHMP Minutes	New
08/10/2026	Document: Minutes of the CHMP meeting 20-23 July 2026	New
08/10/2026	Event: Committee for Medicinal Products for Human Use (CHMP): 20-23 April 2026	Updated
08/10/2026	Document: Annex to 20-23 April 2026 CHMP Minutes	New
08/10/2026	Document: Minutes of the CHMP meeting 20-23 April 2026	New
08/10/2026	Medicine: Tepmetko tepotinib	Updated
08/10/2026	PSUSA: PSUSA/00010947/202602 - periodic safety update report single assessment telmisartan / indapamide	New
08/10/2026	PSUSA: PSUSA/00010280/202602 - periodic safety update report single assessment acetylsalicylic acid / atorvastatin / ramipril	New
08/10/2026	Medicine: Lucentis ranibizumab	Updated

08/10/2026	Medicine: Increlex mecasermin	Updated
08/10/2026	Medicine: Tafamidis Accord tafamidis	Updated
08/10/2026	PSUSA: PSUSA/00001568/202602 - periodic safety update report single assessment granisetron (all formulations except transdermal patch)	New
07/10/2026	PSUSA: PSUSA/00009266/202601 - periodic safety update report single assessment potassium canrenoate	New
07/10/2026	Document: List of clinical evaluation consultation procedure (CECP) opinions issued for medical devices awaiting finalisation of conformity assessment	Updated
07/10/2026	Medicine: Zinmyleo trilaciclib	Updated
07/10/2026	Medicine: Kuvan sapropterin	Updated
07/10/2026	Medicine: Nulibry fosdenopterin	Updated
07/10/2026	Document: Minutes of the HMPC meeting 6-8 July 2026	Updated
07/10/2026	Medicine: Cibinqo abrocitinib	Updated
07/10/2026	Medicine: Imbruvica ibrutinib	Updated
07/10/2026	Medicine: Mysimba naltrexone; bupropion	Updated
07/10/2026	Medicine: Zokinvy lonafarnib	Updated
07/10/2026	Medicine: Ritonavir Viatriis (previously Ritonavir Mylan) ritonavir	Updated
07/10/2026	Medicine: Lunsumio mosunetuzumab	Updated
07/10/2026	Medicine: Calquence acalabrutinib	Updated
07/10/2026	Orphan: EU/3/18/2068 - orphan designation for treatment of growth hormone deficiency somapacitan	Updated
07/10/2026	Medicine: Sogroya somapacitan	Updated
07/10/2026	Medicine: Besremi ropeginterferon alfa-2b	Updated
07/10/2026	Medicine: Brukinsa zanubrutinib	Updated
07/10/2026	Medicine: Thiotepa Riemser thiotepa	Updated
07/10/2026	Medicine: Scenesse afamelanotide	Updated
07/10/2026	PSUSA: PSUSA/00001204/202602 - periodic safety update report single assessment eletriptan	New
07/10/2026	PSUSA: PSUSA/00009057/202601 - periodic safety update report single assessment argatroban	New

07/10/2026	Medicine: Cenrifki tolebrutinib	Updated
06/10/2026	Page: PRIME: eligibility requests and outcomes	New
06/10/2026	Page: PRIME: priority medicines	Updated
06/10/2026	Document: Recommendations on eligibility to PRIME scheme adopted at the CHMP meetings of 2026	New
06/10/2026	Document: List of medicines currently in PRIME scheme	Updated
06/10/2026	Medicine: Kinzalmono (previously Telmisartan Boehringer Ingelheim Pharma KG) telmisartan	Updated
06/10/2026	Page: How to submit information on authorised and investigational medicines	Updated
06/10/2026	Page: Reporting requirements for marketing-authorisation holders	Updated
06/10/2026	Medicine: Otulfi ustekinumab	Updated
06/10/2026	Document: PRAC rules of procedure	Updated
06/10/2026	Medicine: Steqeyma ustekinumab	Updated
06/10/2026	Scientific guideline: Good pharmacogenomic practice - Scientific guideline	Updated
06/10/2026	Document: Concept paper on the guideline revision on good pharmacogenomic practice	New
06/10/2026	Event: Management Board meeting: 30 September 2026	Updated
06/10/2026	Document: Agenda - Management Board meeting: 30 September 2026	Updated
06/10/2026	PSUSA: PSUSA/00001584/202602 - periodic safety update report single assessment haemophilus type b conjugate vaccines	New
06/10/2026	PSUSA: PSUSA/00001955/202602 - periodic safety update report single assessment mefloquine	New
06/10/2026	PSUSA: PSUSA/00001248/202602 - periodic safety update report single assessment erdosteine	New
06/10/2026	Event: European Medicines Agency workshop on bacteriophage therapy	Updated
06/10/2026	Medicine: Usymro ustekinumab	Updated
06/10/2026	PSUSA: PSUSA/00001781/202601 - periodic safety update report single assessment ipratropium / salbutamol	New
06/10/2026	PSUSA: PSUSA/00001583/202602 - periodic safety update report single assessment haemophilus type b and meningococcal group C conjugate vaccine	New
06/10/2026	Medicine: Myalepta metreleptin	Updated
06/10/2026	Post-authorisation: Imfinzi - withdrawal of application for variation to marketing authorisation durvalumab	Updated
06/10/2026	PSUSA: PSUSA/00002951/202601 - periodic safety update report single assessment tick-borne encephalitis vaccine (inactivated)	New
06/10/2026	Medicine: Ruxience rituximab	Updated
06/10/2026	Event: Committee for Orphan Medicinal Products (COMP): 6-8 October 2026	Updated

06/10/2026	Document: Agenda of the COMP Meeting 6-8 October 2026	New
06/10/2026	Document: Product Management Service (PMS) - Frequently Asked Questions (FAQs)	Updated
06/10/2026	Event: Ninth European Medicines Agency (EMA) and EFPIA bilateral meeting	Updated
06/10/2026	Medicine: Orladeyo berostralstat	Updated
06/10/2026	Document: Records of data processing activity relating to the management and processing of documents related to absences due to illness or accident and consultations with the occupational health physicians	New
06/10/2026	Event: European platform for regulatory science research meeting: October 2026	Updated
06/10/2026	Page: Developing cancer medicines for children	Updated
06/10/2026	Document: European Medicines Agency pre-authorisation procedural advice for users of the centralised procedure	Updated
06/10/2026	Document: European Medicines Agency pre-authorisation procedural advice for users of the centralised procedure: document with tracked changes	Updated
06/10/2026	Document: European Medicines Agency post-authorisation procedural advice for users of the centralised procedure	Updated
06/10/2026	Document: European Medicines Agency post-authorisation procedural advice for users of the centralised procedure: document with tracked changes	Updated
06/10/2026	Document: Template for response to list of questions/list of outstanding issues: Quality / Non-clinical / Clinical	Updated
06/10/2026	Page: Obtaining and maintaining a scientific opinion on a medicine for use outside the European Union	Updated
06/10/2026	Page: Accelerated assessment	Updated
06/10/2026	Page: Periodic safety update reports (PSURs)	Updated
06/10/2026	Page: Pre-authorisation guidance	Updated
06/10/2026	Page: Type-II variations: questions and answers	Updated
06/10/2026	Page: Extensions of marketing authorisations: questions and answers	Updated
06/10/2026	Page: Type-IA variations: questions and answers	Updated
06/10/2026	Page: Changing the labelling and package leaflet (Article 61(3) notifications)	Updated
06/10/2026	Medicine: Filsuvez birch bark extract	Updated
06/10/2026	Event: Committee for Medicinal Products for Veterinary Use (CVMP): 6-8 October 2026	Updated
06/10/2026	Document: Agenda of the CVMP meeting 6-8 October 2026	New
05/10/2026	Medicine: Byooviz ranibizumab	Updated
05/10/2026	Medicine: Ertapenem SUN ertapenem	Updated
05/10/2026	Medicine: Kinzalkomb telmisartan; hydrochlorothiazide	Updated
05/10/2026	Medicine: PritorPlus telmisartan; hydrochlorothiazide	Updated
05/10/2026	Medicine: Aumseqa Aumolertinib	Updated
05/10/2026	Medicine: Aimovig erenumab	Updated
05/10/2026	Document: Minutes of the CHMP meeting 15-18 September 2025	New

05/10/2026	Medicine: Hexacima diphtheria, tetanus, pertussis (acellular, component), hepatitis B (rDNA), poliomyelitis (inactivated) and Haemophilus influenzae type b conjugate vaccine (adsorbed)	Updated
05/10/2026	PSUSA: PSUSA/00011084/202603 - periodic safety update report single assessment dienogest / ethinylestradiol	New
05/10/2026	Medicine: Hexyon diphtheria, tetanus, pertussis (acellular, component), hepatitis B (rDNA), poliomyelitis (inactivated) and Haemophilus influenzae type b conjugate vaccine (adsorbed)	Updated
05/10/2026	Medicine: Opdualag relatlimab; nivolumab	Updated
05/10/2026	PSUSA: PSUSA/00000110/202601 - periodic safety update report single assessment alprostadil	New
05/10/2026	Document: Minutes of the CAT meeting 12-14 August 2026	New
05/10/2026	Document: Minutes of the CAT meeting 15-17 July 2026	New
05/10/2026	Document: User manual for the eXtended EudraVigilance Medicinal Product Dictionary (XEVMPD) user interface (XEVMPDweb)	Updated
05/10/2026	Event: Second HMA/EMA multi-stakeholder forum on EudraVigilance and signal detection	Updated
05/10/2026	Event: First European Medicines Agency (EMA) - International Society for Cell and Gene Therapy (ISCT) bilateral meeting	Updated

NOTICE TO APPLICANTS

No updates since July 10th, 2026.

BFARM - PHARMAKOVIGILANZ (SPECIFIC FOR GERMANY)

Date	Title
09.10.2026	Aktuelle Hinweise zu Einreichung und Genehmigung von Schulungsmaterial Aktualisierung der Hilfestellungsdokumente zur Einreichung und Genehmigung von behördlich genehmigten Schulungsmaterialien.

BFARM – MEDIZINPRODUKTE (SPECIFIC FOR GERMANY)

No updates since September 25th, 2026.

PEI - VIGILANZ (SPECIFIC FOR GERMANY)

Date	Title
09.10.2026	Das Paul-Ehrlich-Institut und das Bundesinstitut für Arzneimittel und Medizinprodukte bitten um erneute Übermittlung von Nebenwirkungen, die zwischen dem 07. – 09.10.2026 im Online-Meldeportal eingegeben wurden
08.10.2026	Rote-Hand-Brief: Ocrevus (Ocrelizumab)

PHARMEUROPA TEXTS FOR COMMENT

Information on Pharmeuropa updates will be presented quarterly.

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