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HEADS OF AGENCIES – CMDh

04 August

- [UPDATE - Guidance published by Member States on the implementation of the Falsified Medicines Directive](#)

HEADS OF AGENCIES – PAEDIATRIC REGULATION

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

EUROPEAN MEDICINES AGENCY (EMA)

Date	Content	Status
10/08/2026	Document: Name Review Group (NRG) plenary meeting dates: 2026-2027	Updated
10/08/2026	Document: Article 57 product data	Updated
10/08/2026	Document: European Medicines Agency's data protection notice for committees, Working Parties (WPs), Scientific Advisory Groups (SAGs) and Ad-Hoc Expert Groups (AHEGs)	Updated
10/08/2026	Document: Minutes of the COMP meeting 16-18 June 2026	New
10/08/2026	Page: PRIME: priority medicines	Updated
10/08/2026	Document: Recommendations on eligibility to PRIME scheme - Adopted at the CHMP meeting of 20-23 July 2026	New
10/08/2026	Document: List of medicines currently in PRIME scheme	Updated
07/08/2026	Page: Medicine shortages and availability issues: guidance for companies	Updated
07/08/2026	Medicine: Lacosamide Adroiq lacosamide	Updated
07/08/2026	Medicine: Epysqli eculizumab	Updated

Date	Content	Status
07/08/2026	Medicine: Imvanex smallpox and monkeypox vaccine (Live Modified Vaccinia Virus Ankara)	Updated
07/08/2026	PSUSA: PSUSA/00010462/202510 - periodic safety update report single assessment bisoprolol / perindopril	New
07/08/2026	PSUSA: PSUSA/00000419/202509 - periodic safety update report single assessment bisoprolol	New
07/08/2026	Medicine: Scemblix asciminib	Updated
07/08/2026	Document: Presentation - Why are NAMs important? (S. Ponzano)	New
07/08/2026	Document: Applications for new human medicines under evaluation: August 2026	New
07/08/2026	Medicine: Tecvayli teclistamab	Updated
07/08/2026	Medicine: Spedra avanafil	Updated
07/08/2026	Medicine: Hexacima diphtheria, tetanus, pertussis (acellular, component), hepatitis B (rDNA), poliomyelitis (inactivated) and Haemophilus influenzae type b conjugate vaccine (adsorbed)	Updated
07/08/2026	Medicine: Hexyon diphtheria, tetanus, pertussis (acellular, component), hepatitis B (rDNA), poliomyelitis (inactivated) and Haemophilus influenzae type b conjugate vaccine (adsorbed)	Updated
07/08/2026	Medicine: Nuvaxovid COVID-19 Vaccine (recombinant, adjuvanted)	Updated
07/08/2026	Page: CHMP opinions on consultation procedures on ancillary substances incorporated in a medical device	Updated
07/08/2026	Event: Clinical Trials Information System (CTIS) bitesize talk: Annual safety report (ASR) new safety module	Updated
07/08/2026	Document: Surgiflo haemostatic matrix kit - Ferrosan - Procedural steps and scientific information after initial consultation	New
07/08/2026	Document: Guidance for industry on implementing Shortage Prevention Plans (SPP)	New
06/08/2026	Medicine: Vumerity diroximel fumarate	Updated
06/08/2026	Medicine: Hyftor sirolimus	Updated

Date	Content	Status
06/08/2026	Medicine: Tenkasi (previously Orbactiv) oritavancin	Updated
06/08/2026	Medicine: Docetaxel Kabi docetaxel	Updated
06/08/2026	Medicine: Synjardy empagliflozin; metformin	Updated
06/08/2026	Medicine: Zynlonta loncastuximab tesirine	Updated
06/08/2026	Medicine: Thiotepa Riemser thiotepa	Updated
06/08/2026	Medicine: Neuraceq florbetaben (18F)	Updated
06/08/2026	Medicine: Cholib fenofibrate; simvastatin	Updated
06/08/2026	Medicine: MabThera rituximab	Updated
06/08/2026	Medicine: Abrysvo respiratory syncytial virus vaccine (bivalent, recombinant)	Updated
06/08/2026	Medicine: Breyanzi lisocabtagene maraleucel	Updated
06/08/2026	Medicine: Idacio adalimumab	Updated
06/08/2026	Medicine: Firazyr icatibant	Updated
06/08/2026	Medicine: Tepkinly epcoritamab	Updated
06/08/2026	Medicine: Comirnaty COVID-19 mRNA vaccine	Updated
06/08/2026	Medicine: Cibinqo abrocitinib	Updated
06/08/2026	Medicine: Ozawade pitolisant	Updated
06/08/2026	Page: Expert panel support for breakthrough medical devices: pilot programme	Updated
06/08/2026	Medicine: Deqdynet copper (⁶⁴ Cu) oxodotreotide	Updated
06/08/2026	Event: Quarterly System Demo - Q3 2026	Updated

Date	Content	Status
06/08/2026	Medicine: Spikevax (previously COVID-19 Vaccine Moderna) COVID-19 mRNA vaccine	Updated
06/08/2026	Document: Minutes - Meeting of the Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG) - July 2026	New
06/08/2026	Referral: Tavneos - referral avacopan	Updated
06/08/2026	Page: Fees payable to the European Medicines Agency: Guidance for all applicants	Updated
06/08/2026	Medicine: Wakix pitolisant	Updated
06/08/2026	DHPC: Desogestrel / etonogestrel - direct healthcare professional communication (DHPC) desogestrel; etonogestrel	New
05/08/2026	PSUSA: PSUSA/00000736/202509 - periodic safety update report single assessment choriogonadotropin alfa, chorionic gonadotrophin	New
05/08/2026	PSUSA: PSUSA/00000669/202512 - periodic safety update report single assessment chlorhexidine gluconate / isopropyl alcohol (covers other synonymous terms such as 2-propanol)	New
05/08/2026	Medicine: Degarelix Accord degarelix	Updated
05/08/2026	Medicine: Ninlaro ixazomib	Updated
05/08/2026	Medicine: Nexpovio selinexor	Updated
05/08/2026	Medicine: Kyprolis carfilzomib	Updated
05/08/2026	Medicine: Rolufta Ellipta (previously Rolufta) umeclidinium	Updated
05/08/2026	Medicine: Humira adalimumab	Updated
05/08/2026	Medicine: Leqembi lecanemab	Updated
05/08/2026	Medicine: Arikayce liposomal amikacin	Updated
05/08/2026	Medicine: Signifor pasireotide	Updated

Date	Content	Status
05/08/2026	Medicine: Iqirvo ela fibranor	Updated
05/08/2026	Medicine: Caprelsa vandetanib	Updated
05/08/2026	Medicine: Vantobra (previously Tobramycin PARI) tobramycin	Updated
05/08/2026	Medicine: Kisqali ribociclib	Updated
04/08/2026	Medicine: Loqtorzi toripalimab	Updated
04/08/2026	Medicine: Silapo epoetin zeta	Updated
04/08/2026	Medicine: Elmiron pentosan polysulfate sodium	Updated
04/08/2026	Medicine: Obodence denosumab	Updated
04/08/2026	Medicine: Bimervax COVID-19 Vaccine (recombinant, adjuvanted)	Updated
04/08/2026	Orphan: EU/3/19/2183 - orphan designation for treatment of WHIM syndrome mavorixafor	Updated
04/08/2026	Medicine: Dzuveo sufentanil	Updated
04/08/2026	Medicine: Vyxeos liposomal (previously Vyxeos) daunorubicin; cytarabine	Updated
04/08/2026	Orphan: EU/3/26/3201 - orphan designation for treatment of mesothelioma Measles virus Schwarz strain (live, attenuated)	Updated
04/08/2026	Orphan: EU/3/24/3012 - orphan designation for treatment of hepatitis delta virus infection tobevibart	Updated
04/08/2026	Orphan: EU/3/24/3010 - orphan designation for treatment of hepatitis delta virus infection elebsiran	Updated
04/08/2026	Orphan: EU/3/21/2475 - orphan designation for treatment of achondroplasia Infigratinib	Updated
04/08/2026	Medicine: Qinlock riporetinib	Updated

Date	Content	Status
04/08/2026	Orphan: EU/3/15/1450 - orphan designation for diagnosis of gastro-entero-pancreatic neuroendocrine tumours Gallium (68Ga)-edotreotide	Updated
04/08/2026	Orphan: EU/3/07/523 - orphan designation for treatment of gastro-entero-pancreatic neuroendocrine tumours Lutetium (177Lu)-N-[(4,7,10-Tricarboxymethyl-1,4,7,10-tetraazacyclododec-1-yl)acetyl]-D-phenylalanyl-L-cysteinyl-L-tyrosyl-D-tryptophanyl-L-lysyl-L-threoninyl-L-cysteinyl-L-threonine-cyclic(2-7)disulfide (lutetium (177Lu) oxodotreotide)	Updated
04/08/2026	Orphan: EU/3/25/3118 - orphan designation for treatment of primary hyperoxaluria mRNA encoding Cas12HF endonuclease, Single guide RNA against the human HAO1 gene	Updated
04/08/2026	Orphan: EU/3/25/3032 - orphan designation for treatment of Olmsted syndrome (R)-(3-(2'-cyclopropyl-3-(hydroxymethyl)-[1,1'-biphenyl]-4-yl)pyrrolidin-1-yl)(5-hydroxy-6-methylpyridin-2-yl)methanone	Updated
04/08/2026	Orphan: EU/3/20/2286 - orphan designation for treatment of soft tissue sarcoma autologous CD4+ and CD8+ T cells transduced with a lentiviral vector encoding an affinity enhanced T cell receptor specific to MAGE-A4	Updated
04/08/2026	Medicine: SomaKit TOC edotreotide	Updated
04/08/2026	Page: United for health at WorldPride 2026	New
04/08/2026	Medicine: Orserdu elacestrant	Updated
04/08/2026	Medicine: Vitrakvi larotrectinib	Updated
04/08/2026	Medicine: Skyclarys omaveloxolone	Updated
04/08/2026	Medicine: Spinraza nusinersen	Updated
04/08/2026	PSUSA: PSUSA/00003186/202511 - periodic safety update report single assessment a-tocopheril, a-tocopherol, vitamin E	New
04/08/2026	Document: List of clinical evaluation consultation procedure (CECP) opinions issued for medical devices awaiting finalisation of conformity assessment	Updated

Date	Content	Status
04/08/2026	Document: Retinal stimulation systems - Notified Body 0344 - 12/06/2026 - Expert decision and opinion in the context of the clinical evaluation consultation procedure (CECP)	New
04/08/2026	Medicine: Irbesartan Hydrochlorothiazide Zentiva (previously Irbesartan Hydrochlorothiazide Winthrop) irbesartan; hydrochlorothiazide	Updated
04/08/2026	Medicine: Leflunomide medac leflunomide	Updated
04/08/2026	Medicine: Twinrix Adult hepatitis A (inactivated) and hepatitis B (rDNA) (HAB) vaccine (adsorbed)	Updated
04/08/2026	Medicine: Orblid bevacizumab	Updated
04/08/2026	Orphan: EU/3/14/1262 - orphan designation for prevention of bronchopulmonary dysplasia recombinant human surfactant protein D	Updated
04/08/2026	Page: Enpr-EMA priority activities	Updated
04/08/2026	Document: Meeting summary - Medicine Shortages SPOC Working Party meeting 16-17 June 2026	New
04/08/2026	Page: Plasma master file certificates	Updated
04/08/2026	Orphan: EU/3/16/1694 - orphan designation for treatment of soft tissue sarcoma autologous CD4+ and CD8+ T cells transduced with lentiviral vector containing an affinity-enhanced T-cell receptor targeting the New York esophageal antigen-1	Updated
04/08/2026	Document: Silapo : EPAR - All Authorised presentations	Updated
03/08/2026	Medicine: Vabysmo faricimab	Updated
03/08/2026	Medicine: Clopidogrel Zentiva (previously Clopidogrel Winthrop) clopidogrel	Updated
03/08/2026	Medicine: Takhzyro lanadelumab	Updated
03/08/2026	Medicine: Lytenava bevacizumab	Updated
03/08/2026	Medicine: Opzelura ruxolitinib	Updated
03/08/2026	Medicine: Palsonify paltusotine	Updated

Date	Content	Status
03/08/2026	Medicine: Ambirix hepatitis A (inactivated) and hepatitis B (rDNA) (HAB) vaccine (adsorbed)	Updated
03/08/2026	Medicine: Twinrix Paediatric hepatitis A (inactivated) and hepatitis B (rDNA) (HAB) vaccine (adsorbed)	Updated
03/08/2026	Referral: Veterinary medicinal products containing albendazole as a single active substance presented as oral suspension in sheep - referral albendazole	Updated
03/08/2026	Document: New product information wording: extracts from PRAC recommendations on signals adopted at the 6-9 July 2026 PRAC	New
03/08/2026	Document: European Union Member State Public Holidays Recorded in CTIS (year: 2027)	New
03/08/2026	Medicine: Svariya (previously Rivaroxaban Koanaa) rivaroxaban	Updated
03/08/2026	Event: Enpr-EMA Coordinating Group meeting June 2026	New
03/08/2026	Document: PRAC recommendations on signals adopted at the 6-9 July 2026 PRAC meeting	New
03/08/2026	Document: List of signals discussed at PRAC since September 2012	Updated
03/08/2026	Document: Breakthrough status request: Template for applicants for breakthrough medical devices pilot	Updated
03/08/2026	Event: European platform for regulatory science research meeting: October 2026	New
03/08/2026	Event: Fifth European Medicines Agency (EMA) and Affordable Medicines Europe bilateral meeting	New
03/08/2026	Event: Ninth European Medicines Agency (EMA) and EFPIA bilateral meeting	New
03/08/2026	Page: Veterinary Medicines	Updated
03/08/2026	Document: Organisation chart: Veterinary Medicines	Updated
03/08/2026	Document: Organisation chart: Advisory functions	Updated

NOTICE TO APPLICANTS

No updates since June 24th, 2026.

BFARM - PHARMAKOVIGILANZ (SPECIFIC FOR GERMANY)

Date	Title
10.08.2026	Rote-Hand-Brief zu Litfolo (Ritlecitinib): Risiko für schwerwiegende unerwünschte kardiovaskuläre Ereignisse, maligne Erkrankungen, venöse Thromboembolien, schwerwiegende Infektionen und Mortalität Wirkstoff: RitlecitinibDie Firma Pfizer Europe MA EEIG informiert über aktualisierte Empfehlungen zur Minimierung des Risikos für schwerwiegende unerwünschte kardiovaskuläre Ereignisse, maligne Erkrankungen, venöse Thromboembolien, schwerwiegende Infektionen und Mortalität.
10.08.2026	Informationen zu Einreichung und Genehmigung von Schulungsmaterial Aktualisierung der Hilfestellungsdokumente zur Einreichung und Genehmigung von behördlich genehmigten Schulungsmaterialien.
06.08.2026	Rote-Hand-Brief zu desogestrel- und etonogestrelhaltigen Arzneimitteln: Risiko eines Meningeoms und Maßnahmen zur Risikominimierung Wirkstoff: Desogestrel, EtonogestrelDie Zulassungsinhaber von desogestrel- und etonogestrelhaltigen Arzneimitteln informieren über ein gering erhöhtes Risiko für das Auftreten eines Meningeoms bei längerfristiger Anwendung.

BFARM – MEDIZINPRODUKTE (SPECIFIC FOR GERMANY)

Date	Title
	No updates since August 3rd, 2026.

PEI - VIGILANZ (SPECIFIC FOR GERMANY)

Date	Title
	No updates since August 3rd, 2026

PHARMEUROPA TEXTS FOR COMMENT

Information on Pharmeduropa updates will be presented quarterly.

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