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HEADS OF AGENCIES – CMDh

21 May

[UPDATE - Contact Points](#)

18 May

[NEW - 19-20 May CMDh agenda](#)

HEADS OF AGENCIES – PAEDIATRIC REGULATION

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

EUROPEAN MEDICINES AGENCY (EMA)

Date	Content	Status
22/05/2026	Document: Questions and answers on periodic safety update report single-assessment (PSUSA): Guidance document for assessors	Updated
22/05/2026	Document: Guideline on good pharmacovigilance practices (GVP): Module VII – Periodic safety update report - Explanatory note	Updated
22/05/2026	Medicine: Adempas riociguat	Updated
22/05/2026	News: Meeting highlights from the Committee for Veterinary Medicinal Products (CVMP) 19-21 May 2026	New
22/05/2026	Medicine: Uplizna inebilizumab	Updated
22/05/2026	Post-authorisation: Respivac aMPV (previously Respivac TRT) - opinion on variation to marketing authorisation turkey rhinotracheitis virus, strain 1062, live	New

Date	Content	Status
22/05/2026	Page: Scientific and technical recommendations: Veterinary Medicines Regulation	Updated
22/05/2026	Medicine: Nobivac NXT HCP felid herpesvirus 1, strain G2620A, live; feline calicivirus, strain F9, live; feline panleucopenia virus, strain MW-1, live	New
22/05/2026	Medicine: Nobivac NXT HC feline calicivirolosis and feline viral rhinotracheitis vaccine (live)	New
22/05/2026	Medicine: Nobivac NXT HCPCh feline calicivirolosis, feline rhinotracheitis, feline panleucopenia and feline chlamydiosis (live) vaccine	New
22/05/2026	Document: Questions to EMA on midazolam	New
22/05/2026	Document: EC letter to EMA - Request pursuant to Article 141(1)(f) of Regulation (EU) 2019/6	New
22/05/2026	Document: Guidance under Article 141(1)(f) of Regulation (EU) 2019/6 on veterinary medicinal products with regards five substances not included in Commission Implementing Regulation (EU) 2025/901	New
22/05/2026	Document: Questions for CVMP in relation to EMA's recommendations under Article 107(6) and Article 114(3)	New
22/05/2026	Document: Guidance under Article 141(1)(f) of Regulation (EU) 2019/6 on veterinary medicinal products in relation to Articles 107(6) and 114(3)	New
22/05/2026	Document: EC request to EMA for guidance on scientific issues in relation to Articles 107(6) and 114(3) of Regulation (EU) 2019/6	New
22/05/2026	Medicine: Piasky crovalimab	Updated
22/05/2026	Medicine: Yttriga yttrium [90Y] chloride	Updated
22/05/2026	Medicine: Yuvanci macitentan; tadalafil	Updated
22/05/2026	Medicine: Mekinist trametinib	Updated
22/05/2026	Medicine: Sephience sepiapterin	Updated

Date	Content	Status
22/05/2026	Post-authorisation: BTVPUR - opinion on variation to marketing authorisation inactivated vaccine against bluetongue virus serotypes 1 and 8	New
22/05/2026	Medicine: Jubereq denosumab	Updated
22/05/2026	Medicine: Osvyrti denosumab	Updated
22/05/2026	News: Meeting highlights from the Committee for Medicinal Products for Human Use (CHMP) 18-21 May 2026	New
22/05/2026	Post-authorisation: Braftovi - opinion on variation to marketing authorisation encorafenib	New
22/05/2026	Post-authorisation: Tepkinly - opinion on variation to marketing authorisation epcoritamab	New
22/05/2026	Post-authorisation: Iclusig - opinion on variation to marketing authorisation ponatinib	New
22/05/2026	Medicine: Colchicine Agepha Pharma colchicine	New
22/05/2026	Orphan: EU/3/22/2727 - orphan designation for diagnosis of neuroendocrine neoplasms Copper (64Cu) oxodotreotide	Updated
22/05/2026	Orphan: EU/3/21/2420 - orphan designation for treatment of PIK3CA related overgrowth spectrum alpelisib	Updated
22/05/2026	Orphan: EU/3/14/1390 - orphan designation for treatment of hereditary haemorrhagic telangiectasia bevacizumab	Updated
22/05/2026	News: New medicine for two types of pulmonary fibrosis	New
22/05/2026	News: First oral GLP-1 treatment for weight management	New
22/05/2026	News: First medicine to treat rare uncontrolled growth of body tissues	New
22/05/2026	Medicine: Deqynet copper (64Cu) oxodotreotide	New
22/05/2026	Medicine: Ablymico liraglutide	New
22/05/2026	Medicine: Vijoice alpelisib	New

Date	Content	Status
22/05/2026	Medicine: Etcamah camizestrant	New
22/05/2026	Medicine: Vislyfa ranibizumab	New
22/05/2026	Medicine: Orblid bevacizumab	New
22/05/2026	Medicine: Liraglutide STADA liraglutide	New
22/05/2026	Medicine: Veblocema infliximab	New
22/05/2026	Post-authorisation: Erbitux - opinion on variation to marketing authorisation cetuximab	New
22/05/2026	Post-authorisation: Palyzinq - opinion on variation to marketing authorisation pegvaliase	New
22/05/2026	Post-authorisation: Wegovy - opinion on variation to marketing authorisation semaglutide	New
22/05/2026	Post-authorisation: Erbitux - opinion on variation to marketing authorisation cetuximab	New
22/05/2026	Post-authorisation: Keytruda - opinion on variation to marketing authorisation pembrolizumab	New
22/05/2026	Post-authorisation: Maviret - opinion on variation to marketing authorisation glecaprevir; pibrentasvir	New
22/05/2026	Post-authorisation: Padcev - opinion on variation to marketing authorisation enfortumab vedotin	New
22/05/2026	Post-authorisation: Fasenra - opinion on variation to marketing authorisation benralizumab	New
22/05/2026	Post-authorisation: Enhertu - opinion on variation to marketing authorisation trastuzumab deruxtecan	New
22/05/2026	Post-authorisation: Hetronifly - opinion on variation to marketing authorisation serplulimab	New
22/05/2026	Post-authorisation: Trodelvy - opinion on variation to marketing authorisation sacituzumab govitecan	New
22/05/2026	Post-authorisation: Sogroya - opinion on variation to marketing authorisation somapacitan	New
22/05/2026	Post-authorisation: Keytruda - opinion on variation to marketing authorisation pembrolizumab	New
22/05/2026	Document: Overview of (invented) names reviewed in April 2026 by the Name Review Group (NRG) adopted at the CHMP meeting of 21 May 2026	New

Date	Content	Status
22/05/2026	Page: Hantavirus	New
22/05/2026	PSUSA: PSUSA/00003006/202503 - periodic safety update report single assessment tranexamic acid	Updated
21/05/2026	Medicine: Nuwiq simoctocog alfa	Updated
21/05/2026	Medicine: Zoledronic acid Teva zoledronic acid	Updated
21/05/2026	Medicine: Bavencio avelumab	Updated
21/05/2026	Document: Scientific advice and protocol assistance adopted during the CHMP meeting 20-23 April 2026	New
21/05/2026	Medicine: Exjade deferasirox	Updated
21/05/2026	Medicine: Ceprotin human protein C	Updated
21/05/2026	Document: List of eligible industry stakeholder organisations	Updated
21/05/2026	Medicine: Kisqali ribociclib	Updated
21/05/2026	News: EMA closed on Whit Monday, 25 May	New
21/05/2026	Page: Website outages and upgrades	Updated
21/05/2026	Medicine: Pyrukynd mitapivat	Updated
21/05/2026	Document: Guidance on the details of the classification of variations requiring assessment according to Article 62 of Regulation (EU) 2019/6 for veterinary medicinal products and on the documentation to be submitted pursuant to those variations	Updated
21/05/2026	Event: Virtual live hands-on training course for clinical trials sponsors using EudraVigilance system - November 2026	New
21/05/2026	Event: Virtual live hands-on training course for clinical trials sponsors using EudraVigilance system - October 2026	New
20/05/2026	Medicine: Ruconest conestat alfa	Updated
20/05/2026	Medicine: Feracru ferric maltol	Updated
20/05/2026	Medicine: Ryeqo relugolix; estradiol; norethisterone acetate	Updated
20/05/2026	Medicine: Xofluza baloxavir marboxil	Updated
20/05/2026	Page: Data Analysis and Real World Interrogation Network (DARWIN EU)	Updated
20/05/2026	Medicine: Mimpara cinacalcet	Updated

Date	Content	Status
20/05/2026	Event: Mandatory use of ISO/ICH E2B(R3) individual case safety reporting in the EU: hands-on training course using the EudraVigilance system	New
20/05/2026	Event: Mandatory use of ISO/ICH E2B(R3) individual case safety reporting in the EU: hands-on training course using the EudraVigilance system	New
20/05/2026	Event: Mandatory use of ISO/ICH E2B(R3) individual case safety reporting in the EU: hands-on training course using the EudraVigilance system	New
20/05/2026	Event: Mandatory use of ISO/ICH E2B(R3) individual case safety reporting in the EU: hands-on training course using the EudraVigilance system	New
20/05/2026	Medicine: Iloperidone Vanda Pharmaceuticals iloperidone	Updated
20/05/2026	Document: HMPC meeting report on European Union herbal monographs, guidelines and other activities - 4-6 May 2026	New
20/05/2026	Medicine: Dazparda insulin aspart	Updated
20/05/2026	Event: Webinar on new approach methodologies (NAMs) in ecotoxicology: In silico approaches for fish acute toxicity	New
20/05/2026	News: EU tracks progress towards 2030 clinical trial targets	New
20/05/2026	Page: Clinical trials in human medicines	Updated
20/05/2026	Medicine: Cerdelga eliglustat	Updated
19/05/2026	Medicine: Arava leflunomide	Updated
19/05/2026	Medicine: Synflorix pneumococcal polysaccharide conjugate vaccine (adsorbed)	Updated
19/05/2026	Medicine: Tecartus brexucabtagene autoleucl	Updated
19/05/2026	Page: Product-specific bioequivalence guidance	Updated
19/05/2026	Document: Start of procedure: Type II Variation - Extension of indication under evaluation by the CHMP (27 March 2026 - 23 April 2026)	New
19/05/2026	Medicine: Cimzia certolizumab pegol	Updated
19/05/2026	Medicine: Yescarta axicabtagene ciloleucl	Updated
19/05/2026	Medicine: Tuyory tocilizumab	Updated
19/05/2026	Medicine: Tafinlar dabrafenib	Updated
19/05/2026	Document: Agenda of the CVMP meeting 19-21 May 2026	New

Date	Content	Status
19/05/2026	Document: Presentation - CTIS Bitesize Talk: End of transition period and notifications including serious breaches	Updated
19/05/2026	Medicine: Spexotras trametinib	Updated
19/05/2026	Medicine: Voranigo vorasidenib	Updated
19/05/2026	Medicine: Procysbi mercaptamine	Updated
19/05/2026	Medicine: Arexvy recombinant respiratory syncytial virus pre-fusion F protein, adjuvanted with AS01E	Updated
19/05/2026	Medicine: Zoledronic acid medac zoledronic acid	Updated
19/05/2026	Document: Application form for the involvement of healthcare professionals' organisations in the activities of the European Medicines Agency	Updated
19/05/2026	Medicine: Ibrance palbociclib	Updated
19/05/2026	Page: Executive Steering Group on Shortages of Medical Devices	Updated
18/05/2026	Orphan: EU/3/16/1716 - orphan designation for treatment of Duchenne muscular dystrophy adeno-associated viral vector serotype 9 containing the human mini-dystrophin gene	Updated
18/05/2026	Orphan: EU/3/25/3114 - orphan designation for treatment of alpha-1 antitrypsin deficiency RNA editing antisense oligonucleotide against the Z mutation of the human SERPINA1 mRNA transcript, sodium salt	Updated
18/05/2026	Page: Ebola	Updated
18/05/2026	Medicine: Ixchiq Chikungunya vaccine (live)	Updated
18/05/2026	Document: Start of procedure: Type II Variation - Extension of indication under evaluation by the CHMP (27 February 2026 - 26 March 2026)	New
18/05/2026	Document: Start of procedure: Type II Variation - Extension of indication under evaluation by the CHMP (30 January 2026 - 26 February 2026)	New
18/05/2026	Medicine: Paxlovid nirmatrelvir; ritonavir	Updated
18/05/2026	Document: Questions and answers - Practical arrangements on the companion diagnostics consultation procedure to the European Medicines Agency by notified bodies	Updated
18/05/2026	Document: Questions and answers - Practical arrangements on the companion diagnostics consultation procedure to the European Medicines Agency by notified bodies - tracked changes	Updated
18/05/2026	Medicine: Besponsa inotuzumab ozogamicin	Updated

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18/05/2026	Medicine: Zercepac trastuzumab	Updated
18/05/2026	Medicine: Imfinzi durvalumab	Updated
18/05/2026	Document: Highlights from the third expert panels and notified bodies workshop	New
18/05/2026	Medicine: Usrenty ustekinumab	Updated
18/05/2026	Event: EMA risk management information day	New
18/05/2026	Document: Highlights from the second expert panels and notified bodies workshop	New
18/05/2026	Event: Q&A clinic on Product Management Service (PMS) Product User Interface (PUI) and Application Programming Interface (API) - March 2026	Updated
18/05/2026	Document: Annex to agenda of the CHMP meeting 18-21 May 2026	New
18/05/2026	Document: Agenda of the CHMP meeting 18-21 May 2026	New
18/05/2026	Medicine: Sapropterin Dipharma sapropterin	Updated
18/05/2026	Orphan: EU/3/25/3159 - orphan designation for treatment of idiopathic pulmonary fibrosis orvepitant maleate	Updated
18/05/2026	Orphan: EU/3/20/2376 - orphan designation for treatment of congenital hyperinsulinism 4-[(3S)-3-aminopyrrolidin-1-yl]-6-cyano-5-(3,5-difluorophenyl)-N-[(2S)-1,1,1-trifluoropropan-2-yl]pyridine-3-carboxamide	Updated
18/05/2026	Orphan: EU/3/22/2731 - orphan designation for treatment of small cell lung cancer serplulimab	Updated
18/05/2026	Orphan: EU/3/04/230 - orphan designation for treatment of cystic fibrosis Dexamethasone sodium phosphate encapsulated in human erythrocytes	Updated
18/05/2026	Orphan: EU/3/13/1158 - orphan designation for treatment of ataxia telangiectasia Dexamethasone sodium phosphate encapsulated in human autologous erythrocytes	Updated
18/05/2026	Orphan: EU/3/18/2004 - orphan designation for treatment of diffuse large B-cell lymphoma tazemetostat	Updated
18/05/2026	Orphan: EU/3/18/2006 - orphan designation for treatment of malignant mesothelioma tazemetostat	Updated
18/05/2026	Orphan: EU/3/24/2989 - orphan designation for treatment of systemic sclerosis avenciguat	Updated
18/05/2026	Orphan: EU/3/12/1010 - orphan designation for treatment of Becker muscular dystrophy ataluren	Updated

Date	Content	Status
18/05/2026	Orphan: EU/3/20/2333 - orphan designation for treatment of peripheral T-cell lymphoma tipifarnib	Updated
18/05/2026	Orphan: EU/3/15/1561 - orphan designation for treatment of aniridia ataluren	Updated
18/05/2026	Orphan: EU/3/05/269 - orphan designation for treatment of acute myeloid leukaemia tipifarnib	Updated
18/05/2026	Orphan: EU/3/24/2966 - orphan designation for treatment of gastric cancer bemarituzumab	Updated
18/05/2026	Orphan: EU/3/13/1108 - orphan designation for treatment of systemic sclerosis 2-[4-Methoxy-3-(2-m-tolyl-ethoxy)-benzoylamino]-indan-2-carboxylic acid	Updated
18/05/2026	Orphan: EU/3/17/1854 - orphan designation for treatment of thromboangiitis obliterans (Buerger's disease) autologous adipose tissue-derived mesenchymal stem cells	Updated
18/05/2026	Orphan: EU/3/10/842 - orphan designation for treatment of squamous-cell carcinoma of the head and neck in patients undergoing radiotherapy nimorazole	Updated
18/05/2026	Orphan: EU/3/10/823 - orphan designation for treatment of familial chylomicronaemia Lomitapide	Updated
18/05/2026	Orphan: EU/3/11/937 - orphan designation for treatment of Leigh syndrome alpha-tocotrienol quinone	Updated
18/05/2026	Medicine: Imvanex smallpox and monkeypox vaccine (Live Modified Vaccinia Virus Ankara)	Updated
18/05/2026	Orphan: EU/3/22/2654 - orphan designation for treatment of fibrodysplasia ossificans progressiva (S)-1-(4-(1-(3,4,5-trimethoxyphenyl)-1H-imidazol-4-ylamino)thieno[2,3-d]pyrimidin-2-yl)pyrrolidine-2-carboxamide	Updated

NOTICE TO APPLICANTS

No updates since October 30th, 2025.

BFARM - PHARMAKOVIGILANZ (SPECIFIC FOR GERMANY)

Date	Title
21.05.2026	<p>Umsetzung des einstimmigen Beschlusses der Koordinierungsgruppe vom 25.03.2026 betreffend die Zulassungen für Humanarzneimittel mit dem Wirkstoff Pethidin</p> <p>Das BfArM veröffentlicht den Umsetzungsbescheid für den Wirkstoff Pethidin infolge des Europäischen PSUR Single Assessment Verfahrens nach Artikel 107d) bis g) der Richtlinie 2001/83/EG.</p>

Date	Title
21.05.2026	Umsetzung des einstimmigen Beschlusses der Koordinierungsgruppe vom 25.03.2026 betreffend die Zulassungen für Humanarzneimittel mit den Wirkstoffkombinationen Buclizin/Codein/Paracetamol und/oder Coffein/Codein/Paracetamol Das BfArM veröffentlicht den Umsetzungsbescheid für die Wirkstoffkombinationen Buclizin/Codein/Paracetamol und/oder Coffein/Codein/Paracetamol infolge des Europäischen PSUR Single Assessment Verfahrens nach Artikel 107d) bis g) der Richtlinie 2001/83/EG.
21.05.2026	Umsetzung des einstimmigen Beschlusses der Koordinierungsgruppe vom 26.03.2026 betreffend die Zulassungen für Humanarzneimittel mit dem Wirkstoff Piretanid und der Wirkstoffkombination Piretanid/Ramipril Das BfArM veröffentlicht den Umsetzungsbescheid für den Wirkstoff Piretanid und die Wirkstoffkombination Piretanid/Ramipril 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 April 17th, 2026.

PEI - VIGILANZ (SPECIFIC FOR GERMANY)

No updates since May 12th, 2026.

PHARMEUROPA TEXTS FOR COMMENT

Information on Pharmeuropa updates will be presented quarterly.

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