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HEADS OF AGENCIES – CMDh

22 October

- [UPDATE - Decisions on additional year of market protection/data exclusivity for new therapeutic indication and new active substance status agreed by the CMDh](#)

22 October

- [UPDATE - MRP/RUP request form](#)
- [UPDATE - 'Blue-box' requirements](#)
- [UPDATE - List of active substances for which data has been submitted in accordance with Art. 45](#)
- [UPDATE - Request form for RMS in DCP](#)
- [UPDATE - Data requested for Variations and/or Renewal Applications in the MRP/DCP](#)
- [UPDATE - Data requested for New Applications in the MRP/DCP](#)
- [UPDATE - Procedural advice on Validation of MR/Repeat-use/DC Procedures](#)
- [UPDATE - CMDh Recommendation for classification of unforeseen variations according to Article 5 of Commission Regulation \(EC\) 1234/2008](#)
- [NEW - Report from the meeting held on 13-14 October 2026](#)

21 October

- [NEW - 15-17 September CMDh Minutes](#)

HEADS OF AGENCIES – PAEDIATRIC REGULATION

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

EUROPEAN MEDICINES AGENCY (EMA)

Date	Content	Status
23/10/2026	Page: Ebola	Updated
23/10/2026	Page: Emergency Task Force (ETF) recommendations	Updated
23/10/2026	Document: Position paper on clinical development of Bundibugyo vaccines	New
23/10/2026	Event: Media seminar on vaccines	New
23/10/2026	Page: Scientific publications	Updated
23/10/2026	Document: Minutes of the COMP meeting 8-10 September 2026	New
23/10/2026	Event: EMA/FVE information session for veterinary students: the importance of pharmacovigilance	Updated

23/10/2026	Document: Records of data processing activity for the EMA intranet	Updated
23/10/2026	Medicine: Voriconazole Hikma (previously Voriconazole Hospira) voriconazole	Updated
23/10/2026	Event: Sixth Veterinary Big Data Stakeholder Forum	Updated
23/10/2026	Document: Agenda - Sixth Veterinary Data Stakeholder Forum	New
23/10/2026	Page: Pre-authorisation guidance under the Veterinary Medicinal Products Regulation (Regulation (EU) 2019/6)	Updated
23/10/2026	PSUSA: PSUSA/00001026/202512 - periodic safety update report single assessment diacerein	New
23/10/2026	Page: Health technology assessment bodies	Updated
23/10/2026	Medicine: Leqvio inclisiran	Updated
23/10/2026	Medicine: Silapo epoetin zeta	Updated
23/10/2026	Document: Highlights - First European Medicines Agency (EMA) - International Society for Cell and Gene Therapy (ISCT) bilateral meeting	New
23/10/2026	Document: Minutes of PRAC meeting on 31 August - 3 September 2026	New
23/10/2026	Medicine: Trixeo Aerosphere formoterol; glycopyrronium bromide; budesonide	Updated
23/10/2026	Medicine: Lamzede velmanase alfa	Updated
23/10/2026	Medicine: Prolia denosumab	Updated
23/10/2026	News: AMA and EMA issue joint guidance on Ebola vaccine development	New
23/10/2026	Page: Veterinary limited markets	Updated
23/10/2026	Document: One year of additional market protection for new indication assessment report template	Updated
23/10/2026	Event: Meeting of the Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG) - October 2026	Updated
22/10/2026	Medicine: Vevzuo denosumab	Updated
22/10/2026	Medicine: Cejemly sugemalimab	Updated
22/10/2026	Medicine: Filgrastim Hexal filgrastim	Updated
22/10/2026	Medicine: Zarzio filgrastim	Updated
22/10/2026	Medicine: Amyvid florbetapir (18F)	Updated
22/10/2026	Medicine: Vydura rimegepant	Updated
22/10/2026	Medicine: Instanyl fentanyl	Updated
22/10/2026	Document: Start of procedure: Extension of marketing authorisation (18 September 2026 - 15 October 2026)	New
22/10/2026	Document: CHMP PROM minutes for the meeting on 13 April 2026	New
22/10/2026	Medicine: Kostaive zapomeran	Updated
22/10/2026	Medicine: Eklira Genuair aclidinium bromide	Updated
22/10/2026	Medicine: Duaklir Genuair aclidinium bromide; formoterol	Updated

22/10/2026	Medicine: Byfavo remimazolam	Updated
22/10/2026	Medicine: Taxotere docetaxel	Updated
22/10/2026	PIP: EMA-003002-PIP04-23 - paediatric investigation plan avenciguat	Updated
22/10/2026	PIP: EMA-002537-PIP02-19 - paediatric investigation plan darunavir; ritonavir	Updated
22/10/2026	Medicine: Kygevv doxycitine; doxibutimide	Updated
22/10/2026	Event: Immunogenicity and efficacy of pneumococcal vaccines	New
21/10/2026	PSUSA: PSUSA/00000078/202601 - periodic safety update report single assessment alendronate	New
21/10/2026	Medicine: GONAL-f follitropin alfa	Updated
21/10/2026	Medicine: Vyvgart efgartigimod alfa	Updated
21/10/2026	Medicine: Rayvow lasmiditan	Updated
21/10/2026	Event: Meeting of the Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG) - September 2026	Updated
21/10/2026	Document: Minutes - Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG) - 23 September 2026	New
21/10/2026	Document: Agenda - HMA / EMA multistakeholder AI and Data forum: Build trustworthy AI on strong data foundations	Updated
21/10/2026	Document: CHMP PROM minutes for the meeting on 19 January 2026	New
21/10/2026	PIP: EMA-002644-PIP01-19-M01 - paediatric investigation plan cyclophosphamide	Updated
21/10/2026	PIP: EMA-001841-PIP01-15 - paediatric investigation plan bexagliflozin	Updated
21/10/2026	Medicine: Orladeyo berotralstat	Updated
21/10/2026	Medicine: Anzupgo delgocitinib	Updated
21/10/2026	Page: Class III implantable devices and Class IIb medical devices intended to administer or remove medicinal products: expert panel opinions	Updated
21/10/2026	Document: Vascular and cardiac prostheses – other - Notified Body 0344 - 25/11/2025 - Expert decision and opinion in the context of the clinical evaluation consultation procedure (CECP)	New
21/10/2026	Document: General medicine therapeutic treatment instruments - Notified Body 2797 - 12/05/2026 - Expert decision and opinion in the context of the clinical evaluation consultation procedure (CECP)	New
21/10/2026	Medicine: Libmeldy autologous CD34+ cells encoding ARSA gene	Updated
21/10/2026	Medicine: Cavoley pegfilgrastim	Updated
21/10/2026	Document: Minutes - HMA-EMA joint Network Data Steering Group meeting - 10 September 2026	New
21/10/2026	Document: Minutes - HMA-EMA joint Network Data Steering Group meeting - 17 July 2026	New
21/10/2026	Page: Guidance on good manufacturing practice and good distribution practice: Questions and answers	Updated

21/10/2026	Document: CHMP PROM minutes for the meeting on 16 February 2026	New
21/10/2026	Document: Template for HMPC Assessment Report Summary for the Public (ARSP)	New
21/10/2026	Document: List of Union reference dates and frequency of submission of periodic safety update reports (PSURs)	Updated
20/10/2026	PSUSA: PSUSA/00010187/202601 - periodic safety update report single assessment amino acid combinations (only combinations of pure amino acids or combination of amino acids with mineral compounds/electrolytes, i.v. application)	Updated
20/10/2026	Medicine: Imuldosa ustekinumab	Updated
20/10/2026	Medicine: Darunavir Viatris (previously Darunavir Mylan) darunavir	Updated
20/10/2026	Medicine: Deferasirox Accord deferasirox	Updated
20/10/2026	Medicine: Tosmova (previously Tocilizumab STADA and Tofidence) tocilizumab	Updated
20/10/2026	Medicine: Kanjinti trastuzumab	Updated
20/10/2026	Post-authorisation: Kaftrio - withdrawal of application for variation to marketing authorisation ivacaftor; tezacaftor; elexacaftor	Updated
20/10/2026	Medicine: Prevenar 20 (previously Apexxnar) pneumococcal polysaccharide conjugate vaccine (20-valent, adsorbed)	Updated
20/10/2026	Document: Pilot phase for the revised pre-submission interactions: Annex to request for rapporteurship	Updated
20/10/2026	Medicine: Afqlir aflibercept	Updated
20/10/2026	Medicine: Nordimet methotrexate	Updated
20/10/2026	Medicine: Bimervax COVID-19 Vaccine (recombinant, adjuvanted)	Updated
20/10/2026	Medicine: Enhertu trastuzumab deruxtecan	Updated
20/10/2026	Medicine: Degarelix Accord degarelix	Updated
20/10/2026	Medicine: Skyclarys omaveloxolone	Updated
20/10/2026	Medicine: Shingrix herpes zoster vaccine (recombinant, adjuvanted)	Updated
20/10/2026	Medicine: Victoza liraglutide	Updated
20/10/2026	Medicine: Exjade deferasirox	Updated
20/10/2026	Medicine: Jivi damoctocog alfa pegol	Updated
20/10/2026	Medicine: Polivy polatuzumab vedotin	Updated
20/10/2026	Medicine: Zolsketil pegylated liposomal doxorubicin	Updated
20/10/2026	Medicine: Xofigo radium Ra223 dichloride	Updated

20/10/2026	Medicine: Tookad padeliporfin	Updated
20/10/2026	Medicine: Jevtana cabazitaxel	Updated
20/10/2026	Medicine: Firmagon degarelix	Updated
20/10/2026	Medicine: Enzalutamide Viatriis enzalutamide	Updated
20/10/2026	Medicine: Cabazitaxel Accord cabazitaxel	Updated
20/10/2026	Medicine: Poteligeo mogamulizumab	Updated
20/10/2026	Medicine: Beyontra acoramidis	Updated
20/10/2026	Medicine: Columvi glofitamab	Updated
20/10/2026	Medicine: Ontozry cenobamate	Updated
20/10/2026	Medicine: Arikayce liposomal amikacin	Updated
20/10/2026	Medicine: Zinplava bezlotoxumab	Updated
20/10/2026	Page: Podcast: Inside EMA	Updated
20/10/2026	Page: Access to documents	Updated
20/10/2026	Page: How to prepare and review a summary of product characteristics	Updated
20/10/2026	Event: ACT EU workshop on multiplicity in confirmatory clinical trials: From two-arm to platform trials	Updated
20/10/2026	Document: Timetable: Safety signal - Assessment of responses to request for supplementary information (RSI)	Updated
20/10/2026	Event: Second ACT EU webinar on contractual agreements	New
20/10/2026	Document: Records of data processing activity for the declaration of gainful employment of staff members' spouses and registered partners	New
20/10/2026	Document: Recommended submission dates for veterinary medicinal products	Updated
20/10/2026	Document: Agenda - European Medicines Agency workshop on bacteriophage therapy	Updated
20/10/2026	Document: Records of data processing activity for the engagement in active senior initiative	New
20/10/2026	Document: List of clinical evaluation consultation procedure (CECP) opinions issued for medical devices awaiting finalisation of conformity assessment	Updated
20/10/2026	Event: Real-world data collection in Duchenne muscular dystrophy: Joint Heads of Medicines Agencies (HMA) / European Medicines Agency (EMA) multistakeholder workshop	Updated
20/10/2026	Medicine: Afinitor everolimus	Updated
20/10/2026	Medicine: Yondelis trabectedin	Updated
20/10/2026	Document: Agenda - Combination products operational group, In vitro diagnostics (IVD) stream, 21 October 2026	New
19/10/2026	Page: European Sales and Use of Antimicrobials for Veterinary Medicine (ESUAvet) annual surveillance reports	Updated
19/10/2026	Document: Terms of reference for the European Sales and Use of Antimicrobials for veterinary medicine (ESUAvet) network	New

19/10/2026	Medicine: Spectrila asparaginase	Updated
19/10/2026	Medicine: Capvaxive pneumococcal polysaccharide conjugate vaccine (21-valent)	Updated
19/10/2026	Medicine: mNexspike COVID-19 mRNA vaccine	Updated
19/10/2026	Medicine: Orphacol cholic acid	Updated
19/10/2026	Medicine: Delstrigo doravirine; lamivudine; tenofovir disoproxil	Updated
19/10/2026	Medicine: Pifeltro doravirine	Updated
19/10/2026	Medicine: Opuviz afibercept	Updated
19/10/2026	Event: Clinical Trials Information System (CTIS) bitesize talk: CTIS training environment and role management	New
19/10/2026	Medicine: Siklos hydroxycarbamide	Updated
19/10/2026	Medicine: Pyrukynd mitapivat	Updated
19/10/2026	Medicine: Eltrombopag Accord eltrombopag	Updated
19/10/2026	Medicine: Febuxostat Viartis (previously Febuxostat Mylan) febuxostat	Updated
19/10/2026	Medicine: Fasenra benralizumab	Updated
19/10/2026	Medicine: Diacomit stiripentol	Updated
19/10/2026	Document: Agenda - EMA Methodology Working Party (MWP) interested parties meeting 2026	New
19/10/2026	Medicine: Beromun tasonermin	Updated
19/10/2026	Medicine: Vizimpro dacomitinib	Updated
19/10/2026	Medicine: Iressa gefitinib	Updated
19/10/2026	Event: EMA Methodology Working Party interested parties meeting 2026	Updated
19/10/2026	Page: Data quality framework for medicines regulation	Updated
19/10/2026	Document: Draft Data Quality Framework (DQF) for EU medicines regulation: application to collection, management and submission of Adverse Drug Reaction reports	New
19/10/2026	Medicine: Yesafili afibercept	Updated
19/10/2026	Medicine: Vgenfli afibercept	Updated
19/10/2026	Medicine: Pavblu afibercept	Updated
19/10/2026	Medicine: Mynzepli afibercept	Updated
19/10/2026	Medicine: Eyluxvi afibercept	Updated
19/10/2026	Medicine: Eylea afibercept	Updated

19/10/2026	Medicine: Eiyzey aflibercept	Updated
19/10/2026	Medicine: Afiveg aflibercept	Updated
19/10/2026	Medicine: Baiaama aflibercept	Updated
19/10/2026	Medicine: Eydenzelt aflibercept	Updated
19/10/2026	Document: Agenda - 21st industry stakeholder platform - operation of EU pharmacovigilance	Updated
19/10/2026	Medicine: Ahzantive aflibercept	Updated
19/10/2026	Scientific guideline: Platform trials - Scientific guideline	Updated
19/10/2026	Document: Reflection paper on methodological aspects in confirmatory platform trials	New
19/10/2026	Scientific guideline: Clinical investigation on medicinal products in the treatment of hypertension - Scientific guideline	Updated
19/10/2026	Document: Concept paper on the need for revision of the guideline on clinical investigation of medicinal products in the treatment of hypertension (EMA/CHMP/29947/2013/Rev.4)	New
19/10/2026	Document: Day 80 assessment report - Clinical template with guidance - Rev. 10.26 - Revamp	Updated
19/10/2026	Document: Methodological Principles for the Assessment of Section 5.1 of the Summary of Product Characteristics	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)

No updates since October 15th, 2026.

PHARMEUROPA TEXTS FOR COMMENT

Information on Pharmeduropa updates will be presented quarterly.

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