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HEADS OF AGENCIES – CMDh

09. November

- NEW - 10-12 November CMDh agenda

HEADS OF AGENCIES – PAEDIATRIC REGULATION

Article 45 work-sharing: *click here*

EUROPEAN MEDICINES AGENCY (EMA)

Date	Content	Status
13/11/2026	**Event**: European platform for regulatory science research meeting: October 2026	Updated
13/11/2026	**PIP**: EMEA-000810-PIP01-09 - paediatric investigation plan grass pollen; rye pollen; birch pollen	Updated
13/11/2026	**PIP**: EMEA-000898-PIP01-10-M02 - paediatric investigation plan Meropenem	Updated
13/11/2026	**PIP**: EMEA-002364-PIP03-19 - paediatric investigation plan Dihomo-γ-linolenic acid	Updated
13/11/2026	**PIP**: EMEA-002364-PIP02-18 - paediatric investigation plan Dihomo-γ-linolenic acid (DS107)	Updated
13/11/2026	**PIP**: EMEA-001267-PIP01-12 - paediatric investigation plan N-{4-chloro-2-[(1-oxido-4-pyridinyl)carbonyl]phenyl}-4-(1,1-dimethylethyl) benzenesulfonamide, sodium salt	Updated
13/11/2026	**Medicine**: Ruxolitinib Zentiva ruxolitinib	Updated
13/11/2026	**Page**: Signal management (veterinary medicines)	Updated

Date	Content	Status
13/11/2026	**Medicine**: Spevigo spesolimab	Updated
13/11/2026	**Document**: Targeted signal management (TSM) procedure on phenobarbital - final translations of the product information text into EU languages	New
13/11/2026	**Document**: Minutes of the CVMP meeting 16-18 June 2026	New
13/11/2026	**Document**: Minutes of the CVMP meeting 14-16 July 2026	New
13/11/2026	**Document**: Minutes of the CVMP meeting 8-10 September 2026	New
13/11/2026	**Document**: Minutes of the CVMP meeting 6-8 October 2026	New
13/11/2026	**Page**: Veterinary good pharmacovigilance practices (VGVP)	Updated
13/11/2026	**Document**: Draft guideline on veterinary good pharmacovigilance practices (VGVP) - List of medically important (MI) VeDDRA terms	New
13/11/2026	**Document**: VICH GL49: Studies to evaluate the metabolism and residue kinetics of veterinary drugs in food producing animals: validation of analytical methods used in residue depletion studies - Revision 2	New
13/11/2026	**Scientific guideline**: VICH GL49 Studies to evaluate the metabolism and residue kinetics of veterinary drugs in food-producing animals: validation of analytical methods used in residue depletion studies - Scientific guideline	Updated
13/11/2026	**Event**: Immunogenicity and efficacy of pneumococcal vaccines	Updated
13/11/2026	**Medicine**: Baxfendy baxdrostat	New
13/11/2026	**Medicine**: Donrafylix insulin aspart	New
13/11/2026	**Medicine**: Qezzaqar catequentinib	Updated
13/11/2026	**Medicine**: Ruxolitinib Krka ruxolitinib	New
13/11/2026	**Medicine**: Aumseqa Aumolertinib	New
13/11/2026	**Medicine**: Garzulys insulin aspart	New
13/11/2026	**Medicine**: Amlypave anselamimab	New
13/11/2026	**Medicine**: Zybrivo sintilimab	New
13/11/2026	**Medicine**: KemSu sufentanil; ketamine	Updated

Date	Content	Status
13/11/2026	**Medicine**: Meplyffa arimoclomol	Updated
13/11/2026	**Medicine**: Fondaparinux sodium Evumed fondaparinux sodium	New
13/11/2026	**News**: Meeting highlights from the Committee for Medicinal Products for Human Use (CHMP) 9-12 November 2026	New
13/11/2026	**News**: EMA recommends extending Gazyvaro's use to systemic lupus erythematosus	New
13/11/2026	**Orphan**: EU/3/13/1100 - orphan designation for treatment of amyloid light-chain amyloidosis Humanised IgG1 kappa antibody against serum amyloid A and AL amyloid	Updated
13/11/2026	**Post-authorisation**: Enflonsia - opinion on variation to marketing authorisation clesrovimab	New
13/11/2026	**Post-authorisation**: Bexsero - opinion on variation to marketing authorisation meningococcal group B Vaccine (rDNA, component, adsorbed)	New
13/11/2026	**Post-authorisation**: Gazyvaro - opinion on variation to marketing authorisation obinutuzumab	New
13/11/2026	**Post-authorisation**: Sunlenca - opinion on variation to marketing authorisation lenacapavir	New
13/11/2026	**Post-authorisation**: Welireg - opinion on variation to marketing authorisation belzutifan	New
13/11/2026	**Post-authorisation**: Dovato - opinion on variation to marketing authorisation dolutegravir; lamivudine	New
13/11/2026	**Post-authorisation**: Tivicay - opinion on variation to marketing authorisation dolutegravir	New
13/11/2026	**Post-authorisation**: Steglatro - opinion on variation to marketing authorisation ertugliflozin	New
13/11/2026	**Post-authorisation**: Talzenna - opinion on variation to marketing authorisation talazoparib	New
13/11/2026	**Post-authorisation**: Isturisa - opinion on variation to marketing authorisation osilodrostat	New
13/11/2026	**Post-authorisation**: Cosentyx - opinion on variation to marketing authorisation secukinumab	New

Date	Content	Status
13/11/2026	**EU-M4all**: Dapivirine Vaginal Ring - opinion on medicine for use outside EU dapivirine	Updated
13/11/2026	**Page**: EU Innovation Network (EU-IN)	New
12/11/2026	**Document**: Agenda of the COMP Meeting 6-8 October 2026	Updated
12/11/2026	**Event**: Real-world data collection in Duchenne muscular dystrophy: Joint Heads of Medicines Agencies (HMA) / European Medicines Agency (EMA) multistakeholder workshop	Updated
12/11/2026	**Medicine**: AviGate S. Typhimurium Salmonella enterica, subsp. enterica, serovar Typhimurium, strain Nal2/Rif9/Rtt, Live	Updated
12/11/2026	**Event**: EMA annual call with General Practitioner Organisations' representatives	Updated
12/11/2026	**Referral**: Parenteral iron-containing medicinal products - referral ferric carboxymaltose; ferric derisomaltose; ferric gluconate; ferric hydroxide polymaltose complex; iron dextran; iron sucrose	Updated
12/11/2026	**Medicine**: Riximyo rituximab	Updated
12/11/2026	**Medicine**: Rixathon rituximab	Updated
12/11/2026	**Document**: Article 57 product data	Updated
12/11/2026	**Page**: Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG)	Updated
12/11/2026	**Document**: Mandate and objectives for the Working Group of the MSSG on critical medicine supply security	Updated
12/11/2026	**Event**: Seventeenth meeting of the industry stakeholder platform on the operation of the centralised procedure for human medicines	Updated
12/11/2026	**Event**: Meeting of the Medicine Shortages Single Point of Contact (SPOC) Working Party	Updated
12/11/2026	**Event**: Webinar on Product Management Service (PMS) public API	Updated
12/11/2026	**Document**: Agenda - HMA / EMA multistakeholder AI and Data forum: Build trustworthy AI on strong data foundations	New
12/11/2026	**Medicine**: Jivi damoctocog alfa pegol	Updated
12/11/2026	**Medicine**: Intrarosa prasterone	Updated
12/11/2026	**Document**: Medicine shortage communication (MSC): Tegsedi - updated marketing cessation date	Updated
12/11/2026	**Shortage**: Tegsedi inotersen	New

Date	Content	Status
12/11/2026	**Page**: Non-clinical Working Party	Updated
12/11/2026	**Page**: 3Rs Working Party	Updated
12/11/2026	**Page**: International arrangements	Updated
12/11/2026	**Page**: Singapore	Updated
12/11/2026	**Document**: Working arrangement for the collaboration and exchange of information on medicinal products, medical devices, in vitro diagnostics medical devices/health products between DG SANTE/EMA and Health Sciences Authority of Singapore (HSA)	New
12/11/2026	**Medicine**: Myalepta metreleptin	New
12/11/2026	**Page**: EU enlargement	Updated
12/11/2026	**Page**: Clinical Trials Information System (CTIS)	Updated
12/11/2026	**Page**: Quality Working Party	Updated
12/11/2026	**PIP**: EMA/PE/0000232766 - paediatric investigation plan apazunersen	Updated
12/11/2026	**Page**: Information Management	New
12/11/2026	**Document**: Organisation chart: Information Management	Updated
12/11/2026	**Page**: Artificial intelligence	Updated
11/11/2026	**Page**: Artificial intelligence in medicine regulation: from concept to practice	Updated
11/11/2026	**Page**: Collaboration on artificial intelligence	New
11/11/2026	**Page**: Artificial intelligence governance and policies	New
11/11/2026	**Page**: Principles and rules on using artificial intelligence at EMA	New
11/11/2026	**Page**: Artificial intelligence guidance	New
11/11/2026	**Page**: Artificial intelligence tools and technology	New
11/11/2026	**Medicine**: Braftovi encorafenib	New
11/11/2026	**Medicine**: Ervebo Ebola Zaire vaccine (rVSVΔG-ZEBOV-GP, live)	Updated
11/11/2026	**Medicine**: Emblaveo aztreonam; avibactam	Updated
11/11/2026	**Medicine**: Cejemly sugemalimab	Updated
11/11/2026	**Medicine**: Fetcroja cefiderocol	Updated
11/11/2026	**Medicine**: Mektovi binimetinib	Updated
11/11/2026	**Medicine**: CellCept mycophenolate mofetil	Updated
11/11/2026	**Medicine**: Flixabi infliximab	Updated
11/11/2026	**Medicine**: Ganirelix Gedeon Richter ganirelix	Updated

Date	Content	Status
11/11/2026	**Medicine**: Enhertu trastuzumab deruxtecan	Updated
11/11/2026	**Medicine**: Padcev enfortumab vedotin	Updated
11/11/2026	**Medicine**: Tosmova (previously Tocilizumab STADA and Tofidence) tocilizumab	Updated
11/11/2026	**Event**: SME info day - navigating EMA support: From innovation to marketing authorisation	Updated
10/11/2026	**Medicine**: Livtencity maribavir	Updated
10/11/2026	**Medicine**: Trisenox arsenic trioxide	Updated
10/11/2026	**Medicine**: Eydenzelt aflibercept	Updated
10/11/2026	**Medicine**: Fampyra fampridine	Updated
10/11/2026	**Medicine**: Glivec imatinib	Updated
10/11/2026	**Medicine**: Palbociclib Viatris palbociclib	Updated
10/11/2026	**Medicine**: Tenkasi (previously Orbactiv) oritavancin	Updated
10/11/2026	**Event**: SPOR and XEVMPD status update webinar	Updated
10/11/2026	**Document**: CHMP meeting dates 2027 and 2028	New
10/11/2026	**Medicine**: Pemazyre pemigatinib	Updated
10/11/2026	**Document**: Agenda - Second HMA/EMA multi-stakeholder forum on EudraVigilance and signal detection	Updated
10/11/2026	**Medicine**: Vyepti eptinezumab	Updated
10/11/2026	**Document**: Medicinal products for human use: monthly figures - October 2026	Updated
10/11/2026	**Medicine**: Winlevi clascoterone	New
10/11/2026	**Medicine**: Spinraza nusinersen	Updated
10/11/2026	**Medicine**: Eurneffy epinephrine	Updated
10/11/2026	**Event**: Training on clinical trials for EU candidate countries under the Instrument for Pre-accession Assistance (IPA) programme	Updated
10/11/2026	**Page**: Reform of the EU pharmaceutical legislation	New
10/11/2026	**Medicine**: Herwenda trastuzumab	Updated
10/11/2026	**Medicine**: Andembry garadacimab	Updated

Date	Content	Status
10/11/2026	**Document**: Agenda - PDCO agenda of the 10-13 November 2026 meeting	Updated
10/11/2026	**Medicine**: Kesimpta ofatumumab	New
10/11/2026	**Medicine**: Imfinzi durvalumab	Updated
10/11/2026	**Orphan**: EU/3/21/2486 - orphan designation for treatment of multiple myeloma talquetamab	Updated
10/11/2026	**Medicine**: Talvey talquetamab	Updated
10/11/2026	**Page**: Clinical Pharmacology Operational Expert Group	Updated
10/11/2026	**Page**: Biostatistics Operational Expert Group	Updated
10/11/2026	**Page**: Modelling and Simulation Operational Expert Group	Updated
10/11/2026	**Page**: Biologics Working Party Plasma Master File Quality Operational Expert Group (PMF OEG)	Updated
10/11/2026	**Page**: Biologics Working Party Vaccines Quality Operational Expert Group (BV OEG)	Updated
10/11/2026	**Page**: Paediatric Formulation Operational Expert Group	Updated
10/11/2026	**Medicine**: Advagraf tacrolimus	Updated
10/11/2026	**Page**: EudraVigilance training and support	Updated
10/11/2026	**Document**: Agenda - Stakeholder meeting, November 2026	Updated
10/11/2026	**Document**: Applications for new human medicines under evaluation: November 2026	Updated
10/11/2026	**Page**: Scientific advice for veterinary medicines	New
09/11/2026	**Document**: Antimicrobial Sales and Use (ASU) Platform: Release notes	Updated
09/11/2026	**Page**: CVMP: Working parties and other groups	Updated
09/11/2026	**Post-authorisation**: Dupixent - withdrawal of application for variation to marketing authorisation dupilumab	Updated
09/11/2026	**Page**: Novel Therapies and Technologies European Specialised Expert Community	Updated
09/11/2026	**Medicine**: Trizivir abacavir; lamivudine; zidovudine	New
09/11/2026	**Document**: Mandate, objectives and rules of procedure for the novel therapies & technologies European Specialised Expert Community	Updated
09/11/2026	**Medicine**: Ayvakyt avapritinib	New
09/11/2026	**Medicine**: Wezenla ustekinumab	Updated

Date	Content	Status
09/11/2026	**Event**: Mandatory use of ISO/ICH E2B(R3) Individual Case Safety Reporting in the EU: Hands-on training course using the EudraVigilance system	Updated
09/11/2026	**Event**: Mandatory use of ISO/ICH E2B(R3) Individual Case Safety Reporting in the EU: Hands-on training course using the EudraVigilance system	New
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09/11/2026	**Event**: Mandatory use of ISO/ICH E2B(R3) Individual Case Safety Reporting in the EU: Hands-on training course using the EudraVigilance system	New
09/11/2026	**Medicine**: Jascayd nerandomilast	New
09/11/2026	**Medicine**: Herceptin trastuzumab	Updated
09/11/2026	**Medicine**: Trixeo Aerosphere formoterol; glycopyrronium bromide; budesonide	Updated
09/11/2026	**Medicine**: Ahzantive aflibercept	Updated
09/11/2026	**Document**: Environmental statement 2025	Updated
09/11/2026	**Document**: Annex to agenda of the CHMP meeting 9-12 November 2026	New
09/11/2026	**Document**: Agenda of the CHMP meeting 9-12 November 2026	New
09/11/2026	**Medicine**: Baiama aflibercept	New
09/11/2026	**Medicine**: Phesgo pertuzumab; trastuzumab	Updated
09/11/2026	**Document**: Pharmacovigilance-related regulatory recommendations for centrally authorised veterinary medicinal products during 2026	Updated
09/11/2026	**Page**: Vaccine-preventable diseases: key facts	Updated
09/11/2026	**Document**: Mandate, objectives, and rules of procedure for working parties under the quality, non-clinical, methodology, clinical and veterinary domains	Updated

Date	Content	Status
09/11/2026	**Medicine**: Itvisma onasemnogene abeparvovec	Updated
09/11/2026	**Document**: Understanding vaccines: key scientific terms and platforms	Updated
09/11/2026	**Scientific guideline**: Risk assessment of medicinal products on human reproduction and lactation: from data to labelling - Scientific guideline	New
09/11/2026	**Document**: Draft guideline on risk assessment of medicinal products in human reproduction and breastfeeding: from data to product information - Revision 1	Updated
09/11/2026	**Scientific guideline**: Predictive biomarker assays in the context of medicinal product lifecycle - Scientific guideline	New
09/11/2026	**Document**: Draft guideline on predictive biomarker assays in the context of medicinal product lifecycle	Updated
09/11/2026	**Event**: EMA workshop on vaccine antigen master files and vaccine platform technology master files	New
09/11/2026	**Event**: Quality Working Party industry workshop	New

NOTICE TO APPLICANTS

No updates since July 10th, 2026.

BFARM - PHARMAKOVIGILANZ (SPECIFIC FOR GERMANY)

Date	Content
11.11.2026	Ergebnisprotokoll der 99. Routinesitzung nach § 63 AMG am 28. September 2026 Das BfArM gibt das Ergebnisprotokoll der 99. Routinesitzung vom 28. September 2026 bekannt.

BFARM – MEDIZINPRODUKTE (SPECIFIC FOR GERMANY)

No updates since September 25th, 2026.

PEI - VIGILANZ (SPECIFIC FOR GERMANY)

No updates since October 30th, 2026

PHARMEUROPA TEXTS FOR COMMENT

Information on Pharmeuropa updates will be presented quarterly.

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